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Rule R313-12. General Provisions.

As in effect on September 1, 2002

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R313-12-1. Authority.

The rules set forth herein are adopted pursuant to the provisions of Subsections 19-3-104(3) and 19-3- 104(6) and Section 63-38-3.

R313-12-2. Purpose and Scope.

It is the purpose of these rules to state such requirements as shall be applied in the use of radiation, radiation machines, and radioactive materials to ensure the maximum protection of the public health and safety to all persons at, or in the vicinity of, the place of use, storage, or disposal. These rules are intended to be consistent with the proper use of radiation machines and radioactive materials. Except as otherwise specifically provided, these rules apply to all persons who receive, possess, use, transfer, own or acquire any source of radiation, provided, however, that nothing in these rules shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission. See also Section R313-12-55.

R313-12-3. Definitions.

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

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

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

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

"Accelerator produced material" means a 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 that is identified on the license and where radioactive material may be received, used or stored.

"Agreement State" means a state with which the United States Nuclear Regulatory Commission has entered into an effective agreement under Section 274 b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

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

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

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

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

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

"Area of use" means a portion of an address of use that has been set aside for the purpose of

receiving, using, or storing radioactive material.

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

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

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

"Board" means the 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; and

(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 or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

"Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of the year shall begin in January, and subsequent calendar quarters shall be arranged so that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. The method observed by the licensee or registrant for determining calendar quarters shall only be changed at the beginning of a year.

"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.

"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.

"Committed dose equivalent" ($H_{T,50}$), 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" ($H_{E,50}$), 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.

"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).

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

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

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

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

"Department" means the Utah State 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.

"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.

"Executive Secretary" means the executive secretary of the board.

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

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

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

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

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

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

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

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

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

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

"Generally applicable environmental radiation standards" means standards issued by the U.S. Environmental Protection Agency under the authority of the Atomic Energy Act of 1954, as

amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

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

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

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

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

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

"Individual" means a human being.

"Individual monitoring" means the assessment of:

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

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

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

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

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

"Lens dose equivalent" (LDE) applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm²).

"License" means a license issued by the Executive Secretary in accordance with the rules adopted

by the Board.

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

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

"Licensing state" means a state which has been provisionally or finally designated as such by the Conference of Radiation Control Program Directors, Inc., which reviews state regulations to establish equivalency with the Suggested State Regulations and ascertains whether a State has an effective program for control of naturally occurring or accelerator produced radioactive material (NARM). The Conference will designate as Licensing States those states with regulations for control of radiation relating to, and an effective program for, the regulatory control of NARM.

"Limits". See "Dose limits".

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

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

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

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

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

"NARM" means a naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source or special nuclear material.

"NORM" means a naturally occurring radioactive material.

"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 Section R313-32-75, 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 MeV.

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

"Permittee" means a person who is permitted by the Department 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 practice pharmacy. See Sections 58-17a-101 through 58-17a-801.

"Physician" means an individual licensed by this state to practice medicine and surgery in all its branches. See Sections 58-67-101 through 58-67-803.

"Practitioner" means an individual licensed by this state in the practice of a healing art. Examples would be, physician, dentist, podiatrist, osteopath, and chiropractor.

"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 sources of radiation from licensed or registered operations. 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 Section R313-32-75, or from voluntary participation in medical research programs.

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

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

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

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

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

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

"Radiation safety officer" means an individual who has the knowledge and responsibility to apply appropriate radiation protection rules and has been assigned such responsibility by the licensee or registrant.

"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 Executive Secretary or is legally obligated to register with the Executive Secretary pursuant to these rules and the Act.

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

"Regulations of the U.S. Department of Transportation" means 49 CFR 100 through 189.

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

"Research and development" means:

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

(b) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

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

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

"Roentgen" (R) means the special unit of EXPOSURE. One roentgen equals 2.58×10^{-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.

"Shallow dose equivalent" (H_s) which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (seven mg per cm^2), averaged over an area of one square centimeter.

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

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

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

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

"Source material" means:

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

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

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

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

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

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

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

(c) it satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission in 10 CFR 71.75. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory

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

"Special nuclear material" means:

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

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

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

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

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

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

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

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

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

"U.S. Department of Energy" means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c), and (d) of Public Law 93- 438, October 11, 1974, 88 Stat. 1233 at 1237, effective January 19, 1975 known as the Energy Reorganization Act of 1974, and retransferred to the Secretary of Energy pursuant to section 301(a) of Public Law 95-91, August 14, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977 known as the Department of Energy Organization

Act.

"Unrefined and unprocessed ore" means ore in its natural form prior to processing, like grinding, roasting, beneficiating or refining.

