



State of Utah

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DIVISION OF WASTE MANAGEMENT
AND RADIATION CONTROL

Douglas J. Hansen
Director

October 17, 2023

Theresa V. Clark, Deputy Director
Division of Materials Safety, Security, State and Tribal Programs
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
T8-E18
Washington, D.C. 20555-0001

RE: Final Rule Changes Associated with RATS ID 2020-2, 2020-3, and 2018-1

Dear Ms. Clark:

Enclosed is a copy of the final revisions to R313-12, *Definitions*, and R313-32, *Medical Use of Radioactive Material*, of the Utah Administrative Code (Radiation Control Rules) to incorporate federal regulations associated with RATS ID 2020-2 and 2020-3. The final revisions were approved by the Utah Waste Management and Radiation Control Board on September 14, 2023, with an effective date of September 18, 2023.

It was discovered during the IMPEP this year that the Division never submitted a letter to the NRC for the final adoption of rule changes associated with RATS ID 2018-1. Also enclosed is a copy of the final revisions to R313-19, R313-22, and R313-32 of the Utah Administrative Code (Radiation Control Rules) to incorporate the federal regulations associated with RATS ID 2018-1. The final revisions were approved by the Utah Waste Management and Radiation Control Board on August 8, 2019, with an effective date of August 9, 2019. Please note that the date 2019 found in the opening paragraph of R313-32-2 was amended to 2020 by RATS ID 2020-2 and 3.

The rule changes are identified by underline/strikeout and highlighted in yellow and correspond to the following equivalent amendments to NRC's regulations. Copies of the Notice of Effective Date from the Utah State Bulletins (Utah's analog to the Federal Register) dated September 1, 2019 and October 1, 2023 are attached.

(Over)

DRC-2023-073470

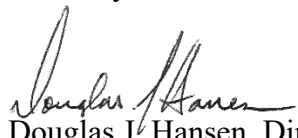
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<u>RATS ID</u>	<u>Title</u>	<u>State Sections</u>
2018-1	Medical Use of Byproduct Material - Medical Event Definitions, Training And Experience, and Clarifying Amendments	R313-19-34, R313-22-75 R313-32-2
2020-2	Social Security Number Fraud Prevention	R313-32-2
2020-3	Miscellaneous Corrections	R313-12-3, R313-32-2

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

If you have any questions, please call Tom Ball at 385-454-5574.

Sincerely,



Douglas J. Hansen, Director
Division of Waste Management and Radiation Control

DJH/TIB/jk

Enclosures: R313-12-3 (DRC-2023-073476)
R313-19-34 (DRC-2023-073482)
R313-22-75 (DRC-2023-073486)
R313-32-2, RATS ID 2018-1 Version, (DRC-2023-073490)
R313-32-2, RATS ID 2020-2 and 3 Version, (DRC-2023-073478)
September 1, 2019 Utah State Bulletin Notice of Effective Date (DRC-2023-073538)
October 1, 2023 Utah State Bulletin Notice of Effective Date (DRC-2023-073474)

c: Michelle Beardsley, NRC, State Regulation Review Coordinator (Email)
Theresa V. Clark, Deputy Director, Division of Materials Safety, Security, State and Tribal
Programs (Email)
Stevie Norcross, Asst. Director, Division of Waste Management and Radiation Control, UDEQ
Spencer Wickham, Division of Waste Management and Radiation Control, UDEQ

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.

R313-12. General Provisions.

R313-12-3. Definitions.

As used in Rules R313-12, R313-14 through R313-19, R313-21, R313-22, R313-24 through R313-26, R313-28, R313-30, R313-32, R313-34 through R313-38 and R313-70, these terms shall have the definitions set forth in Section R313-12-3. 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, (2020) 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, (2020) 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) [H]in excess of the derived air concentrations (DACs), specified in Rule R313-15; or

(b) [F]to 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% of the annual limit on intake (ALI), or 12 DAC-hours.

