UTAH STATE BULLETIN

OFFICIAL NOTICES OF UTAH STATE GOVERNMENT
Filed July 15, 2017, 12:00 a.m. through August 01, 2017, 11:59 p.m.

Number 2017-16
August 15, 2017

Nancy L. Lancaster, Managing Editor

The *Utah State Bulletin (Bulletin)* is an official noticing publication of the executive branch of Utah state government. The Office of Administrative Rules, part of the Department of Administrative Services, produces the *Bulletin* under authority of Section 63G-3-402.

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Inquiries concerning the substance or applicability of an administrative rule that appears in the *Bulletin* should be addressed to the contact person for the rule. Questions about the *Bulletin* or the rulemaking process may be addressed to: Office of Administrative Rules, PO Box 141007, Salt Lake City, Utah 84114-1007, telephone 801-538-3003. Additional rulemaking information and electronic versions of all administrative rule publications are available at https://rules.utah.gov/.

The information in this *Bulletin* is summarized in the *Utah State Digest (Digest)* of the same volume and issue number. The *Digest* is available by e-mail subscription or online. Visit https://rules.utah.gov/ for additional information.

Office of Administrative Rules, Salt Lake City 84114

Utah state bulletin.
Semimonthly.
1. Delegated legislation--Utah--Periodicals. 2. Administrative procedure--Utah--Periodicals.
I. Utah. Office of Administrative Rules.

KFU440.A73S7
348.792'025--DDC 85-643197

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NOTICE OF PROPOSED RULE
(Amendment)
DAR FILE NO.: 41991
FILED: 08/01/2017

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: The proposed changes incorporate corresponding revisions made by the U.S. Nuclear Regulatory Commission (NRC) in a final rule published in the Federal Register on 05/29/2013 (78 FR 32310) under the title of Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions. As an Agreement State with the NRC for the radioactive materials program in Utah, the proposed changes are made in order to maintain regulatory compatibility with the federal radioactive materials regulations and our agreement state status with the NRC. Changes are proposed in selected sections of Rules R313-12, R313-19, R313-21, and R313-22 in order to incorporate all of the corresponding revisions issued under NRC's final rule promulgated on 05/29/2013. Additional proposed changes not directly associated with NRC's final rule are being made to update noted references and citations. (EDITOR'S NOTE: A proposed amendment to Rule R313-19 is under Filing No. 41992, a proposed amendment to Rule R313-21 is under Filing No. 41993, and a proposed amendment to Rule R313-22 in under Filing No. 41994 in this issue, August 15, 20017, of the Bulletin.)

SUMMARY OF THE RULE OR CHANGE: On 07/13/2017, the Waste Management and Radiation Control Board authorized the proposed changes to be published for public review and comment. Proposed changes to Rules R313-12, R313-19, R313-21, and R313-22 reflect those revisions made by the NRC to selected sections of 10 CFR Part 40, as promulgated on 05/29/2013 (78 FR 32310). The majority of the changes are required to retain regulatory compatibility for the radioactive materials program, other proposed changes provide added clarification or correct textual errors. Specifically, incorporating the revisions promulgated by the NRC into the appropriate sections of Rule R313-12 require the initial distribution of source material to exempt persons or to general licensees be explicitly authorized by a specific license and institute new reporting requirements to provide timely information on the types and quantities of source

material distributed for use either under exemption or by general licensees. In addition, the rule modifies the existing possession and use requirements of the general license for small quantities of source material to better align the requirements with current health and safety standards. The regulatory amendments will create a regulatory framework for the initial distribution of source material to inform the Division, in the event of any manufacturer or distributor of source material becomes licensed in Utah, of what types and quantities of products containing source material are distributed for use under the exemptions from licensing and to identify persons using significant quantities of source material under the general license in Rule R313-21-21. It will also ensure that general licensees under Section R313-21-21 are informed of applicable regulations before they obtain source material. Also, the proposed rule changes revise, clarify, or delete certain source material exemptions from licensing to make the exemptions more risk informed. The NRC's final rule and the associated proposed rule changes in the Utah radiation control rules also affect the possession and use of source material under a general license or an applicable license exemption. References to the Utah Code are being updated to match the existing respective statutes in the definitions for "Dentist" and "Pharmacist". A clarification is being added to the definition of "Regulations of the U.S. Department of Transportation" to explicitly reference federal transportation regulations that are also applicable. A change to the definition of "Unrefined and unprocessed ore" is being made to be compatible with the corresponding NRC regulation of 10 CFR 40.4. Text is being added to the Records section (R313-12-51) to be compatible with the corresponding NRC regulations of 10 CFR 40.61(a) and (b) and the subsequent subsections are being renumbered. Text is being added to the Communications section (R313-12-110) to clarify that communications, reports, and applications are to be addressed to the director of the division.

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Section 19-3-104 and Section 19-6-104

ANTICIPATED COST OR SAVINGS TO:

♦ THE STATE BUDGET: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no state agencies that manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. However, state academic institutions that may possess or use radioactive source material for research or other academic-related purposes beyond the proposed quantity limit may need to apply for and receive a specific licenses. Any costs associated with the specific license application process and subsequent implementation procedures are unique to each licensing action and are therefore not quantifiable. However, additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302) . A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

♦ LOCAL GOVERNMENTS: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no local governments that manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. Additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

♦ SMALL BUSINESSES: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no small businesses in Utah that manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. However, a small business that may possess or use radioactive source material for commercial, operational, research, development, or other business-related purposes beyond the proposed quantity limit may need to apply for and receive a specific licenses. Any costs associated with the specific license application process and subsequent implementation procedures are unique to each licensing action and are therefore not quantifiable. Additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

♦ PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no other entities in Utah that currently manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. However, a person that may possess or use radioactive source material for commercial, operational, research, development, or other business-related purposes beyond the proposed quantity limit may need to apply for and receive a specific licenses. Any costs associated with the specific license application process and subsequent implementation procedures are unique to each licensing action and are therefore not quantifiable. Additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's

regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

COMPLIANCE COSTS FOR AFFECTED PERSONS: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no entities in Utah that will be affected by the proposed rule changes since no entities in Utah manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. However, a business or person that may possess or use radioactive source material for commercial, operational, research, development, or other business-related purposes beyond the proposed quantity limit may need to apply for and receive a specific licenses. Any costs associated with the specific license application process and subsequent implementation procedures are unique to each licensing action and are therefore not quantifiable. Additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no entities in Utah that manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. However, a business or person that may possess or use radioactive source material for commercial, operational, research, development, or other business-related purposes beyond the proposed quantity limit may need to apply for and receive a specific licenses. Any costs associated with the specific license application process and subsequent implementation procedures are unique to each licensing action and are therefore not quantifiable. Additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
ENVIRONMENTAL QUALITY
WASTE MANAGEMENT AND RADIATION CONTROL, RADIATION
SECOND FLOOR
195 N 1950 W
SALT LAKE CITY, UT 84116-4880
or at the Office of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Rusty Lundberg by phone at 801-536-4257, by FAX at 801-536-0222, or by Internet E-mail at rlundberg@utah.gov
♦ Thomas Ball by phone at 801-536-0251, or by Internet E-mail at tball@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 09/15/2017

THIS RULE MAY BECOME EFFECTIVE ON: 10/16/2017

AUTHORIZED BY: Scott Anderson, Director

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.
R313-12. General Provisions.
R313-12-3. Definitions.

As used in these rules, these terms shall have the definitions set forth below. Additional definitions used only in a certain rule will be found in that rule.

"A1" means the maximum activity of special form radioactive material permitted in a Type A package.

"A2" means the maximum activity of radioactive material, other than special form radioactive material, low specific activity, and surface contaminated object material permitted in a Type A package. These values are either listed in 10 CFR 71, Appendix A, which is incorporated by reference in Section R313-19-100 or may be derived in accordance with the procedures prescribed in 10 CFR 71, Appendix A, which is incorporated by reference in Section R313-19-100.

"Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

"Accelerator produced radioactive material" means material made radioactive by a particle accelerator.

"Act" means Utah Radiation Control Act, Title 19, Chapter 3.

"Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

"Adult" means an individual 18 or more years of age.

"Address of use" means the building or buildings that are identified on the license and where radioactive material may be received, used or stored.

"Advanced practice registered nurse" means an individual licensed by this state to engage in the practice of advanced practice registered nursing. See Sections 58-31b-101 through 58-31b-801, Nurse Practice Act.