"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 that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as in the Low-Level Radioactive Waste Policy Act, P.L. 96-573, as amended by P.L. 99-240, effective January 15, 1986; that is, radioactive waste:

(a) not classified as high-level radioactive waste, spent nuclear fuel, or byproduct material as defined in Section 11e.(2) of the Atomic Energy Act (uranium or thorium tailings and waste) and

(b) classified by the U.S. Nuclear Regulatory Commission as low-level radioactive waste consistent with existing law and in accordance with (a) above.

"Waste collector licensees" means persons licensed to receive and store radioactive wastes prior to disposal or persons licensed to dispose of radioactive waste.

"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 Executive Secretary and controlled by a licensee or registrant, but does not include the licensee or registrant.

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

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

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

R313-12-20. Units of Exposure and Dose.

(1) As used in these rules, the unit of EXPOSURE is the coulomb per kilogram (C per kg). One roentgen is equal to 2.58×10^{-4} coulomb per kilogram of air.

(2) As used in these rules, the units of dose are:

(a) Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule per kilogram. One gray equals 100 rad.

(b) Rad is 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. One rad equals 0.01 Gy.

(c) Rem is 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 Sv.

(d) Sievert (Sv) is 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.

(3) As used in these rules, the quality factors for converting absorbed dose to dose equivalent are shown in Table 1.

TABLE 1

Quality Factors and Absorbed Dose Equivalencie

| Type of Radiation | Quality Factor (Q) | Absorbed Dose Equal to a Unit Dose Equivalent |
|--|--------------------|---|
| X, gamma, or beta radiation and high-speed electrons | 1 | 1 |
| Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge | 20 | 0.05 |
| Neutrons of unknown energy | 10 | 0.1 |
| High energy protons | 10 | 0.1 |

For the column in Table 1 labeled "Absorbed Dose Equal to a Unit Dose Equivale to one rem or the absorbed dose in gray is equal to one Sv.

(4) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in Subsection R313-12-20 (3), 0.01 Sv of neutron radiation of unknown energies may, for purposes of these rules, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table 2 to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

TABLE 2

Mean Quality Factors, Q, and Fluence Per Unit Dc Equivalent for Monoenergetic Neutrons

| Fluence per Unit Dose | Fluence per Unit Dose |
|-----------------------|-----------------------|
|-----------------------|-----------------------|

| | Neutron Energy Mev | Quality Factor Q | Equivalent neutrons cm ⁻² rem ⁻¹ | Equivalent neutrons cm ⁻² Sv ⁻¹ |
|---------|------------------------|---------------------|---|--|
| thermal | 2.5 x 10 ⁻⁸ | 2 | 980 x 10 ⁶ | 980 x 10 ⁸ |
| | 1 x 10 ⁻⁷ | 2 | 980 x 10 ⁶ | 980 x 10 ⁸ |
| | 1 x 10 ⁻⁶ | 2 | 810 x 10 ⁶ | 810 x 10 ⁸ |
| | 1 x 10 ⁻⁵ | 2 | 810 x 10 ⁶ | 810 x 10 ⁸ |
| | 1 x 10 ⁻⁴ | 2 | 840 x 10 ⁶ | 840 x 10 ⁸ |
| | 1 x 10 ⁻³ | 2 | 980 x 10 ⁶ | 980 x 10 ⁸ |
| | 1 x 10 ⁻² | 2.5 | 1010 x 10 ⁶ | 1010 x 10 ⁸ |
| | 1 x 10 ⁻¹ | 7.5 | 170 x 10 ⁶ | 170 x 10 ⁸ |
| | 5 x 10 ⁻¹ | 11 | 39 x 10 ⁶ | 39 x 10 ⁸ |
| | 1 | 11 | 27 x 10 ⁶ | 27 x 10 ⁸ |
| | 2.5 | 9 | 29 x 10 ⁶ | 29 x 10 ⁸ |
| | 5 | 8 | 23 x 10 ⁶ | 23 x 10 ⁸ |
| | 7 | 7 | 24 x 10 ⁶ | 24 x 10 ⁸ |
| | 10 | 6.5 | 24 x 10 ⁶ | 24 x 10 ⁸ |
| | 14 | 7.5 | 17 x 10 ⁶ | 17 x 10 ⁸ |
| | 20 | 8 | 16 x 10 ⁶ | 16 x 10 ⁸ |
| | 40 | 7 | 14 x 10 ⁶ | 14 x 10 ⁸ |
| | 60 | 5.5 | 16 x 10 ⁶ | 16 x 10 ⁸ |
| | 1 x 10 ² | 4 | 20 x 10 ⁶ | 20 x 10 ⁸ |
| | 2 x 10 ² | 3.5 | 19 x 10 ⁶ | 19 x 10 ⁸ |
| | 3 x 10 ² | 3.5 | 16 x 10 ⁶ | 16 x 10 ⁸ |
| | 4 x 10 ² | 3.5 | 14 x 10 ⁶ | 14 x 10 ⁸ |

For the column in Table 2 labeled "Quality Factor", the values of Q are at the maximum in a 30 cm diameter cylinder tissue-equivalent phantom.