"As low as reasonably achievable" (ALARA) means making [every]each 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 to receive, use, or store 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. [u]Background radiation[u] 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 R313-12, R313-14 through R313-19, R313-21, R313-22, R313-24 through R313-26, R313-28, R313-30, R313-32, R313-34 through R313-38 and R313-70.

"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 [u]byproduct material[u] 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 [F]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) [B]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 [C]construction[C] 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 shall 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 [C]construction[C] 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 3.7×10^{10} 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 ~~[40]~~ten 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/cm²).

"Dentist" means an individual licensed by this state to engage in the practice of dentistry. See Sections 58-69-101 through 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 ~~[D]~~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~~]if capitalized, means the quotient of dQ by dm where $[^A]dQ[^A]$ 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 $[^A]dm[^A]$ 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~~]if not capitalized, 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]~~regulations 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 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/cm²).

"License" means a license issued by the [D]director in accordance with the rules adopted by the [B]board.

"Licensee" means a person who is licensed by the [D]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 [D]director.

"Licensing state" means a state which, before November 30, 2007, was provisionally or finally designated as [such] a licensing state 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 [S]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 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 [D]director in accordance with the rules adopted by the [B]board.

"Permitee" means a person who is permitted by the [D]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-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 this responsibility by the licensee or registrant. For a licensee authorized to use radioactive materials in accordance with the requirements of Rule R313-32[7];

(1) the individual named as the [R]Radiation Safety Officer[R] shall meet the training requirements for a Radiation Safety Officer as stated in Rule R313-32; or

(2) the individual shall be identified as a [R]Radiation Safety Officer[R] on;

(a) a specific license issued by the [D]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 [D]director or is legally obligated to register with the [D]director pursuant to these rules and the Act.

"Registration" means registration with the [D]director in accordance with the rules adopted by the [B]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 any 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 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 2.58×10^{-4} 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%), 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 of 10 CFR 71.4 in effect on June 30, 1983, and constructed before 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, 1996, and constructed before April 1, 1998, and special form material that was successfully tested before September 10, 2015 in accordance with the requirements of 10 CFR 71.75(d) in effect before September 10, 2015 may continue to be used. Any other special form encapsulation shall 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 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 previously in this definition for the same kind of special nuclear material. The sum of the ratios for [all]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.[-

—————]
$$\frac{(175(\text{Grams contained U-235})/350) + (50(\text{Grams U-233}/200) + (50(\text{Grams Pu})/200))}{1}$$
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]If appropriate, this evaluation includes 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 R313-12, R313-14 through R313-19, R313-21, R313-22, R313-24 through R313-26, R313-28, R313-30, R313-32, R313-34 through R313-38 and R313-70["].

"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 [D]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 [D]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 these rules. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant if the decision to make the change is made before 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.

KEY: definitions, units, inspections, exemptions

Date of Last Change: May 16, 2022

Notice of Continuation: April 8, 2021

Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-104

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.

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

R313-19-34. Terms and Conditions of Licenses.

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

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

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

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

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

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

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

(5) Licensees shall notify the Director in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11, Bankruptcy, of the United States Code by or against:

(a) the licensee;

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

(c) an affiliate, as that term is defined in 11 USC 101(2), of the licensee.

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

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

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

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

(8) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with Rule R313-32 (incorporating 10 CFR 35.204 by reference). The licensee shall record the results of each test and retain each record for three years after the record is made. The licensee shall report the results of each test that exceeds the permissible concentration listed in R313-32 (incorporating 10 CFR 35.204(a)) at the time of generator elution, in accordance with R313-32 (incorporating 10 CFR 35.3204).

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

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

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

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

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

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

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

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

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

KEY: licenses, reciprocity, transportation, exemptions

Date of Enactment or Last Substantive Amendment: [October 13, 2017]

Notice of Continuation: July 1, 2016

Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-104

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.

R313-22. Specific Licenses.

R313-22-75. Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices Which Contain Radioactive Material.

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

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

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

(2) Licensing the distribution of radioactive material in exempt quantities. Authority to transfer possession or control by the manufacturer, processor or producer of equipment, devices, commodities or other products containing byproduct material whose subsequent possession, use, transfer, and disposal by other persons who are exempted from regulatory requirements may be obtained only from the Nuclear Regulatory Commission, Washington, D.C. 20555.