"Agreement State" means a state with which the United States Nuclear Regulatory Commission or the Atomic Energy

Commission has entered into an effective agreement under Section 274 b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

"Airborne radioactive material" means a radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

"Airborne radioactivity area" means: a room, enclosure, or area in which airborne radioactive material exists in concentrations:

(a) In excess of the derived air concentrations (DACs), specified in Rule R313-15, or

(b) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI), or 12 DAC hours.

"As low as reasonably achievable" (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

"Area of use" means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing radioactive material.

"Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include sources of radiation from radioactive materials regulated by the Division of Waste Management and Radiation Control under the Radiation Control Act or Rules.

"Becquerel" (Bq) means the SI unit of activity. One becquerel is equal to one disintegration or transformation per second.

"Bioassay" means the determination of kinds, quantities or concentrations, and in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these rules, "radiobioassay" is an equivalent term.

"Board" means the Waste Management and Radiation Control Board created under Section 19-1-106.

"Byproduct material" means:

(a) a radioactive material, with the exception of special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material;

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

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

(ii) material that

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

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

(d) a discrete source of naturally occurring radioactive material, other than source material, that

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, has determined would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

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

"Calibration" means the determination of:

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

(b) the strength of a source of radiation relative to a standard.

"CFR" means Code of Federal Regulations.

"Chelating agent" means a chemical ligand that can form coordination compounds in which the ligand occupies more than one coordination position. The agents include beta diketones, certain proteins, amine polycarboxylic acids, hydroxycarboxylic acids, gluconic acid, and polycarboxylic acids.

"Chiropractor" means an individual licensed by this state to engage in the practice of chiropractic. See Sections 58-73-101 through 58-73-701, Chiropractic Physician Practice Act.

"Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

"Commencement of construction" means taking any action defined as "construction" or any other activity at the site of a facility subject to these rules that have a reasonable nexus to radiological health and safety.

"Commission" means the U.S. Nuclear Regulatory Commission.

"Committed dose equivalent" (HT,50), means the dose equivalent to organs or tissues of reference (T), that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

"Committed effective dose equivalent" (HE,50), is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues.

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

"Construction" means the installation of wells associated with radiological operations; for example, production, injection, or

monitoring well networks associated with in-situ recovery or other facilities; the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to these rules that are related to radiological safety or security. The term "construction" does not include:

(a) changes for temporary use of the land for public recreational purposes;

(b) site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

(c) preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

(d) erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this part;

(e) excavation;

(f) erection of support buildings; for example, construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings; for use in connection with the construction of the facility;

(g) building of service facilities; for example, paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines;

(h) procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or

(i) taking any other action that has no reasonable nexus to radiological health and safety.

"Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee or registrant for any reason.

"Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

"Curie" means a unit of measurement of activity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7 x 10 to the tenth power disintegrations or transformations per second (dps or tps).

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

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

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

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

"Deep dose equivalent" (H_d), which applies to external whole body exposure, means the dose equivalent at a tissue depth of one centimeter (1000 mg/cm^2).

"Dentist" means an individual licensed by this state to engage in the practice of dentistry. See sections 58-69-101 through [~~58-69-805~~]58-69-806, Dentist and Dental Hygienist Practice Act.

"Department" means the Utah Department of Environmental Quality.

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

"Diffuse source" means a radionuclide that has been unintentionally produced or concentrated during the processing of materials for use for commercial, medical, or research activities.

"Director" means the Director of the Division of Waste Management and Radiation Control.

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

"Distinguishable from background" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

"Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent. For purposes of these rules, "radiation dose" is an equivalent term.

"Dose equivalent" (H_T), means the product of the absorbed dose in tissue, quality factor, and other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

"Dose limits" means the permissible upper bounds of radiation doses established in accordance with these rules. For purpose of these rules, "limits" is an equivalent term.

"Effective dose equivalent" (H_E), means the sum of the products of the dose equivalent to each organ or tissue (H_T), and the weighting factor (w_T,) applicable to each of the body organs or tissues that are irradiated.

"Embryo/fetus" means the developing human organism from conception until the time of birth.

"Entrance or access point" means an opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

"Explosive material" means a chemical compound, mixture, or device which produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

"EXPOSURE" when capitalized, means the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons, both negatrons and positrons, liberated by photons in a volume element of air having a mass of "dm" are completely stopped in air. The special unit of EXPOSURE is the roentgen (R). See Section R313-12-20 Units of exposure and dose for the SI equivalent. For purposes of these rules, this term is used as a noun.

"Exposure" when not capitalized as the above term, means being exposed to ionizing radiation or to radioactive material. For purposes of these rules, this term is used as a verb.

"EXPOSURE rate" means the EXPOSURE per unit of time, such as roentgen per minute and milliroentgen per hour.

"External dose" means that portion of the dose equivalent received from a source of radiation outside the body.

"Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

"Facility" means the location within one building, vehicle, or under one roof and under the same administrative control

(a) at which the use, processing or storage of radioactive material is or was authorized; or

(b) at which one or more radiation-producing machines or radioactivity-inducing machines are installed or located.

"Former United States Atomic Energy Commission (AEC) or United States Nuclear Regulatory Commission (NRC) licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

"Generally applicable environmental radiation standards" means standards issued by the U.S. Environmental Protection Agency under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

"Gray" (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule per kilogram.

"Hazardous waste" means those wastes designated as hazardous by the U.S. Environmental Protection Agency rules in 40 CFR Part 261.

"Healing arts" means the disciplines of medicine, dentistry, osteopathy, chiropractic, and podiatry.

"High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of one mSv (0.1 rem), in one hour at 30 centimeters from the source of radiation or from a surface that the radiation penetrates. For purposes of these rules, rooms or areas in which diagnostic x-ray systems are used for healing arts purposes are not considered high radiation areas.

"Human use" means the intentional internal or external administration of radiation or radioactive material to human beings.

"Individual" means a human being.

"Individual monitoring" means the assessment of:

(a) dose equivalent, by the use of individual monitoring devices or, by the use of survey data; or

(b) committed effective dose equivalent by bioassay or by determination of the time weighted air concentrations to which an individual has been exposed, that is, DAC-hours.

"Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these rules, individual monitoring equipment and personnel monitoring equipment are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescence dosimeters (TLD's), pocket ionization chambers, and personal air sampling devices.

"Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, orders, requirements and conditions applicable to radiation sources.

"Interlock" means a device arranged or connected requiring the occurrence of an event or condition before a second condition can occur or continue to occur.

"Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

"Lens dose equivalent" (LDE) applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

"License" means a license issued by the Director in accordance with the rules adopted by the Board.

"Licensee" means a person who is licensed by the Department in accordance with these rules and the Act.

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

"Licensing state" means a state which, prior to November 30, 2007, was provisionally or finally designated as such by the Conference of Radiation Control Program Directors, Inc., which reviewed state regulations to establish equivalency with the Suggested State Regulations and ascertained whether a State has an effective program for control of natural occurring or accelerator produced radioactive material.

"Limits". See "Dose limits".

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

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

"Member of the public" means an individual except when that individual is receiving an occupational dose.

"Minor" means an individual less than 18 years of age.

"Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material, and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these rules, radiation monitoring and radiation protection monitoring are equivalent terms.

"Natural radioactivity" means radioactivity of naturally occurring nuclides.

"Nuclear Regulatory Commission" (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

"Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties for the licensee or registrant involve exposure to sources of radiation, whether or not the sources of radiation are in the possession of the licensee, registrant, or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure

to individuals administered radioactive material and released in accordance with Rule R313-32, from voluntary participation in medical research programs, or as a member of the public.

"Package" means the packaging together with its radioactive contents as presented for transport.

"Particle accelerator" means a machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one megaelectron volt. For purposes of these rules, "accelerator" is an equivalent term.

"Permit" means a permit issued by the Director in accordance with the rules adopted by the Board.

"Permitee" means a person who is permitted by the Director in accordance with these rules and the Act.

"Person" means an individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, or another state or political subdivision or agency thereof, and a legal successor, representative, agent or agency of the foregoing.

"Personnel monitoring equipment," see individual monitoring devices.

"Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy. See Sections 58-17b-101 through [~~58-17b-801~~]58-17b-806, Pharmacy Practice Act.

"Physician" means both physicians and surgeons licensed under Section 58-67-301, Utah Medical Practice Act, and osteopathic physicians and surgeons licensed under Section 58-68-301, Utah Osteopathic Medical Practice Act.

"Physician assistant" means an individual licensed by this state to engage in practice as a physician assistant. See Sections 58-70a-101 through 58-70a-504, Physician Assistant Act.

"Podiatrist" means an individual licensed by this state to engage in the practice of podiatry. See Sections 58-5a-101 through 58-5a-501, Podiatric Physician Licensing Act.