For the columns in Table 2 labeled "Fluence per Unit Dose Equivalent", the values are normally on a 30 cm diameter cylinder tissue equivalent phantom.

R313-12-40. Units of Radioactivity.

For purposes of these rules, activity is expressed in the SI unit of becquerel (Bq), or in the special unit of curie (Ci), or their multiples, or disintegrations or transformations per unit of time.

(1) One becquerel (Bq) equals one disintegration or transformation per second.

(2) One curie (Ci) equals 3.7 x 10¹⁰ disintegrations or transformations per second, which equals 3.7 x 10¹⁰ becquerel, which equals 2.22 x 10¹² disintegrations or transformations per minute.

R313-12-51. Records.

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

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

(a) records of disposal of licensed material made under Sections R313-15-1002 (including burials

authorized before January 28, 1981), R313-15-1003, R313-15-1004, and R313-15-1005; and

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

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

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

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

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

(4) Prior to license termination, each licensee may forward the records required by Subsection R313- 22-35(7) to the Executive Secretary.

(5) Additional records requirements are specified elsewhere in these rules.

R313-12-52. Inspections.

(1) A licensee or registrant shall afford representatives of the Executive Secretary, at reasonable times, opportunity to inspect sources of radiation and the premises and facilities wherein those sources of radiation are used or stored.

(2) A licensee or registrant shall make available to representatives of the Executive Secretary for inspection, upon reasonable notice, records maintained pursuant to these rules.

R313-12-53. Tests.

(1) A licensee or registrant shall perform upon instructions from a representative of the Board or the Executive Secretary or shall permit the representative to perform reasonable tests as the representative deems appropriate or necessary including, but not limited to, tests of:

(a) sources of radiation;

(b) facilities wherein sources of radiation are used or stored;

(c) radiation detection and monitoring instruments; and

(d) other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

R313-12-54. Additional Requirements.

The Board may, by rule, or order, impose upon a licensee or registrant requirements in addition to those established in these rules that it deems appropriate or necessary to minimize any danger to public health and safety or the environment.

R313-12-55. Exemptions.

- (1) The Board may, upon application or upon its own initiative, grant exemptions or exceptions from the requirements of these rules as it determines are authorized by law and will not result in undue hazard to public health and safety or the environment.
- (2) U.S. Department of Energy contractors or subcontractors and U.S. Nuclear Regulatory Commission contractors or subcontractors operating within this state are exempt from these rules to the extent that the contractor or subcontractor under his contract receives, possesses, uses, transfers, or acquires sources of radiation. The following contractor categories are included:
- (a) prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or controlled sites, including the transportation of sources of radiation to or from the sites and the performance of contract services during temporary interruptions of the transportation;
 - (b) prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof;
 - (c) prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and
 - (d) any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the state and the U.S. Nuclear Regulatory Commission jointly determine (i) that the exemption of the prime contractor or subcontractor is authorized by law; and (ii) that under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

R313-12-70. Impounding.

Sources of radiation shall be subject to impounding pursuant to Section 19-3-111. Persons who have a source of radiation impounded are subject to fees established in accordance with the Legislative Appropriations Act for the actual cost of the management and oversight activities performed by representatives of the Executive Secretary.

R313-12-100. Prohibited Uses.

- (1) A hand-held fluoroscopic screen using x-ray equipment shall not be used unless it has been listed in the Registry of Sealed Source and Devices or accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health.
- (2) A shoe-fitting fluoroscopic device shall not be used.

R313-12-110. Communications.

All communications and reports concerning these rules, and applications filed thereunder, should be addressed to the Division of Radiation Control, P.O. Box 144850, 168 North 1950 West, Salt Lake City, Utah 84114-4850.

KEY

definitions, units, inspections, exemptions

Date of Enactment or Last Substantive Amendment

September 14, 2001

Notice of Continuation

July 23, 2001

Authorizing, Implemented, or Interpreted Law

19-3-104; 19-3-108

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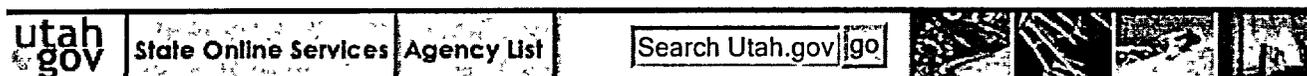
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Rule R313-14. Violations and Escalated Enforcement.

As in effect on September 1, 2002

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- **KEY**
- **Date of Enactment or Last Substantive Amendment**
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R313-14-1. Introduction and Purpose.

(1) The purpose of the radiation control inspection and compliance program is to assure the radiological safety of the public, radiation workers, and the environment by:

(a) ensuring compliance with Utah Radiation Control rules or license conditions;

(b) obtaining prompt correction of violations;

(c) deterring future violations; and

(d) encouraging improvement of licensee, permittee or registrant performance, including the prompt identification, reporting, and correction of potential safety problems.