(3) Reserved

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

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

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

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

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

(B) under ordinary conditions of handling, storage and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that a person will receive in one year, a dose in excess of ten percent of the annual limits specified in Subsection R313-15-201(1), and

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

commitment in excess of the following organ doses:

TABLE

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

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

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

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

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

(I) "The receipt, possession, use and transfer of this device, Model No., Serial No., are subject to a general license or the equivalent, and the regulations of the Nuclear Regulatory Commission or a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited." The label shall be printed with the words "CAUTION -RADIOACTIVE MATERIAL" and the name of the manufacturer or distributor shall appear on the label. The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

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

(iv) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing,

a durable label containing the device model number and serial number, the isotope and quantity, the words, "Caution-Radioactive Material," the radiation symbol described in Section R313-15-901, and the name of the manufacturer or initial distributor.

(v) Each device meeting the criteria of Subsection R313-21-22(4)(c)(xiii)(A), bears a permanent label, for example, embossed, etched, stamped, or engraved, affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in Section R313-15-901.

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

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

- (i) primary containment, or source capsule;
- (ii) protection of primary containment;
- (iii) method of sealing containment;
- (iv) containment construction materials;
- (v) form of contained radioactive material;
- (vi) maximum temperature withstood during prototype tests;
- (vii) maximum pressure withstood during prototype tests;
- (viii) maximum quantity of contained radioactive material;
- (ix) radiotoxicity of contained radioactive material; and
- (x) operating experience with identical devices or similarly designed and constructed devices.

(c) In the event the applicant desires that the general licensee under Subsection R313-21-22(4), or under equivalent regulations of the Nuclear Regulatory Commission, an Agreement State or a Licensing State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with this activity or activities, and basis for these estimates. The submitted information shall demonstrate that performance of this activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of ten percent of the annual limits specified in Subsection R313-15-201(1).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(I) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternative address for the general licensee shall be submitted along with information on the actual location of use.

(II) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(III) The date of transfer;

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

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

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

(D) For devices received from a Subsection R313-21-22(4) general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

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

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

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

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

the report must so indicate.

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

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

(I) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternative address for the general licensee shall be submitted along with information on the actual location of use.

(II) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(III) The date of transfer;

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

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

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

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

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

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

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

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

request of the agency.

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

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

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

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

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

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

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

(7) Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license.

An application for a specific license to manufacture or distribute radioactive material for use under the general license of Subsection R313-21-22(9) will be approved if:

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

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

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

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

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

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

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

(vi) cobalt-57 in units not exceeding 370 kilobecquerel (ten uCi) each;

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

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

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

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

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

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

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

.....
Name of Manufacturer"

(ii) "This radioactive material shall be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a Licensing State.

.....
Name of Manufacturer"

(e) the label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source shall also contain directions to the licensee regarding the waste disposal requirements set out in Section R313-15-1001.

(8) Licensing the manufacture and distribution of ice detection devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under Subsection R313-21-22(10) will be approved if:

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

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

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

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

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

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

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

(A) registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

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

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

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

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

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

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

(A) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days, the time may be omitted.

(B) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

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

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

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

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

reference);

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

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

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

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

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

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

(v) Shall provide to the Director:

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

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

(C) the permit issued by a licensee or Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

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

(E) documentation that only accelerator produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

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

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

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

and make adjustments when necessary; and

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

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

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

(10) Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed under Rule R313-32 for use as a calibration, transmission, or reference source or for the uses listed in Rule R313-32 (incorporating 10 CFR 35.400, 10 CFR 35.500, 10 CFR 35.600, and 35.1000 by reference) will be approved if:

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

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

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

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

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

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

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

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

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

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

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

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

and Device Registry.