"Practitioner" means an individual licensed by this state in the practice of a healing art. For these rules, only the following are considered to be a practitioner: physician, dentist, podiatrist, chiropractor, physician assistant, and advanced practice registered nurse.

"Protective apron" means an apron made of radiation-attenuating materials used to reduce exposure to radiation.

"Public dose" means the dose received by a member of the public from exposure to radiation or to radioactive materials released by a licensee, or to any other source of radiation under the control of a licensee or registrant. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Rule R313-32, or from voluntary participation in medical research programs.

"Pyrophoric material" means any liquid that ignites spontaneously in dry or moist air at or below 130 degrees Fahrenheit (54.4 degrees Celsius) or any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

"Quality factor" (Q) means the modifying factor, listed in Tables 1 and 2 of Section R313-12-20 that is used to derive dose equivalent from absorbed dose.

"Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram

"Radiation" means alpha particles, beta particles, gamma rays, x-rays, neutrons, high speed electrons, high speed protons, and other particles capable of producing ions. For purposes of these rules, ionizing radiation is an equivalent term. Radiation, as used in these rules, does not include non-ionizing radiation, like radiowaves or microwaves, visible, infrared, or ultraviolet light.

"Radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem), in one hour at 30 centimeters from the source of radiation or from a surface that the radiation penetrates.

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

"Radiation safety officer" means an individual who has the knowledge and responsibility to apply appropriate radiation protection rules and has been assigned such responsibility by the licensee or registrant. For a licensee authorized to use radioactive materials in accordance with the requirements of Rule R313-32,

(1) the individual named as the "Radiation Safety Officer" must meet the training requirements for a Radiation Safety Officer as stated in Rule R313-32; or

(2) the individual must be identified as a "Radiation Safety Officer" on

(a) a specific license issued by the Director, the U.S. Nuclear Regulatory Commission, or an Agreement State that authorizes the medical use of radioactive materials; or

(b) a medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee.

"Radiation source". See "Source of radiation."

"Radioactive material" means a solid, liquid, or gas which emits radiation spontaneously.

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

"Radiobioassay". See "Bioassay".

"Registrant" means any person who is registered with respect to radioactive materials or radiation machines with the Director or is legally obligated to register with the Director pursuant to these rules and the Act.

"Registration" means registration with the Director in accordance with the rules adopted by the Board.

"Regulations of the U.S. Department of Transportation" means 49 CFR 100 through 189 and 49 CFR 390 through 397, as referenced in 49 CFR 177.

"Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor. One rem equals 0.01 sievert (Sv).

"Research and development" means:

(a) theoretical analysis, exploration, or experimentation; or

(b) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production

and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

"Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of Rule R313-15.

"Restricted area" means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. A "Restricted area" does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

"Roentgen" (R) means the special unit of EXPOSURE. One roentgen equals 2.58 x 10 to the -4 power coulombs per kilogram of air. See EXPOSURE.

"Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

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

"Shallow dose equivalent" (Hs) which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (seven mg per square centimeter).

"SI" means an abbreviation of the International System of Units.

"Sievert" (Sv) means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor. One Sv equals 100 rem.

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

"Source container" means a device in which sealed sources are transported or stored.

"Source material" means:

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

(b) ores that contain by weight one-twentieth of one percent (0.05 percent), or more of, uranium, thorium, or any combination of uranium and thorium. Source material does not include special nuclear material.

"Source material milling" means any activity that results in the production of byproduct material as defined by (b) of "byproduct material".

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

"Special form radioactive material" means radioactive material which satisfies the following conditions:

(a) it is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(b) the piece or capsule has at least one dimension not less than five millimeters (0.197 inch); and

(c) it satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission in 10 CFR 71.75. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation designed in accordance with the requirements of 10 CFR 71.4 in effect on March 31, 1996, (see 10 CFR 71 revised January 1, 1983), and constructed before April 1, 1998, may continue to be used. Any other special form encapsulation must meet the specifications of this definition.

"Special nuclear material" means:

(a) plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and other material that the U.S. Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

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

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

((175(Grams contained U-235)/350) + (50(Grams U-233/200) + (50(Grams Pu)/200)) is equal to one.

"Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations and measurements of levels of radiation or concentrations of radioactive material present.

"Test" means the process of verifying compliance with an applicable rule.

"These rules" means "Utah Radiation Control Rules".

"Total effective dose equivalent" (TEDE) means the sum of the effective dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

"Total organ dose equivalent" (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in Subsection R313-15-1107(1)(f).

"U.S. Department of Energy" means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the Department exercises

functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c), and (d) of Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, effective January 19, 1975 known as the Energy Reorganization Act of 1974, and retransferred to the Secretary of Energy pursuant to section 301(a) of Public Law 95-91, August 14, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977 known as the Department of Energy Organization Act.

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

"Unrestricted area" means an area, to which access is neither limited nor controlled by the licensee or registrant. For purposes of these rules, "uncontrolled area" is an equivalent term.

"Waste" means those low-level radioactive wastes containing radioactive material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs (b), (c), and (d) of the definition of byproduct material found in Section R313-12-3.

"Week" means seven consecutive days starting on Sunday.

"Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knees.

"Worker" means an individual engaged in work under a license or registration issued by the Director and controlled by a licensee or registrant, but does not include the licensee or registrant.

"Working level" (WL), means any combination of short-lived radon daughters in one liter of air that will result in the ultimate emission of 1.3×10^5 MeV of potential alpha particle energy. The short-lived radon daughters are, for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon 220: polonium-216, lead-212, bismuth-212, and polonium-212.

"Working level month" (WLM), means an exposure to one working level for 170 hours. 2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

"Year" means the period of time beginning in January used to determine compliance with the provisions of these rules. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the decision to make the change is made not later than December 31 of the previous year. If a licensee or registrant changes in a year, the licensee or registrant shall assure that no day is omitted or duplicated in consecutive years.

R313-12-51. Records.

(1) A person who receives source or byproduct material pursuant to a license issued pursuant to the regulations in this part shall keep records showing the receipt, transfer, and disposal of this source or byproduct material as follows:

(a) The licensee shall retain each record of receipt of source or byproduct material as long as the material is possessed and for three years following transfer or disposition of the source or byproduct material.

(b) The licensee who transferred the material shall retain each record of transfer of source or byproduct material until the Director terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(c) The licensee shall retain each record of disposal of source or byproduct material until the Director terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(d) If source or byproduct material is combined or mixed with other licensed material and subsequently treated in a manner that makes direct correlation of a receipt record with a transfer, export, or disposition record impossible, the licensee may use evaluative techniques, such as first-in-first-out, to make the records that are required by Section R313-12-51 account for 100 percent of the material received.

(2) The licensee shall retain each record that is required by Section R313-12-51 or by license condition for the period specified by the appropriate rule or license condition. If a retention period is not otherwise specified by rule or license condition, each record must be maintained until the Director terminates the license that authorizes the activity that is subject to the recordkeeping requirement.

[~~(1)~~](3) A licensee or registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation.

[~~(2)~~](4) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, may forward the following records to the Director:

(a) records of disposal of licensed material made under Sections R313-15-1002 (including burials authorized before January 28, 1981), R313-15-1003, R313-15-1004, and R313-15-1005; and

(b) records required by Subsection R313-15-1103(2)(d).

NOTE: 10 CFR 20.304 permitted burial of small quantities of licensed materials in soil before January 28, 1981, without specific U.S. Nuclear Regulatory Commission authorization. See 20.304 contained in the 10 CFR, parts 0 to 199, edition revised as of January 1, 1981.

[~~(3)~~](5) If licensed activities are transferred or assigned in accordance with Subsection R313-19-34(2), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(a) records of disposal of licensed material made under Sections R313-15-1002 (including burials authorized before January 28, 1981), R313-15-1003, R313-15-1004, R313-15-1005, and R313-15-1008; and

(b) records required by Subsection R313-15-1103(2)(d).

[~~(4)~~](6) Prior to license termination, each licensee may forward the records required by Subsection R313-22-35(7) to the Director.

[~~(5)~~](7) Additional records requirements are specified elsewhere in these rules.

R313-12-110. Communications.

All communications and reports concerning these rules, and applications filed thereunder, should be addressed to the Director of the Division of Waste Management and Radiation Control, P.O. Box 144880, 195 North 1950 West, Salt Lake City, Utah 84114-4880.