(2) Consistent with the purpose of the radiation control inspection and compliance program, prompt and vigorous enforcement action shall be taken when dealing with licensees, permittees or registrants who fail to demonstrate adherence to these rules. Enforcement action is dependent on the circumstances of the case and may require that discretion be exercised after consideration of these standards. Sanctions have been designed to ensure that a licensee, permittee or registrant does not deliberately profit from violations of the Utah Radiation Control rules.

R313-14-2. Responsibilities.

(1) The Board has authorized the Executive Secretary to:

(a) enforce rules through the issuance of orders and assess penalties in accordance with Section 19- 3-109; and

(b) impound radioactive material in accordance with Section 19-3-111.

(2) The Executive Secretary is authorized to issue Notices of Violations.

R313-14-3. Definitions.

As used in R313-14, the following definitions apply:

(1) "Material False Statement" means a statement that is false by omission or commission and is relevant to the regulatory process.

(2) "Requirement" means a legally binding requirement such as a statute, rule, license condition, permit, registration, technical specification, or order.

(3) "Similar" means those violations which could have been reasonably expected to have been prevented by the licensee's, permittee's or registrant's corrective action for a previous violation.

(4) "Willfulness" means the deliberate intent to violate or falsify, and includes careless disregard for requirements. Acts which do not rise to the level of careless disregard are not included in this definition.

R313-14-10. Severity of Violations.

(1) Violations are placed in one of two major categories. These categories are:

(a) electronically produced radiation operations; or

(b) radioactive materials operations.

(2) Regulatory requirements vary in public health and environmental safety significance. Therefore, it is essential that the relative importance of violations be identified as the first step in the enforcement process. Based upon their relative hazard, violations are assigned to one of five levels of severity.

(3) Severity Level I is assigned to violations that are the most significant and Severity Level V violations are the least significant. In general, violations that are included in Severity Levels I and II involve actual or high potential impact on the public. Severity Level III violations are cause for significant concern. Severity Level IV violations are less serious but are of more than minor concern, however, if left uncorrected, they could lead to a more serious concern. Severity Level V violations are of minor safety or environmental concern.

(4) The severity of a violation shall be characterized at the level best suited to the significance of the particular violation. A severity level may be increased if the circumstances surrounding the violation involve careless disregard of requirements, deception, or other indications of willfulness. In determining the specific severity level of a violation involving willfulness, consideration will be given to factors like the position of the person involved in the violation, the significance of an underlying violation, the intent of the violator and the economic advantage gained by the

violation. The relative weight given to these factors in arriving at the appropriate severity level is dependent on the circumstances of the violation.

(5) The severity level assigned to material false statements may be Severity Level I, II or III, depending on the circumstances surrounding the statement. In determining the specific severity level of a violation involving material false statements or falsification of records, consideration is given to factors like the position of the person involved in the violation, for example, a first line supervisor as opposed to a senior manager, the significance of the information involved, and the intent of the violator. Negligence not amounting to careless disregard would be weighted differently than careless disregard or deliberateness. The relative weight given to these factors in arriving at the appropriate severity level is dependent on the circumstances of the violation.

R313-14-15. Enforcement Actions.

This Section describes the enforcement sanctions available to the Executive Secretary and specifies the conditions under which they are to be used.

(1) Notice of Violation

(a) A Notice of Violation is a written notice setting forth one or more violations of a legally binding requirement. The notice normally requires the licensee, permittee or registrant to provide a written statement describing:

(i) corrective steps which have been taken by the licensee, permittee or registrant and the results achieved;

(ii) corrective steps which shall be taken to prevent recurrence; and

(iii) the date when full compliance will be achieved.

(b) The Executive Secretary may require responses to Notices of Violation to be under oath. Normally, responses under oath may be required only in connection with civil penalties and orders.

(c) A Notice of Violation is used by the Executive Secretary as the method for formalizing the existence of a violation. The Notice may be the only enforcement action taken or it may be used as a basis for other enforcement actions. Licensee, permittee or registrant initiative for self-identification and correction of problems is encouraged. The Executive Secretary shall not generally issue Notices of Violation for a violation that meets the five following tests:

(i) It was identified by the licensee, permittee or registrant;

(ii) it fits in Severity Level IV or V;

(iii) it was reported, in writing, to the Executive Secretary;

(iv) it was or will be corrected, including measures to prevent recurrence, within a reasonable time; and

(v) it was not a violation that could reasonably be expected to have been prevented by the licensee's, permittee's or registrant's corrective action for a previous violation.

(d) Licensees, permittees or registrants are not ordinarily cited for violations resulting from matters outside of their control, like equipment failures that were not avoidable by reasonable quality assurance measures or management controls. Generally however, licensees, permittees and registrants are held responsible for the acts of their employees. Accordingly, the rules should not be construed to excuse personal errors.