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

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

- (i) primary containment or source capsule,
- (ii) protection of primary containment,
- (iii) method of sealing containment,
- (iv) containment construction materials,
- (v) form of contained radioactive material,
- (vi) maximum temperature withstood during prototype tests,
- (vii) maximum pressure withstood during prototype tests,
- (viii) maximum quantity of contained radioactive material,
- (ix) radiotoxicity of contained radioactive material, and
- (x) operating experience with identical sources or devices or similarly designed and constructed sources or devices.

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

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

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

(ii) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses and potential hazards of the industrial product or device to provide reasonable assurance that possession, use or transfer of the depleted uranium in the product or device is not likely to cause an individual to receive a radiation dose in excess of ten percent of the annual limits specified in Subsection R313-15-201(1); and

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

(b) In the case of an industrial product or device whose unique benefits are questionable, the Director will approve an application for a specific license under Subsection R313-22-75(11) only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

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

product or device cannot be reasonably foreseen.

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

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

(ii) label or mark each unit to:

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

(B) state that the receipt, possession, use and transfer of the product or device are subject to a general license or the equivalent and the regulations of the Nuclear Regulatory Commission or an Agreement State;

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

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

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

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

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

(vi) provide certain other reports as follows:

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

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

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

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

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

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

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

KEY: specific licenses, decommissioning, broad scope, radioactive materials

Date of Enactment or Last Substantive Amendment: [October 13, 2017]

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RATS ID 2018-1 Version

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.

R313-32. Medical Use of Radioactive Material.

R313-32-1. Purpose and Authority.

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

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

R313-32-2. Clarifications or Exceptions.

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

(1) The exclusion of the following:

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

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

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

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

(2) The substitution of the following date references:

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

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

(3) The substitution of the following rule references:

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

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

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

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

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

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

~~[-(e)]~~ (g) "Section R313-12-110" for reference to "Sec. 30.6

of this chapter" as found in 10 CFR 35.14(c). ~~[or for reference to "Sec. 30.6(a)" or for reference to "Sec. 30.6(a) of this chapter"];~~

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

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

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

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

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

~~[(k)]~~ (m) "Rules R313-19, R313-22 and Subsection R313-22-75(10) or equivalent U.S. Nuclear Regulatory Commission or Agreement State [regulations] requirements" for reference to "10 CFR Part 30 and Sec. 32.74 of this chapter or equivalent requirements of an Agreement State~~[,]~~" as found in 10 CFR 35.65(b)49(a);

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

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

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

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

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

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

~~[(r)]~~ (t) "Subsection R313-22-75(9) or equivalent Nuclear Regulatory Commission or Agreement State requirements~~[, 10 CFR 32.72,]~~" for reference to "Sec. 32.72 of this chapter or equivalent Agreement State requirements" as found in 10 CFR 35.63(b)(2)(i), 10 CFR 35.63(c)(3)(i), 10 CFR 35.100(a)(1), 10 CFR 35.200(a)(1), and 10 CFR 35.300(a)(1); [~~_____ (s) "Subsection R313-22-75(9)(b)(v)" for reference to "Sec. 32.72(b)(5)"~~

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

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

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

equivalent Agreement State requirements" as found in 10 CFR 35.63(b)(2)(iii), 10 CFR 35.63(c)(3)(ii), 10 CFR 35.100(a)(2), 10 CFR 35.200(a)(2), or 10 CFR 35.300(a)(2).

(4) The substitution of the following terms:

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

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

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

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

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

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

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

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

~~[-(h)-]~~ (i) ~~["Equivalent U.S. Nuclear Regulatory Commission or Agreement State"]~~ "license issued by the Director, the Nuclear Regulatory Commission, or the Agreement State" for reference to ~~["Equivalent Agreement State"]~~ "Commission or Agreement State"

license" ~~[-as found]~~ in 10 CFR 35.14(a)(2) (first instance) ~~[63(b)(2)(i), 10 CFR 35.63(e)(3), 10 CFR 35.65(a), 10 CFR 35.100(a), 10 CFR 35.200(a), and 10 CFR 35.300(a)]~~;