KEY: definitions, units, inspections, exemptions
Date of Enactment or Last Substantive Amendment: [~~June 16, 2015~~]2017
Notice of Continuation: July 1, 2016
Authorizing, and Implemented or Interpreted Law: 19-3-104; [~~19-6-107~~]19-6-104

Environmental Quality, Waste Management and Radiation Control, Radiation
R313-19
Requirements of General Applicability to Licensing of Radioactive Material

NOTICE OF PROPOSED RULE
(Amendment)
DAR FILE NO.: 41992
FILED: 08/01/2017

RULE ANALYSIS
PURPOSE OF THE RULE OR REASON FOR THE CHANGE: The proposed changes incorporate corresponding revisions made by the U.S. Nuclear Regulatory Commission (NRC) in a final rule published in the Federal Register on 05/29/2013 (78 FR 32310) under the title of Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions. As an Agreement State with the NRC for the radioactive materials program in Utah, the proposed changes are made in order to maintain regulatory compatibility with the federal radioactive materials regulations and our agreement state status with the NRC. Changes are proposed in selected sections of Rules R313-12, R313-19, R313-21, and R313-22 in order to incorporate all of the corresponding revisions issued under NRC's final rule promulgated on 05/29/2013. Additional proposed changes not directly associated with NRC's final rule are being made to update noted references and citations. (EDITOR'S NOTE: A proposed amendment to Rule R313-12 is under Filing No. 41991, a proposed amendment to Rule R313-21 is under Filing No. 41993, and a proposed amendment to Rule R313-22 in under Filing No. 41994 in this issue, August 15, 20017, of the Bulletin.)

SUMMARY OF THE RULE OR CHANGE: On 07/13/2017, the Waste Management and Radiation Control Board authorized the proposed changes to be published for public review and comment. Proposed changes to Rules R313-12, R313-19, R313-21, and R313-22 reflect those revisions made by the NRC to selected sections of 10 CFR Part 40, as promulgated on 05/29/2013 (78 FR 32310). The majority of the changes are required to retain regulatory compatibility for the radioactive materials program, other proposed changes provide added clarification or correct textual errors. Specifically, incorporating the revisions promulgated by the NRC into the appropriate sections of Rule R313-19 require the initial distribution of source material to exempt persons or to general licensees be explicitly authorized by a specific license and institute new reporting requirements to provide timely information on the types and quantities of source material distributed for use either under exemption or by general licensees. In addition, the rule modifies the existing possession and use requirements of the general license for small quantities of source material to better align the requirements with current health and safety standards. The regulatory amendments will create a regulatory framework for the initial distribution of source material to inform the Division, in the event of any manufacturer or distributor of source material becomes licensed in Utah, of what types and quantities of products containing source material are distributed for use under the exemptions from licensing and to identify persons using significant quantities of source material under the general license in Section R313-21-21. It will also ensure that general licensees under Section R313-21-21 are informed of applicable regulations before they obtain source material. Also, the proposed rule changes revise, clarify, or delete certain source material exemptions from licensing to make the exemptions more risk informed. The NRC's final rule and the associated proposed rule changes in the Utah radiation control rules also affect the possession and use of source material under a general license or an applicable license exemption. Proposed changes in the Exemptions section (R313-19-13) are being made to be compatible with the corresponding NRC regulations of 10 CFR 40.13 as promulgated on 05/29/2013 (78 FR 32310) regarding the distribution of certain quantities of source material (radioactive material containing uranium and/or thorium). The associated dates noted in the proposed changes in Section R313-19-13 are proposed to be 10/16/2017 based on the Waste Management and Radiation Control Board's action, during their scheduled meeting on 10/12/2017 to set the effective date of the rule changes as 10/16/2017. The edition date of the two incorporations by reference in Section R313-19-50 to Appendix B of 10 CFR Part 20 are updated from 2010 to 2017.

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Section 19-3-104 and Section 19-6-104

MATERIALS INCORPORATED BY REFERENCE:
♦ Updates 10 CFR Part 20, Appendix B, published by Government Printing Office, 01/01/2017

ANTICIPATED COST OR SAVINGS TO:
♦ THE STATE BUDGET: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no state agencies that manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. However, state academic institutions that may possess or use radioactive source material for research or other academic-related purposes beyond the proposed quantity limit may

need to apply for and receive a specific licenses. Any costs associated with the specific license application process and subsequent implementation procedures are unique to each licensing action and are therefore not quantifiable. However, additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

♦ LOCAL GOVERNMENTS: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no local governments that manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. Additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

♦ SMALL BUSINESSES: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no small business in Utah that manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. However, a small business that may possess or use radioactive source material for commercial, operational, research, development, or other business-related purposes beyond the proposed quantity limit may need to apply for and receive a specific licenses. Any costs associated with the specific license application process and subsequent implementation procedures are unique to each licensing action and are therefore not quantifiable. Additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

♦ PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no other entities in Utah that currently manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. However, a person that may possess or use radioactive source material for commercial, operational, research, development, or other business-related purposes beyond the proposed quantity limit may need to apply for and receive a specific licenses. Any costs associated with the specific license application process and subsequent implementation procedures are unique to each licensing action and are therefore not quantifiable. Additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

COMPLIANCE COSTS FOR AFFECTED PERSONS: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no entities in Utah that manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. However, a business or person that may possess or use radioactive source material for commercial, operational, research, development, or other business-related purposes beyond the proposed quantity limit may need to apply for and receive a specific licenses. Any costs associated with the specific license application process and subsequent implementation procedures are unique to each licensing action and are therefore not quantifiable. Additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no entities in Utah that manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. However, a business or person that may possess or use radioactive source material for commercial, operational, research, development, or other business-related purposes beyond the proposed quantity limit may need to apply for and receive a specific licenses. Any costs associated with the specific license application process and subsequent implementation procedures are unique to each licensing action and are therefore not quantifiable. Additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is

available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
ENVIRONMENTAL QUALITY
WASTE MANAGEMENT AND RADIATION CONTROL, RADIATION
SECOND FLOOR
195 N 1950 W
SALT LAKE CITY, UT 84116-4880
or at the Office of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Rusty Lundberg by phone at 801-536-4257, by FAX at 801-536-0222, or by Internet E-mail at rlundberg@utah.gov
♦ Thomas Ball by phone at 801-536-0251, or by Internet E-mail at tball@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 09/15/2017

THIS RULE MAY BECOME EFFECTIVE ON: 10/16/2017

AUTHORIZED BY: Scott Anderson, Director

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.
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 the requirements in Rules R313-15, R313-18, 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 manufactured before October 16, 2017, 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 two percent by weight source material or, for glassware manufactured before October 16, 2017, 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)~~](A) each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM",

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

[~~(D)~~](C) The requirements specified in Subsections R313-19-13(1)(c)(v)[~~(B)~~](A) and [~~(C)~~](B) need not be met by counterweights manufactured prior to December 31, 1969, provided that such counterweights were manufactured under a specific license issued by the Atomic Energy Commission and were[~~are~~] impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM", as previously required by the rules in effect on June 30, 1969, 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 any such 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 or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain

more than 10 percent by weight thorium or uranium or, for lenses manufactured before October 16, 2017, [~~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)~~](viii) 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.

(ix) No person may initially transfer for sale or distribution a product containing source material to persons exempt under Subsection R313-19-13(1)(c), or equivalent regulations of an Agreement State, unless authorized by a license issued under 10 CFR 40.52 to initially transfer such products for sale or distribution.

(A) A person initially distributing source material in products covered by the exemptions in this Subsection R313-19-13(1)(c) before (Utah effective date to be set by the Board), without specific authorization may continue such distribution for one year beyond this date. Initial distribution may also be continued until the director takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than one year beyond this date.

(B) A person authorized to manufacture, process, or produce these materials or products containing source material by an Agreement State, and a person who imports finished products or parts, for sale or distribution must be authorized by a license issued under 10 CFR 40.52 for distribution only and are exempt from the requirements of Rules R313-15 and R313-18 and Subsections R313-22-33(1)(a) and (b).

(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)(iii) 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) diffuse sources of natural occurring radioactive materials containing less than 15 picocuries per gram radium-226.

(ii) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in Rules R313-19, R313-21 and R313-22 and Rules R313-32, R313-34, R313-36, and R313-38 to the extent that the person transfers:

(A) radioactive material contained in a product or material in concentrations not in excess of those specified in R313-19-70; and

(B) introduced into the product or material by a licensee holding a specific license issued by the U.S. Nuclear Regulatory Commission authorizing the introduction.

(C) The exemption in R313-19-13-2(a)(ii)(A) and R313-19-13-2(a)(ii)(B) does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(iii) 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).

(b) Exempt quantities.

(i) Except as provided in Subsections R313-19-13(2)(b)(ii) 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 CFR Part 32 or by the Director 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 CFR Part 31.4 or equivalent regulations of a State 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 radioactive material. This exemption does not apply for diffuse sources of 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 November 30, 2007.