(2) Civil Penalty.

(a) A civil penalty is a monetary penalty that may be imposed for violation of Utah Radiation Control Rules or lawful orders issued by the Executive Secretary. Civil penalties are designed to emphasize the need for lasting remedial action and to deter future violations. Generally, civil penalties are imposed for Severity Level I violations, are imposed for Severity Level II violations, in the absence of mitigating circumstances, are considered for Severity Level III violations, and may be imposed for Severity Level IV and V violations that are similar to previous violations for which the licensee, permittee or registrant failed to take effective corrective action.

(b) The level of a civil penalty is established so that a penalty does not exceed \$5,000 per violation. Except as modified by provision of the next paragraphs, the base civil penalties are as follows:

TABLE

| | |
|-------------------------------|---------|
| Severity Level I Violations | \$5,000 |
| Severity Level II Violations | \$4,000 |
| Severity Level III Violations | \$2,500 |
| Severity Level IV Violations | \$ 750 |
| Severity Level V Violations | \$ 250 |

(i) Comprehensive licensee, permittee or registrant programs for detection, correction and reporting of problems that may constitute, or lead to, violation of regulatory requirements are important and consideration may be given for effective internal audit programs. When licensees, permittees or registrants find, report, and correct a violation expeditiously and effectively, the Executive Secretary may apply adjustment factors to reduce or eliminate a civil penalty.

(ii) Ineffective licensee, permittee or registrant programs for problem identification or correction are unacceptable. In cases involving willfulness, flagrant violations, repeated poor performance in an area of concern, or serious breakdown in management controls, the Executive Secretary may apply the full enforcement authority.

(iii) The Executive Secretary may review the proposed civil penalty case on its own merits and adjust the civil penalty upward or downward appropriately. After considering the relevant circumstances, adjustments to these values may be made for the factors identified below:

(A) Reduction of the civil penalty may be given when a licensee, permittee or registrant identifies the violation and promptly reports, in writing, the violation to the Executive Secretary. No consideration will be given to this factor if the licensee, permittee or registrant does not take immediate action to correct the problem upon discovery.

(B) Recognizing that corrective action is always required to meet regulatory requirements, the promptness and extent to which the licensee, permittee or registrant takes corrective action, including actions to prevent recurrence, may be considered in modifying the civil penalty to be assessed.

(C) Reduction of the civil penalty may be given for prior good performance in the general area of concern.

(D) The civil penalty may be increased as much as 50% for cases where the licensee, permittee or registrant had prior knowledge of a problem as a result of an internal audit, or specific Executive Secretary or industry notification, and had failed to take effective preventive steps.

(E) The civil penalty may be increased as much as 50% where multiple examples of a particular violation are identified during the inspection period.

(c) A violation of a continuing nature shall, for the purposes of calculating the proposed civil penalty, be considered a separate violation for each day of its continuance. A continuing violation is not considered a repeat violation. In the event a violation is repeated within five years, the scheduled amount of the civil penalty may be increased 25%; and for repeat violations of Severity Levels II and III, the penalty may not be avoided by compliance. Other rights and procedures are not affected by the repeat violation.

(d) Payment of civil penalties shall be made within 30 working days of receipt of a Notice of Violation and Notice of Proposed Imposition of a Civil Penalty. An extension may be given when extenuating circumstances are shown to exist. Payment shall be made by check, payable to the Division of Radiation Control and mailed to the Division at the address shown with the Notice of Violation.

(3) Orders.

(a) An Order is a written directive to modify, suspend, or revoke a license, permit or registration; to cease and desist from a given practice or activity; or to take other action that may be necessary.

(b) Modification Orders are issued when some change in licensee, permittee or registrant equipment, procedures or management control is necessary.

(c) Suspension Orders may be used:

(i) to remove a threat to the public health and safety or the environment;

(ii) when the licensee, permittee or registrant has not responded adequately to other enforcement action;

(iii) when the licensee, permittee or registrant interferes with the conduct of an inspection; or

(iv) for a reason not mentioned above for which license, permit or registration revocation is authorized.

(v) Suspensions may apply to all or part of the regulated activity. Ordinarily, an activity is not suspended, nor is a suspension prolonged for failure to comply with requirements when the failure is not willful or when adequate corrective actions have been taken.

(d) Revocation Orders may be used:

(i) when a licensee, permittee or registrant is unable or unwilling to comply with these rules;

- (ii) when a licensee, permittee or registrant refuses to correct a violation;
- (iii) when a licensee, permittee or registrant does not respond to a Notice of Violation;
- (iv) when a licensee, permittee or registrant does not pay a fee required by the Department; or
- (v) for any other reason for which revocation is authorized.

(e) Cease and Desist Orders are used to stop unauthorized activity that has continued despite notification by the Executive Secretary that the activity is unauthorized.