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

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

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

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

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

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

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

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

~~[-(p)]~~ (q) ["Director, a U.S. Nuclear Regulatory Commission, or Agreement State] "Director" for reference to ~~["NRC or Agreement State]~~ "NRC" in 10 CFR 35.~~[63(b)(2)(ii)]~~3045(g)(1), 10 CFR 35.~~[100(e)]~~3047(f)(1), ~~[10 CFR 35.200(e), -]~~ and 10 CFR 35.~~[300(e)]~~35.3204(a) (second instance); and

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

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

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

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

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

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

(1) Requests an amendment to the licensee's radioactive

materials license for the approval;

(2) Can demonstrate that the radioactive waste will be safely stored, and accounted for during the decay-in-storage period and that the additional radioactive waste will not exceed the licensee's radioactive waste storage capacity; and

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

KEY: radioactive materials, radiopharmaceutical, brachytherapy, nuclear medicine

Date of Enactment or Last Substantive Amendment: [October 13, 2010]

Notice of Continuation: July 1, 2016

Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-107

RATS ID 2020-2 & 3 Version

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.

R313-32. Medical Use of Radioactive Material.

R313-32-2. Clarifications or Exceptions.

For the purposes of Rule R313-32, 10 CFR 35.2 through 35.7; 35.10(d) through 35.10(f); 35.11(a) through 35.11(b); 35.12; and 35.13(b) through 35.3204 [~~(2019)~~ (2020)] are incorporated by reference with the following clarifications or exceptions:

(1) The exclusion of the following:

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

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

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

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

(2) The substitution of the following date references:

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

(b) "December 31, 2019" for "January 14, 2019"~~[+]~~.

(3) The substitution of the following rule references:

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

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

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

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

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

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

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

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

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

(j) "Subsection R313-15-301(1) (c)" for reference to "Sec.

20.1301(c) of this chapter" as found in 10 CFR 35.310(a)(2)(ii) and 10 CFR 35.410(a)(4)(ii);

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

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

(m) "Rules R313-19, R313-22 and Subsection R313-22-75(10) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements" for reference to "10 CFR Part 30 and Sec. 32.74 of this chapter or equivalent requirements of an Agreement State" as found in 10 CFR 35.49(a);

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

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

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

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

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

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

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

(u) "Subsection R313-22-32(9) or equivalent Nuclear Regulatory Commission or Agreement State requirements" for reference to "Sec. 30.32(j) of this chapter or equivalent Agreement State requirements" as found in 10 CFR 35.63(b)(2)(iii), 10 CFR 35.63(c)(3)(ii), 10 CFR 35.100(a)(2), 10 CFR 35.200(a)(2), or 10 CFR 35.300(a)(2).

(4) The substitution of the following terms:

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

(b) "a [D]director, a Nuclear Regulatory Commission, or Agreement State" for reference to "an NRC or Agreement State" in 10 CFR 35.63(b)(2)(ii), 10 CFR 35.100(c), 10 CFR 35.200(c), or 10 CFR 35.300(c);

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

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

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

(f) "medical use license issued by the [Ø]director" for reference to "NRC medical use license" in 10 CFR 35.6(c);

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

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

(i) "license issued by the [Ø]director, the Nuclear Regulatory Commission, or the Agreement State" for reference to "Commission or Agreement State license" in 10 CFR 35.14(a) (2) (first instance);

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

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

(l) "[Ø]director at the address specified in Section R313-12-110" for reference to "appropriate NRC Regional Office listed in Sec. 30.6 of this chapter" in 10 CFR 35.3045(d), 10 CFR 35.3047(d),

10 CFR 35.3067, and 10 CFR 35.3204(b);

(m) "[B]board" for reference to "Commission" in 10 CFR 35.18(a)(3) (second instance) and 10 CFR 35.19;

(n) "[D]director" for reference to "Commission" in 10 CFR 35.12(d)(4), 10 CFR 35.14(a), 10 CFR 35.14(b), 10 CFR 35.18(a), 10 CFR 35.18(a)(3) (first instance), 10 CFR 35.18(b), 10 CFR 35.24(a)(1), 10 CFR 35.24(c), 10 CFR 35.26(a), and 10 CFR 35.1000(b);