(B)(I) Static elimination devices which contain, as sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 uCi) of polonium-210 per device.

(II) Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 uCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.

(III) Such devices authorized before October 23, 2012 for use under the general license then provided in 10 CFR 31.3 (January 1, 2012) or equivalent regulations of the Commission or an Agreement State and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Commission or Agreement State.

(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) 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.

(E) 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.

(F) 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.

(G) 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)(G), 0.05 microcurie (1.85 kBq) of americium-241 is considered an exempt quantity under Section R313-19-71.

(ii) Self-luminous products containing radioactive material.

(A) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, and except as provided in R313-19-13(2)(c)(ii)(C), any person is exempt from the regulations in R313-15, R313-19, R313-21, R313-22, R313-32, R313-34, R313-36, and R313-38 to the extent that such a person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, produced, or initially transferred in accordance with a specific license issued pursuant to 10 CFR 32.22 (2015), which license authorizes the initial transfer of the product for use.

(B) Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under R313-19-13(2)(c)(ii)(A), should apply for a license under 10 CFR 32.22 (2015) and for a certificate of registration in accordance with 10 CFR 32.210 (2015).

(C) The exemption in R313-19-13(2)(c)(ii)(A) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

(D) 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, produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from the regulations in parts R313-18, R313-15, R313-19, R313-21, R313-22, R313-32, R313-34, R313-36, and R313-38 to the extent that such

person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect health, safety, or property, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CFR 32.26 (2015), which license authorizes the initial transfer of the product for use under this section. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by a State under comparable provisions to 10 CFR 32.26 (2015) authorizing distribution to persons exempt from regulatory requirements.

(B) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use under paragraph (a)of this section, should apply for a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 32.26 (2015) and for a certificate of registration in accordance with R313-22-210 or equivalent regulations of an Agreement State.

(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) Certain industrial devices.

(A) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the regulations in parts R313-18, R313-15, R313-18, R313-15, R313-19, R313-21, R313-22, R313-32, R313-34, R313-36, and R313-38 to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CFR 32.30 (2015), which license authorizes the initial transfer of the device for use under this rule. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

(B) Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under R313-19-13(2)(c)(v)(A), should apply for a license under 10 CFR 32.30 (2015) and for a certificate of registration in accordance with R313-22-210.

(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.

R313-19-50. Reporting Requirements.

(1) Licensees shall notify the Director as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits. Events may include fires, explosions, toxic gas releases, etc.

(2) The following events involving licensed material require notification of the Director by the licensee within 24 hours:

(a) an unplanned contamination event that:

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

(ii) involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of 10 CFR 20.1001 through 20.2402 [~~(2010)~~](2017), which is incorporated by reference, for the material; and

(iii) has access to the area restricted for a reason other than to allow radionuclides with a half-life of less than 24 hours to decay prior to decontamination; or

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

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

(ii) the equipment is required by rule or license condition to be available and operable; and

(iii) no redundant equipment is available and operable to perform the required safety function; or

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

(d) an unplanned fire or explosion damaging licensed material or a device, container, or equipment containing licensed material when:

(i) the quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of 10 CFR 20.1001 through 20.2402 [~~(2010)~~](2017), which is incorporated by reference, for the material; and

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

(3) Preparation and submission of reports. Reports made by licensees in response to the requirements of Section R313-19-50 must be made as follows:

(a) For radioactive materials, other than special nuclear material, licensees shall make reports required by Subsections R313-19-50(1) and (2) by telephone to the Director. To the extent that the information is available at the time of notification, the information provided in these reports must include:

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

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

(iii) the exact location of the event;

(iv) the radionuclides, quantities, and chemical and physical form of the licensed material involved; and

(v) available personnel radiation exposure data.

(b) For special nuclear materials, licensees shall make reports required by Subsections R313-19-50(1) and (2) by telephone to the Director. To the extent that the information is available at the time of notification, the information provided in these reports must include:

(i) the caller's name, position title, and call-back telephone number;

(ii) the date, time, and exact location of the event; and

(iii) a description of the event, including:

(A) radiological or chemical hazards involved, including isotopes, quantities, and chemical and physical form of any material released; and

(B) actual or potential health and safety consequences to the workers, the public, and the environment, including relevant chemical and radiation data for actual personnel exposures to radiation or radioactive materials or hazardous chemicals produced from radioactive materials (e.g., level of radiation exposure, concentration of chemicals, and duration of exposure).

(c) Written report for materials other than special nuclear materials. A licensee who makes a report required by Subsections R313-19-50(1) or (2) shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other rules may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports shall be sent to the Director. The report shall include the following:

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

(ii) the exact location of the event;

(iii) the radionuclides, quantities, and chemical and physical form of the licensed material involved;

(iv) date and time of the event;

(v) corrective actions taken or planned and results of evaluations or assessments; and

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

(d) Written report for special nuclear material. A licensee who makes a report required by Subsections R313-19-50(1) or (2) shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other rules may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports shall be sent to the Director. The report shall include the following:

(i) the complete applicable information required by Subsection R313-19-50(3)(b);

(ii) the probable cause of the event, including all factors that contributed to the event and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned; and

(iii) corrective actions taken or planned to prevent occurrence of similar or identical events in the future and the results of any evaluations or assessments.

KEY: licenses, reciprocity, transportation, exemptions
Date of Enactment or Last Substantive Amendment: [~~June 10, 2016~~]2017
Notice of Continuation: July 1, 2016
Authorizing, and Implemented or Interpreted Law: 19-3-104; [~~19-6-107~~]19-6-104

Environmental Quality, Waste Management and Radiation Control, Radiation
R313-21
General Licenses

NOTICE OF PROPOSED RULE
(Amendment)
DAR FILE NO.: 41993
FILED: 08/01/2017

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: The proposed changes incorporate corresponding revisions made by the U.S. Nuclear Regulatory Commission (NRC) in a final rule published in the Federal Register on 05/29/2013 (78 FR 32310) under the title of Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions. As an Agreement State with the NRC for the radioactive materials program in Utah, the proposed changes are made in order to maintain regulatory compatibility with the federal radioactive materials regulations and our agreement state status with the NRC. Changes are proposed in selected sections of Rules R313-12, R313-19, R313-21, and R313-22 in order to incorporate all of the corresponding revisions issued under NRC's final rule promulgated on 05/29/2013. Additional proposed changes not directly associated with NRC's final rule are being made to update noted references and citations. (EDITOR'S NOTE: A proposed amendment to Rule R313-12 is under Filing No. 41991, a proposed amendment to Rule R313-19 is under Filing No. 41992, and a proposed amendment to Rule R313-22 in under Filing No. 41994 in this issue, August 15, 20017, of the Bulletin.)

SUMMARY OF THE RULE OR CHANGE: On 07/13/2017, the Waste Management and Radiation Control Board authorized the proposed changes to be published for public review and comment. Proposed changes to Rules R313-12, R313-19, R313-21, and R313-22 reflect those revisions made by the NRC to selected sections of 10 CFR Part 40, as promulgated on 05/29/2013 (78 FR 32310). The majority of the changes are required to retain regulatory compatibility for the radioactive materials program, other proposed changes provide added clarification or correct textual errors. Specifically, incorporating the revisions promulgated by the NRC into the appropriate sections of Rule R313-21 require the initial distribution of source material to exempt persons or to general licensees be explicitly authorized by a specific license and institute new reporting requirements to provide

timely information on the types and quantities of source material distributed for use either under exemption or by general licensees. In addition, the rule modifies the existing possession and use requirements of the general license for small quantities of source material to better align the requirements with current health and safety standards. The regulatory amendments will create a regulatory framework for the initial distribution of source material to inform the Division, in the event of any manufacturer or distributor of source material becomes licensed in Utah, of what types and quantities of products containing source material are distributed for use under the exemptions from licensing and to identify persons using significant quantities of source material under the general license in Section R313-21-21. It will also ensure that general licensees under Section R313-21-21 are informed of applicable regulations before they obtain source material. Also, the proposed rule changes revise, clarify, or delete certain source material exemptions from licensing to make the exemptions more risk informed. The NRC's final rule and the associated proposed rule changes in the Utah radiation control rules also affect the possession and use of source material under a general license or an applicable license exemption. Proposed changes in Section R313-21-21 are being made to be compatible with the corresponding NRC regulations of 10 CFR 40.22 as promulgated on 05/29/2013 (78 FR 32310) regarding the distribution of certain quantities of source material (radioactive material containing uranium and/or thorium). Additionally, other proposed changes set limits to the amount of radioactive source material in certain physical or chemical forms a general licensee can possess, use, or transfer at any one time or receive in a calendar year. A general licensee exceeding these limits will be required to apply for and receive a specific license in place of a general license. The edition date of the reference to 10 CFR 32.71 in Subsection R313-21-22(9)(d)(i) is updated to 2017.