(f) Orders may be made effective immediately, without prior opportunity for hearing, whenever it is determined that the public health, interest, or safety so requires, or when the Order is responding to a violation involving willfulness. Otherwise, a prior opportunity for a hearing is afforded. For cases in which a basis could reasonably exist for not taking the action as proposed, the licensee, permittee or registrant shall be afforded an opportunity to show cause why the Order should not be issued in the proposed manner.

(4) Escalation of Enforcement Sanctions.

(a) In accordance with the provisions of Section 19-3-111 the radioactive material of a person may be impounded. Administrative procedures will be conducted as provided by R313-14-20, prior to disposal of impounded radioactive materials.

(b) Violations of Severity Levels I, II or III are considered to be very serious. If repetitive very serious violations occur, the Executive Secretary may issue Orders in conjunction with other enforcement actions to achieve immediate corrective actions and to deter their recurrence. In accordance with the criteria contained in this section, the Executive Secretary shall carefully consider the circumstances of cases when selecting and applying the appropriate sanctions.

(c) The progression of enforcement actions for repetitive violations may be based on violations under a single license, permit or registration. The actual progression to be used in a particular case may depend on the circumstances. When more than one facility is covered by a single license, permit or registration, the normal progression may be based on repetitive violations under the same license, permit or registration. It should be noted that under some circumstances, for example, where there is common control over some facet of facility operations, repetitive violations may be charged even though the second violation occurred at a different facility or under a different license, permit or registration.

(5) Related Administrative Actions.

(a) In addition to the formal enforcement mechanisms of Notices of Violation and Orders, the Executive Secretary may use administrative mechanisms, like enforcement conferences, bulletins, circulars, information notices, generic letters, and confirmatory action letters as part of the enforcement and regulatory program. Licensees, permittees and registrants are expected to adhere to obligations and commitments resulting from these processes and the Executive Secretary shall, if necessary, issue appropriate orders to make sure that expectation is realized.

(b) Enforcement Conferences are meetings held by the Executive Secretary with licensee, permittee or registrant management to discuss safety, public health, or environmental problems, compliance with regulatory requirements, proposed corrective measures, including schedules for implementation, and enforcement options available to the Executive Secretary.

(c) Bulletins, Circulars, Information Notices, and Generic Letters are written notifications to groups of licensees, permittees or registrants identifying specific problems and calling for or recommending specific actions on their part. Responses to these notifications may be required.

(d) Confirmatory Action Letters are letters confirming a licensee's, permittee's or registrant's agreement to take certain actions to remove significant concerns about health and safety, or the environment.

R313-14-25. Public Disclosure of Enforcement Actions.

Enforcement actions and responses are publicly available for inspection. In addition, press releases are generally issued for Notices of Proposed Imposition of a Civil Penalty and Orders. In the case of orders and civil penalties related to violations at Severity Level I, II or III, press releases may be issued at the time of the Order or the Notice of Proposed Imposition of the Civil Penalty. Press releases are not normally issued for Notices of Violation.

KEY

violations, penalties, enforcement

Date of Enactment or Last Substantive Amendment

June 8, 2001

Notice of Continuation

July 23, 2001

Authorizing, Implemented, or Interpreted Law

19-3-109; 19-3-111

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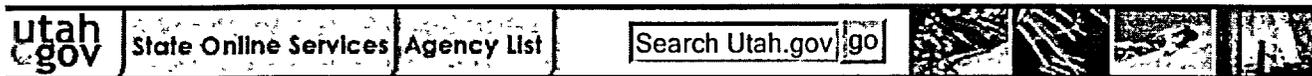
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Rule R313-15. Standards for Protection Against Radiation.

As in effect on September 1, 2002

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- **KEY**
- **Date of Enactment or Last Substantive Amendment**
- **Notice of Continuation**
- **Authorizing, Implemented, or Interpreted Law**

R313-15-1. Purpose, Authority and Scope.

(1) Rule R313-15 establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses issued by the Executive Secretary. These rules are issued pursuant to Sections 19-3-104(3) and 19-3-104(6).

(2) The requirements of Rule R313-15 are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in Rule R313-15. However, nothing in Rule R313-15 shall be construed as limiting actions that may be necessary to protect health and safety.

(3) Except as specifically provided in other sections of these rules, Rule R313-15 applies to persons licensed or registered by the Executive Secretary to receive, possess, use, transfer, or dispose of sources of radiation. The limits in Rule R313-15 do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with Section R313-32-75, or to exposure from voluntary participation in medical research programs.

R313-15-2. Definitions.

"Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix B of 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference.

"Air-purifying respirator" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

"Assigned protection factor" (APF) means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

"Atmosphere-supplying respirator" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

"Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than ten days, for Class W, Weeks, from ten to 100 days, and for Class Y, Years, of greater than 100 days. For purposes of these rules, "lung class" and "inhalation class" are equivalent terms.