(o) "[D]director" for reference to "NRC" in 10 CFR 35.3045(g)(1), 10 CFR 35.3047(f)(1), and 10 CFR 35.3204(a) (second instance);

(p) "Nuclear Regulatory Commission" for reference to "Commission" in 10 CFR 35.67(b)(2);

(q) "[D]director" for reference to "NRC" in 10 CFR 35.3045(g)(1), 10 CFR 35.3047(f)(1), and 10 CFR 35.35.3204(a) (second instance); ~~and~~

(r) "the [D]director" for reference to "NRC" in 10 CFR 35.13(b)(4)(i);

(s) "licenses issued by the [D]director" for reference to "NRC licenses" in 10 CFR 35.57(c);

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

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

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

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

(1) [R]requests an amendment to the licensee's radioactive materials license for the approval;

(2) [E]can demonstrate that the radioactive waste will be safely stored, and accounted for during the decay-in-storage period and that the additional radioactive waste will not exceed the licensee's radioactive waste storage capacity; and

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

KEY: radioactive materials, radiopharmaceutical, brachytherapy, nuclear medicine

Date of Enactment or Last Substantive Amendment: August 9, 2019

Notice of Continuation: July 1, 2016

Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-107

UTAH STATE BULLETIN

OFFICIAL NOTICES OF UTAH STATE GOVERNMENT
Filed August 02, 2019, 12:00 a.m. through August 15, 2019, 11:59 p.m.

Number 2019-17
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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.

The Portable Document Format (PDF) version of the *Bulletin* is the official version. The PDF version of this issue is available at <https://rules.utah.gov/>. Any discrepancy between the PDF version and other versions will be resolved in favor of the PDF version.

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

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I. Utah. Office of Administrative Rules.

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NOTICES OF RULE EFFECTIVE DATES

State law provides for agencies to make their administrative rules effective and enforceable after publication in the *Utah State Bulletin*. In the case of **PROPOSED RULES** or **CHANGES IN PROPOSED RULES** with a designated comment period, the law permits an agency to make a rule effective no fewer than seven calendar days after the close of the public comment period, nor more than 120 days after the publication date. In the case of **CHANGES IN PROPOSED RULES** with no designated comment period, the law permits an agency to make a rule effective on any date including or after the thirtieth day after the rule's publication date, but not more than 120 days after the publication date. If an agency fails to file a **NOTICE OF EFFECTIVE DATE** within 120 days from the publication of a **PROPOSED RULE** or a related **CHANGE IN PROPOSED RULE** the rule lapses.

Agencies have notified the Office of Administrative Rules that the rules listed below have been made effective.

NOTICES OF EFFECTIVE DATE are governed by Subsection 63G-3-301(12), Section 63G-3-303, and Sections R15-4-5a and R15-4-5b.

Abbreviations

AMD = Amendment
CPR = Change in Proposed Rule
NEW = New Rule
R&R = Repeal & Reenact
REP = Repeal

Administrative Services

Debt Collection

No. 43801 (AMD): R21-1. Transfer of Collection Responsibility of State Agencies
Published: 07/01/2019
Effective: 08/07/2019

No. 43802 (AMD): R21-2. Office of State Debt Collection Administrative Procedures
Published: 07/01/2019
Effective: 08/07/2019

No. 43803 (AMD): R21-3. Debt Collection Through Administrative Offset
Published: 07/01/2019
Effective: 08/07/2019

Agriculture and Food

Regulatory Services

No. 43777 (AMD): R70-310. Grade A Pasteurized Milk
Published: 07/01/2019
Effective: 08/13/2019

Commerce

Occupational and Professional Licensing

No. 43779 (AMD): R156-50. Private Probation Provider Licensing Act Rule
Published: 07/01/2019
Effective: 08/08/2019

Environmental Quality

Air Quality

No. 43587 (AMD): R307-110-28. Regional Haze
Published: 04/01/2019
Effective: 08/15/2019

No. 43587 (CPR): R307-110-28. Regional Haze
Published: 07/15/2019
Effective: 08/15/2019