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Section 19-3-104 and Section 19-6-104

ANTICIPATED COST OR SAVINGS TO:

♦ THE STATE BUDGET: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no state agencies that manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. However, state academic institutions that may possess or use radioactive source material for research or other academic-related purposes beyond the proposed quantity limit may need to apply for and receive a specific licenses. Any costs associated with the specific license application process and subsequent implementation procedures are unique to each licensing action and are therefore not quantifiable. However, additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

♦ LOCAL GOVERNMENTS: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no local governments that manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. Additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

♦ SMALL BUSINESSES: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no small business in Utah that manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. However, a small business that may possess or use radioactive source material for commercial, operational, research, development, or other business-related purposes beyond the proposed quantity limit may need to apply for and receive a specific licenses. Any costs associated with the specific license application process and subsequent implementation procedures are unique to each licensing action and are therefore not quantifiable. Additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

♦ PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no other entities in Utah that currently manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. However, a person that may possess or use radioactive source material for commercial, operational, research, development, or other business-related purposes beyond the proposed quantity limit may need to apply for and receive a specific licenses. Any costs associated with the specific license application process and subsequent implementation procedures are unique to each licensing action and are therefore not quantifiable. Additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's

regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

COMPLIANCE COSTS FOR AFFECTED PERSONS: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no entities in Utah that manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. However, a business or person that may possess or use radioactive source material for commercial, operational, research, development, or other business-related purposes beyond the proposed quantity limit may need to apply for and receive a specific licenses. Any costs associated with the specific license application process and subsequent implementation procedures are unique to each licensing action and are therefore not quantifiable. Additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no entities in Utah that manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. However, a business or person that may possess or use radioactive source material for commercial, operational, research, development, or other business-related purposes beyond the proposed quantity limit may need to apply for and receive a specific licenses. Any costs associated with the specific license application process and subsequent implementation procedures are unique to each licensing action and are therefore not quantifiable. Additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
ENVIRONMENTAL QUALITY
WASTE MANAGEMENT AND RADIATION CONTROL, RADIATION
SECOND FLOOR
195 N 1950 W
SALT LAKE CITY, UT 84116-4880
or at the Office of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Rusty Lundberg by phone at 801-536-4257, by FAX at 801-536-0222, or by Internet E-mail at rlundberg@utah.gov
♦ Thomas Ball by phone at 801-536-0251, or by Internet E-mail at tball@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 09/15/2017

THIS RULE MAY BECOME EFFECTIVE ON: 10/16/2017

AUTHORIZED BY: Scott Anderson, Director

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.
R313-21. General Licenses.
R313-21-21. General Licenses--Source Material.

(1) A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local government agencies to receive, possess, use and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium,[~~not more than 6.82 kilogram (15 lb) of source material at any one time~~] for research, development, educational, commercial, or operational purposes in the following forms and quantities:[~~. A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of 68.2 kilogram (150 lb) of source material in any one calendar year.~~]

(a) No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms, for example, gaseous, liquid, powder, etc., at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under Subsection R313-21-21(1) may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year. A person possessing source material in excess of these limits as of October 16, 2017, may continue to possess up to 7 kg (15.4 lb) of uranium and thorium at any one time for one year beyond this date, or until the Director takes final action on a pending application submitted on or before October 16, 2017, for a specific license for this material; and receive up to 70 kg (154 lb) of uranium or thorium in any one calendar year until December 31, 2018, or until the Director takes final action on a pending application submitted on or before October 16, 2018, for a specific license for this material; and

(b) No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under Subsection R313-21-21(1) may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or

physical form of the source material possessed under Subsection R313-21-21(1) unless it is accounted for under the limits of Subsection R313-21-21(1)(a); or

(c) No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under Subsection R313-21-21(1)(a); or

(d) No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under Subsection R313-21-21(1) may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.

(2) Any person[~~Persons~~] who receives, possesses, uses, or transfers source material pursuant to the general license issued in Subsection R313-21-21(1):[~~are exempt from the provisions of R313-15 and R313-18, to the extent that such receipt, possession, use or transfer is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to a person who is also in possession of source material under a specific license issued pursuant to R313-22.~~]

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

(b) Shall not abandon this source material. Source material may be disposed of as follows:

(i) A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of Subsection R313-21-21(2) is exempt from the requirements to obtain a license under Rule R313-22 to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued under Rules R313-19, and R313-22; or

(ii) In accordance with Section R313-15-1001.

(c) Is subject to the provisions in 10 CFR 40.2a through 40.4, 10 CFR 40.41(c), 10 CFR 40.46, and 10 CFR 40.61(a) and (b), which are incorporated by reference in Section R313-24-4, Section R313-12-3, Section R313-19-5, Section R313-19-34, Subsection R313-22-34(2), Section R313-19-41, Section R313-19-50, Section R313-15-1111, Sections R313-12-51 through R313-12-53, Section R313-19-61, Rule R313-14, 10 CFR 40.41(d), 10 CFR 40.41(e)(1) and (e)(3), 10 CFR 40.51(b)(6), and 10 CFR 40.56.

(d) Shall respond to written requests from the Director 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 person cannot provide the requested information within the allotted time, the person shall, within that same time period, request a longer period to supply the information by providing the Director a written justification using the method stated in Section R313-12-110.

(e) Shall not export such source material except in accordance with 10 CFR Part 110 (2017).

(3) Any person who receives, possesses, uses, or transfers source material in accordance with Subsection R313-21-21(1) shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the Director using the method stated in Section R313-12-110 about such contamination and may consult with the Director as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in Section R313-15-402.

[~~(3) Persons who receive, possess, use, or transfer source material pursuant to the general license in R313-21-21(1) are prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the Director in a specific license.~~]

(4) Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in Subsection R313-21-21(1) is exempt from the provisions of Rules R313-15 and R313-18 to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of Sections R313-15-402 and R313-15-1001 to the extent necessary to meet the provisions of Subsections R313-21-21(2)(b) and R313-21-21(3). However, this exemption does not apply to any person who also holds a specific license issued under Rules R313-19 and R313-22.

(5) No person may initially transfer or distribute source material to persons generally licensed under Subsection R313-21-21(1)(a) or R313-21-21(1)(b), or paragraphs (a)(1) or (a)(2) of 10 CFR 40.22 for a non-Agreement State, or equivalent regulations of an Agreement State, unless authorized by a specific license issued in accordance with Subsection R313-22-54 or 10 CFR 40.54 for a non-Agreement State or equivalent provisions of an Agreement State. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally licensed by Subsection R313-21-21(1) before October 16, 2017, without specific authorization may continue for one year beyond this date. Distribution may also be continued until the Director takes final action on a pending application for license or license amendment to specifically authorize distribution submitted on or before October 16, 2018.

[~~(4)~~](6) A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize a person to receive, possess, deliver, use, or transfer source material.

[~~(5)~~](7) Depleted uranium in industrial products and devices.

(a) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of R313-21-21[~~(5)~~](7)(b), (c), (d), and (e), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(b) The general license in R313-21-21[~~(5)~~](7)(a) applies only to industrial products or devices which have been manufactured or initially transferred, either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to R313-22-75(11) or in accordance with a specific license issued to the manufacturer by the Nuclear Regulatory Commission, an Agreement

State, or a Licensing State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

(c)(i) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by R313-21-21[~~(5)~~](7)(a) shall file form DWMRC-12 "Registration Form-Use of Depleted Uranium Under General License," with the Director. The form shall be submitted within 30 days after the first receipt or acquisition of depleted uranium. The registrant shall furnish on form DWMRC-12 the following information and other information as may be required by that form:

(A) name and address of the registrant;

(B) a statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in R313-21-21[~~(5)~~](7)(a) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(C) name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in R313-21-21[~~(5)~~](7)(c)(i)(B).

(ii) The registrant possessing or using depleted uranium under the general license established by R313-21-21[~~(5)~~](7)(a) shall report in writing to the Director any changes in information previously furnished on form DWMRC-12 "Registration Form - Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of the change.