"Constraint (dose constraint)" in accordance with 10 CFR 20.1003, 2001 ed., means a value above which specified licensee actions are required.

"Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

"Demand respirator" means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

"Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these rules, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of Appendix B of 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference.

"Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

"Disposable respirator" means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape- only self-contained breathing apparatus (SCBA).

"Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

"Filtering facepiece" (dust mask) means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

"Fit factor" means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

"Fit test" means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

"Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

"Hood" means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

"Inhalation class", refer to "Class".

"Labeled package" means a package labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations 49 CFR 172.403 and 49 CFR 172.436 through 440, 2000 ed. Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403(m) and (w) and 49 CFR 173.421 through 424, 2000 ed.

"Loose-fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

"Lung class", refer to "Class".

"Negative pressure respirator" (tight fitting) means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

"Nonstochastic effect" means a health effect, the severity of which varies with the dose and for

which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these rules, "deterministic effect" is an equivalent term.

"Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

"Positive pressure respirator" means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

"Powered air-purifying respirator" (PAPR) means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

"Pressure demand respirator" means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

"Qualitative fit test" (QLFT) means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

"Quantitative fit test" (QNFT) means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

"Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

"Reference Man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health employees to standardize results of experiments and to relate biological insult to a common base. A description of the Reference Man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."

"Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

"Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

"Self-contained breathing apparatus" (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

"Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these rules, "probabilistic effect" is an equivalent term.

"Supplied-air respirator" (SAR) or airline respirator means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

"Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the

face.

"User seal check" (fit check) means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

"Very 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 an absorbed dose in excess of five Gy (500 rad) in one hour at one meter from a radiation source or one meter from any surface that the radiation penetrates.

"Weighting factor" w_T for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

TABLE
ORGAN DOSE WEIGHTING FACTORS

| Organ or Tissue | w_T |
|-----------------|----------|
| Gonads | 0.25 |
| Breast | 0.15 |
| Red bone marrow | 0.12 |
| Lung | 0.12 |
| Thyroid | 0.03 |
| Bone surfaces | 0.03 |
| Remainder | 0.30 (1) |
| Whole Body | 1.00 (2) |

(1) 0.30 results from 0.06 for each of five "remainder" organs, excluding the skin at the highest doses.

(2) For the purpose of weighting the external whole body dose, for adding it to the factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external dose on a case-by-case basis until such time as specific guidance is issued.

R313-15-3. Implementation.

(1) Any existing license or registration condition that is more restrictive than Rule R313-15 remains in force until there is an amendment or renewal of the license or registration.

(2) If a license or registration condition exempts a licensee or registrant from a provision of Rule R313-15 in effect on or before January 1, 1994, it also exempts the licensee or registrant from the corresponding provision of Rule R313-15.

(3) If a license or registration condition cites provisions of Rule R313-15 in effect prior to January 1, 1994, which do not correspond to any provisions of Rule R313-15, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

R313-15-101. Radiation Protection Programs.

(1) Each licensee or registrant shall develop, document, and implement a radiation protection

program sufficient to ensure compliance with the provisions of Rule R313-15. See Section R313-15-1102 for recordkeeping requirements relating to these programs.

(2) The licensee or registrant shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

(3) The licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

(4) To implement the ALARA requirements of Subsection R313-15-101(2), and notwithstanding the requirements in Section R313-15-301, a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its decay products, shall be established by licensees or registrants such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 0.1 mSv (0.01 rem) per year from these emissions. If a licensee or registrant subject to this requirement exceeds this dose constraint, the licensee or registrant shall report the exceedance as provided in Section R313-15-1203 and promptly take appropriate corrective action to ensure against recurrence.

R313-15-201. Occupational Dose Limits for Adults.

(1) The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to Section R313-15-206, to the following dose limits:

(a) An annual limit, which is the more limiting of:

(i) The total effective dose equivalent being equal to 0.05 Sv (5 rem); or

(ii) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.50 Sv (50 rem).

(b) The annual limits to the lens of the eye, to the skin, and to the extremities which are:

(i) A lens dose equivalent of 0.15 Sv (15 rem), and

(ii) A shallow dose equivalent of 0.50 Sv (50 rem) to the skin or to any extremity.

(2) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See Subsections R313-15-206(5)(a) and R313-15-206(5)(b).

(3) The assigned deep dose equivalent and shallow dose equivalent shall be for the part of the body receiving the highest exposure.

(a) The deep dose equivalent, lens dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable; or

(b) When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified in Subsection R313-15-502(1)(d), the effective dose equivalent for external radiation shall be determined as follows:

(i) When only one individual monitoring device is used and it is located at the neck outside the protective apron, and the reported dose exceeds 25 percent of the limit specified in Subsection R313-15-201(1), the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or

(ii) When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

(4) Derived air concentration (DAC) and annual limit on intake (ALI) values are specified in Table I of Appendix B of 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference, and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See Section R313-15-1107.