Waste Management and Radiation Control, Radiation
No. 43810 (AMD): R313-19-34. Terms and Conditions of Licenses
Published: 07/01/2019
Effective: 08/09/2019

No. 43809 (AMD): R313-22-75. Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices Which Contain Radioactive Material
Published: 07/01/2019
Effective: 08/09/2019

No. 43812 (AMD): R313-32. Medical Use of Radioactive Material
Published: 07/01/2019
Effective: 08/09/2019

Governor

Economic Development

No. 43814 (AMD): R357-15. Enterprise Zone Tax Credit
Published: 07/01/2019
Effective: 08/12/2019

Money Management Council

Administration

No. 43815 (NEW): R628-22. Conditions and Procedures for the use of Negotiable Brokered Certificates of Deposit
Published: 07/01/2019
Effective: 08/07/2019

NOTICES OF RULE EFFECTIVE DATES

Public Service Commission

Administration

No. 43811 (NEW): R746-460. Rules Governing Customer Information and Marketing for Large-Scale Electric and Gas Utilities

Published: 07/01/2019

Effective: 08/07/2019

School and Institutional Trust Lands

Administration

No. 43792 (AMD): R850-70. Sales of Forest Products From Trust Lands Administration Lands

Published: 07/01/2019

Effective: 08/07/2019

End of the Notices of Rule Effective Dates Section

UTAH STATE BULLETIN

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Nancy L. Lancaster, Managing Editor

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Office of Administrative Rules, Salt Lake City 84114

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Agencies have notified the Office of Administrative Rules that the rules listed below have been made effective.

NOTICES OF EFFECTIVE DATE are governed by Subsection 63G-3-301(12), Section 63G-3-303, and Sections R15-4-5a and R15-4-5b.

Corrections

Administration

No. 55548 (Amendment) R251-703: Vehicle Direction Station
Published: 08/15/2023
Effective: 09/26/2023

Health Care Financing, Coverage and Reimbursement Policy
No. 55528 (Amendment) R414-1-31: Withholding of Payments
Published: 08/01/2023
Effective: 09/14/2023

Environmental Quality

Air Quality

No. 55323 (Amendment) R307-110-13: Section IX, Control Measures for Area and Point Sources, Part D, Ozone
Published: 06/01/2023
Effective: 09/13/2023

Natural Resources

Public Lands Policy Coordinating Office

No. 55457 (New Rule) R654-1: Archaeological Permits
Published: 07/15/2023
Effective: 09/05/2023

Waste Management and Radiation Control, Radiation

No. 55531 (Amendment) R313-12-3: Definitions
Published: 08/01/2023
Effective: 09/18/2023

Public Lands Policy Coordination Office Administration

No. 55443 (Repeal) R694-1: Archeological Permits
Published: 07/15/2023
Effective: 09/05/2023

No. 55532 (Amendment) R313-32-2: Clarifications or Exceptions

Published: 08/01/2023
Effective: 09/18/2023

Public Safety

Emergency Management

No. 55542 (New Rule) R704-4: Response, Recovery, and Post-disaster Mitigation Grant Funding
Published: 08/15/2023
Effective: 09/21/2023

Health and Human Services

Disease Control and Prevention, Health Promotion

No. 55390 (Amendment) R384-415: Requirements to Sell Electronic Cigarette Products
Published: 05/15/2023
Effective: 09/12/2023

Driver License

No. 55526 (Repeal) R708-49: Temporary Identification Card
Published: 08/01/2023
Effective: 09/11/2023

No. 55390 (Change in Proposed Rule) R384-415: Requirements to Sell Electronic Cigarette Products
Published: 06/15/2023
Effective: 09/12/2023

Highway Patrol

No. 55552 (Amendment) R714-560: Technology and Equipment for Officer-Involved Critical Incident Investigation
Published: 08/15/2023
Effective: 09/21/2023

NOTICES OF RULE EFFECTIVE DATES

No. 55587 (New Rule) R714-562: Early Intervention
System Grant Program
Published: 08/15/2023
Effective: 09/21/2023

End of the Notices of Rule Effective Dates Section