(d) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by R313-21-21(5)(a):

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

(ii) shall not abandon depleted uranium;

(iii) shall transfer or dispose of depleted uranium only by transfer in accordance with the provisions of R313-19-41. In the case where the transferee receives the depleted uranium pursuant to the general license established by R313-21-21[~~(5)~~](7)(a), the transferor shall furnish the transferee a copy of R313-21 and a copy of form DWMRC-12. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the Nuclear Regulatory Commission's or Agreement State's regulation equivalent to R313-21-21[~~(5)~~](7)(a), the transferor shall furnish the transferee a copy of this rule and a copy of form DWMRC-12 accompanied by a note explaining that use of the product or device is regulated by the Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in R313-21;

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

(v) shall not export depleted uranium except in accordance with a license issued by the Nuclear Regulatory Commission pursuant to 10 CFR Part 110; and

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

(e) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by R313-21-21[~~(5)~~](7)(a) is exempt from the requirements of R313-15 and R313-18 of these rules with respect to the depleted uranium covered by that general license.

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) RESERVED.

(2) Certain items and self-luminous products containing radium-226.

(a) A general license is hereby issued to a person to acquire, receive, possess, use, or transfer, in accordance with the provisions of Subsections R313-21-22(2)(b), R313-21-22(2)(c), and R313-21-22(2)(d), radium-226 contained in the following products manufactured prior to November 30, 2007.

(i) Antiquities originally intended for use by the general public. For the purposes of Subsection R313-21-22(2)(a), antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

(ii) Intact timepieces containing greater than 37 kilobecquerels (1 uCi), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

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

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

(v) Small radium sources containing no more than 37 kilobecquerels (1 uCi) of radium-226. For the purposes of Subsection R313-21-22(2)(a), "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations such as cloud chambers and spinthariscopes, electron tubes, static eliminators, or as designated by the Director.

(b) Persons who acquire, receive, possess, use, or transfer radioactive material under the general license issued in Subsection R313-21-22(2)(a) are exempt from the provisions of Rules R313-15, R313-18, and Sections R313-12-51 and R313-19-50, to the extent that the receipt, possession, use, or transfers of radioactive material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to a person specifically licensed under Rule R313-22.

(c) A person who acquires, receives, possesses, uses, or transfers radioactive material in accordance with the general license in Subsection R313-21-22(2)(a):

(i) Shall notify the Director should there be an indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Director within 30 days.

(ii) Shall not abandon products containing radium-226. The product, and radioactive material from the product, may only be disposed of according to Section R313-15-1008 or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the Director.

(iii) Shall not export products containing radium-226 except in accordance with 10 CFR Part 110.

(iv) Shall dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with Federal or State solid or hazardous waste laws, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 under Rule R313-22 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State or as otherwise approved by the Director.

(v) Shall respond to written requests from the Director to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Director a written justification using the method stated in Section R313-12-110.

(d) The general license in R313-21-22(2)(a) does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

(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 Director pursuant to R313-22-75(4); or

(B) an equivalent specific license issued by the Nuclear Regulatory Commission or an Agreement State; or

(C) An equivalent specific license issued by a State with provisions comparable to R313-22-75.*

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 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 Director, 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 Director, 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 Director within 30 days. Under these circumstances, the criteria set out in R313-15-402 may be applicable, as determined by the Director 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 Director 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 Director 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 Director:

(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)(xii) 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 Director 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 Director 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 Director 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 Director. The registration information must be submitted to the Director 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 Director:

(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 Director 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 Director 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 Director, 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 Director 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 Subsections R313-21-22(7)(b) and (c), to a person who holds a specific license issued by the Director which authorizes that person to receive, possess, use and transfer radioactive material.

(b) The general license in Subsection 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 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 Director, or an Agreement State which authorizes manufacture of the sources for distribution to persons generally licensed, or in accordance with a specific license issued by a State with requirements equivalent to 10 CFR 32.57 or 10 CFR 70.39.

(c) The general license provided in Subsection R313-21-22(7)(a) is subject to the provisions of Sections R313-12-51 through R313-12-53, R313-12-70, and Rules 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 the general license in Subsection R313-21-22(7)(a):

(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 sources;

(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 issued by the Director, the Nuclear Regulatory Commission, or an Agreement 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.

(d) A general license issued pursuant to Subsection R313-21-22(7)(a) does 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 DWMRC-07, "Registration Form-In Vitro Testing with Radioactive Material Under General License," with the Director and received a Certificate of Registration signed by the Director, 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 DWMRC-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 Subsection 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 Subsection 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 Subsection 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 Subsection 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 Director, 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 Subsection R313-21-22(9)(a)(viii) as required by Section R313-15-1001.

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

(d) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to Subsection 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, or an Agreement State, or before November 30, 2007, in accordance with the provisions of a specific license issued by a State with comparable provisions to 10 CFR 32.71 ([~~2010~~]2017) 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 Subsection R313-21-22(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 Subsection R313-21-22(9)(a) shall report in writing to the Director, changes in the information previously furnished in the "Registration Form-In Vitro Testing with Radioactive Material Under General License", form DWMRC[-]-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 Subsection R313-21-22(9)(a) is exempt from the requirements of Rules 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 Subsection R313-21-22(9)(a)(viii) shall comply with the provisions of Sections 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 Director, 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 Subsection 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 Director, 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 Section 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 Rules R313-15 and R313-18 except that the persons shall comply with the provisions of Sections 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 Sections 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.

KEY: radioactive materials, general licenses, source materials
Date of Enactment or Last Substantive Amendment: [~~August 26, 2015~~]2017
Notice of Continuation: October 4, 2013
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-104

Environmental Quality, Waste Management and Radiation Control, Radiation
R313-22
Specific Licenses

NOTICE OF PROPOSED RULE
(Amendment)
DAR FILE NO.: 41994
FILED: 08/01/2017

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: The proposed changes incorporate corresponding revisions made by the U.S. Nuclear Regulatory Commission (NRC) in a final rule published in the Federal Register on 05/29/2013 (78 FR 32310) under the title of Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions. As an Agreement State with the NRC for the radioactive materials program in Utah, the proposed changes are made in order to maintain regulatory compatibility with the federal radioactive materials regulations and our agreement state status with the NRC. Changes are proposed in selected sections of Rules R313-12, R313-19, R313-21, and R313-22 in order to incorporate all of the corresponding revisions issued under NRC's final rule promulgated on 05/29/2013. Additional proposed changes not directly associated with NRC's final rule are being made to update noted references and citations. (EDITOR'S NOTE: A proposed amendment to Rule R313-12 is under Filing No. 41991, a proposed amendment to Rule R313-19 is under Filing No. 41992, and a proposed amendment to Rule R313-21 in under Filing No. 41993 in this issue, August 15, 20017, of the Bulletin.)

SUMMARY OF THE RULE OR CHANGE: On 07/13/2017, the Waste Management and Radiation Control Board authorized the proposed changes to be published for public review and comment. Proposed changes to Rules R313-12, R313-19, R313-21, and R313-22 reflect those revisions made by the NRC to selected sections of 10 CFR Part 40, as promulgated on 05/29/2013 (78 FR 32310). The majority of the changes are required to retain regulatory compatibility for the radioactive materials program, other proposed changes provide added clarification or correct textual errors. Specifically, incorporating the revisions promulgated by the NRC into the appropriate sections of Rule R313-22 require the initial distribution of source material to exempt persons or to general licensees be explicitly authorized by a specific license and institute new reporting requirements to provide timely information on the types and quantities of source

material distributed for use either under exemption or by general licensees. In addition, the rule modifies the existing possession and use requirements of the general license for small quantities of source material to better align the requirements with current health and safety standards. The regulatory amendments will create a regulatory framework for the initial distribution of source material to inform the Division, in the event of any manufacturer or distributor of source material becomes licensed in Utah, of what types and quantities of products containing source material are distributed for use under the exemptions from licensing and to identify persons using significant quantities of source material under the general license in Section R313-21-21. It will also ensure that general licensees under Section R313-21-21 are informed of applicable regulations before they obtain source material. Also, the proposed rule changes revise, clarify, or delete certain source material exemptions from licensing to make the exemptions more risk informed. The NRC's final rule and the associated proposed rule changes in the Utah radiation control rules also affect the possession and use of source material under a general license or an applicable license exemption. The edition date of the reference to Appendix E of 10 CFR Part 20 in Section R313-22-4 is updated to 2017. Proposed changes in Section R313-22-33 are being made to be compatible with the corresponding NRC regulations of 10 CFR 40.32 as promulgated on 05/29/2013 (78 FR 32310) regarding the distribution of certain quantities of source material (radioactive material containing uranium and/or thorium). Two new subsections are being added in Sections R313-22-54 and R313-22-55 to be compatible with the corresponding NRC regulations of 10 CFR 40.54 and 10 CFR 40.55, respectively, as promulgated on 05/29/2013 (78 FR 32310) regarding the distribution, possession, use, or transfer of certain quantities of source material. Revised references in Subsection R313-22-75(11) in order to match renumbered paragraphs in Section R313-21-21.

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Section 19-3-104 and Section 19-6-104

MATERIALS INCORPORATED BY REFERENCE:

♦ Updates 10 CFR Part 20, Appendix E, published by Government Printing Office, 01/01/2017

ANTICIPATED COST OR SAVINGS TO:

♦ THE STATE BUDGET: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no state agencies that manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. However, state academic institutions that may possess or use radioactive source material for research or other academic-related purposes beyond the proposed quantity limit may need to apply for and receive a specific licenses. Any costs associated with the specific license application process and subsequent implementation procedures are unique to each licensing action and are therefore not quantifiable. However, additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

♦ LOCAL GOVERNMENTS: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no local governments that manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. Additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

♦ SMALL BUSINESSES: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no small business in Utah that manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. However, a small business that may possess or use radioactive source material for commercial, operational, research, development, or other business-related purposes beyond the proposed quantity limit may need to apply for and receive a specific licenses. Any costs associated with the specific license application process and subsequent implementation procedures are unique to each licensing action and are therefore not quantifiable. Additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

♦ PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no other entities in Utah that currently manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. However, a person that may possess or use radioactive source material for commercial, operational, research, development, or other business-related purposes beyond the proposed quantity limit may need to apply for and receive a specific licenses. Any costs associated with the specific license application process and subsequent implementation

procedures are unique to each licensing action and are therefore not quantifiable. Additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

COMPLIANCE COSTS FOR AFFECTED PERSONS: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no entities in Utah that manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. However, a business or person that may possess or use radioactive source material for commercial, operational, research, development, or other business-related purposes beyond the proposed quantity limit may need to apply for and receive a specific licenses. Any costs associated with the specific license application process and subsequent implementation procedures are unique to each licensing action and are therefore not quantifiable. Additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: The primary focus of the proposed rule changes is directed to manufacturers and distributors of radioactive source material (containing by definition a certain quantity of uranium or thorium). There are no entities in Utah that manufacture or distribute radioactive source material to either entities exempt from radioactive materials licensing requirements or to radioactive materials general licensees. However, a business or person that may possess or use radioactive source material for commercial, operational, research, development, or other business-related purposes beyond the proposed quantity limit may need to apply for and receive a specific licenses. Any costs associated with the specific license application process and subsequent implementation procedures are unique to each licensing action and are therefore not quantifiable. Additional information regarding a cost-benefit analysis associated with the NRC's final rule issued on 05/29/2013 (74 FR 32310) can be found in NRC's regulatory analysis document for this final rule (ADAMS Accession No. ML13079A302). A copy of this analysis is available from the Division of Waste Management and Radiation Control Web site at https://deq.utah.gov/Divisions/dwmrc/index.htm.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
ENVIRONMENTAL QUALITY
WASTE MANAGEMENT AND RADIATION
CONTROL, RADIATION
SECOND FLOOR
195 N 1950 W
SALT LAKE CITY, UT 84116-4880
or at the Office of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Rusty Lundberg by phone at 801-536-4257, by FAX at 801-536-0222, or by Internet E-mail at rlundberg@utah.gov
♦ Thomas Ball by phone at 801-536-0251, or by Internet E-mail at tball@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 09/15/2017

THIS RULE MAY BECOME EFFECTIVE ON: 10/16/2017

AUTHORIZED BY: Scott Anderson, Director

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.
R313-22. Specific Licenses.
R313-22-4. Definitions.

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

"Nationally tracked source" is a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix E of 10 CFR 20.1001 to 20.2402 ([~~2010~~]2017), which is incorporated by reference. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

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

"Site Area Emergency" means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by off-site response organizations to protect persons off-site.

R313-22-33. General Requirements for the Issuance of Specific Licenses.

(1) A license application shall be approved if the Director determines that:

(a) the applicant and all personnel who will be handling the radioactive material are qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these rules in a manner as to minimize danger to public health and safety or the environment;

(b) the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or the environment;

(c) the applicant's facilities are permanently located in Utah, otherwise the applicant shall seek reciprocal recognition as required by Section R313-19-30;

(d) the issuance of the license will not be inimical to the health and safety of the public;

(e) the applicant satisfies applicable special requirements in Sections R313-22-50, R313-22-54, and R313-22-75, and Rules R313-24, R313-25, R313-32, R313-34, R313-36, or R313-38; and

(f) in the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, or for the conduct of other activities which the Director determines will significantly affect the quality of the environment, the Director, before commencement of construction of the plant or facility in which the activity will be conducted, has concluded, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. The Director shall respond to the application within 60 days. Commencement of construction prior to a response and conclusion shall be grounds for denial of a license to receive and possess radioactive material in the plant or facility.

R313-22-34. Issuance of Specific Licenses.

(1) Upon a determination that an application meets the requirements of the Act and the rules of the Board, the Director will issue a specific license authorizing the proposed activity in a form and containing conditions and limitations as the Director deems appropriate or necessary.

(a) Specific licenses for a new license application shall have an expiration date five years from the end of the month in which it is issued.

(b) Specific licenses for a renewed license shall expire ten years after the expiration date of the previous version of the license.

(c) Notwithstanding R313-22-34(1)(b), if during the review of the license renewal application, the Director determines issues that need to be reassessed sooner than the ten year renewal interval, the Director may shorten the renewal interval on a case by case basis. Examples of issues that may result in a shortened renewal interval includes new technologies, new company management, poor regulatory compliance, or other situations that would warrant increased attention.

(2) The Director may incorporate in licenses at the time of issuance, or thereafter, additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to Rule R313-22 as the Director deems appropriate or necessary in order to:

(a) minimize danger to public health and safety or the environment;

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

(c) prevent loss or theft of material subject to Rule R313-22.

R313-22-54. Requirements for a Specific License to Initially Transfer Source Material for Use Under Section R313-21-21.

(1) An application for a specific license to initially transfer source material for use under Section R313-21-21, or 10 CFR 40.22 for a non-Agreement State, or equivalent regulations of an Agreement State, will be approved if:

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

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

R313-22-55. Conditions of Specific Licenses to Initially Transfer Source Material for Use Under Section R313-21-21.

(1)(a) Each person licensed under Section R313-22-54 shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words, "radioactive material."

(b) Each person licensed under Section R313-22-54 shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

(c) Each person licensed under Section R313-22-54 shall provide the information specified in Subsections R313-22-55(1)(c)(i) and (c)(ii) to each person to whom source material is transferred for use under Section R313-21-21 or 10 CFR 40.22 for non-Agreement States or equivalent provisions in Agreement State regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

(i) A copy of Sections R313-21-21 and R313-19-41, or relevant equivalent regulations of the Agreement State.

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

(d) Each person licensed under Section R313-22-54 shall report transfers as follows:

(i) File a report with the Director. The report shall include the following information:

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

(B) For each general licensee under Section R313-21-21 or 10 CFR 40.22 for non-Agreement States or equivalent Agreement State provisions to whom greater than 50 grams (0.11 pounds) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name or position or both and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

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

(ii) File a report with:

(A) Each responsible Agreement State agency that identifies all persons, operating under provisions equivalent to 10 CFR 40.22 (2016), to whom greater than 50 grams (0.11 pounds) of source material has been transferred within a single calendar quarter; or

(B) The U.S. Nuclear Regulatory Commission for non-Agreement States, that identifies all persons, operating under 10 CFR 40.22 (2016), to whom greater than 50 grams (0.11 pounds) of source material has been transferred within a single calendar quarter.

(C) The report shall include the following information specific to those transfers made to the Agreement State being reported to:

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

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

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

(iii) Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under Section R313-21-21 or 10 CFR 40.22, or equivalent Agreement State provisions during the current period, a report shall be submitted to the Director indicating so. If no transfers have been made to general licensees in a particular Agreement State or non-Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency or the U.S. Nuclear Regulatory Commission upon request of the agency or Commission.

(e) Each person licensed under Section R313-22-54 shall maintain all information that supports the reports required by Section R313-22-55 concerning each transfer to a general licensee for a period of one year after the event is included in a report to the Director.

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; active blood-forming organs; gonads; or lens of eye	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 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) 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[~~(5)~~](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[~~(5)~~](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[~~(5)~~](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[~~(5)~~](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[~~(5)~~](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[~~(5)~~](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[~~(5)~~](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[~~(5)~~](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[~~(5)~~](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: [~~June 10, 2016~~]2017
Notice of Continuation: July 1, 2016
Authorizing, and Implemented or Interpreted Law: 19-3-104; [~~19-6-107~~]19-6-104