(5) Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to ten milligrams in a week in consideration of chemical toxicity. See footnote 3, of Appendix B of 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference.

(6) The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See Subsection R313-15-205(5).

R313-15-202. Compliance with Requirements for Summation of External and Internal Doses.

(1) If the licensee or registrant is required to monitor pursuant to both Subsections R313-15-502(1) and R313-15-502(2), the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to Subsection R313-15-502(1) or only pursuant to Subsection R313-15-502(2), then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to Subsections R313-15-202(2), R313-15-202(3) and R313-15-202(4). The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

(2) Intake by Inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

(a) The sum of the fractions of the inhalation ALI for each radionuclide, or

(b) The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or

(c) The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, w_T , and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than ten percent of the maximum weighted value of $H_{T,50}$, that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

(3) Intake by Oral Ingestion. If the occupationally exposed individual receives an intake of radionuclides by oral ingestion greater than ten percent of the applicable oral ALI, the licensee or registrant shall account for this intake and include it in demonstrating compliance with the limits.

(4) Intake through Wounds or Absorption through Skin. The licensee or registrant shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for pursuant to Subsection R313-15-202(4).

R313-15-203. Determination of External Dose from Airborne Radioactive Material.

(1) Licensees or registrants shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, lens dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See footnotes 1 and 2 of Appendix B of 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference.

(2) Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

R313-15-204. Determination of Internal Exposure.

(1) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee or registrant shall, when required pursuant to Section R313-15-502, take suitable and timely measurements of:

- (a) Concentrations of radioactive materials in air in work areas; or
- (b) Quantities of radionuclides in the body; or
- (c) Quantities of radionuclides excreted from the body; or
- (d) Combinations of these measurements.

(2) Unless respiratory protective equipment is used, as provided in Section R313-15-703, or the assessment of intake is based on bioassays, the licensee or registrant shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

(3) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee or registrant may:

(a) Use that information to calculate the committed effective dose equivalent, and, if used, the licensee or registrant shall document that information in the individual's record; and

(b) Upon prior approval of the Executive Secretary, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and

(c) Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a

given radionuclide to the committed effective dose equivalent. See Appendix B of 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference.

(4) If the licensee or registrant chooses to assess intakes of Class Y material using the measurements given in Subsections R313-15-204(1)(b) or R313-15-204(1)(c), the licensee or registrant may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by Section R313-15-1202 or Section R313-15-1203. This delay permits the licensee or registrant to make additional measurements basic to the assessments.

(5) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:

(a) The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix B of 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference, for each radionuclide in the mixture; or

(b) The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

(6) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

(7) When a mixture of radionuclides in air exists, a licensee or registrant may disregard certain radionuclides in the mixture if:

(a) The licensee or registrant uses the total activity of the mixture in demonstrating compliance with the dose limits in Section R313-15-201 and in complying with the monitoring requirements in Subsection R313-15-502(2), and

(b) The concentration of any radionuclide disregarded is less than ten percent of its DAC, and

(c) The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

(8) When determining the committed effective dose equivalent, the following information may be considered:

(a) In order to calculate the committed effective dose equivalent, the licensee or registrant may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 0.05 Sv (5 rem) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

(b) For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.50 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix B of 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference. The licensee or registrant may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALI, the licensee or registrant shall also demonstrate that the limit in Subsection R313-15-201(1)(a)(ii) is met.

R313-15-205. Determination of Prior Occupational Dose.

(1) For each individual likely to receive, in a year, an occupational dose requiring monitoring pursuant to Section R313-15-502, the licensee or registrant shall:

(a) Determine the occupational radiation dose received during the current year; and

(b) Attempt to obtain the records of cumulative occupational radiation dose. A licensee or registrant may accept, as the record of cumulative radiation dose, an up-to-date form DRC-05 or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant.

(2) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

(a) The internal and external doses from all previous planned special exposures; and

(b) All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual.

(3) In complying with the requirements of Subsection R313-15-205(1), a licensee or registrant may:

(a) Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and

(b) Obtain reports of the individual's dose equivalents from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, facsimile, other electronic media or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(4) The licensee or registrant shall record the exposure history, as required by Subsection R313-15-205(1), on form DRC-05, or other clear and legible record, of all the information required on that form.

(a) The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing form DRC-05 or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on form DRC-05 or equivalent indicating the periods of time for which data are not available.

(b) For the purpose of complying with this requirement, licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the rules in Rule R313-15 in effect before January 1, 1994. Further, occupational exposure histories obtained and recorded on form DRC-05 or equivalent before January 1, 1994, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

(5) If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:

(a) In establishing administrative controls under Subsection R313-15-201(6) for the current year, that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

(b) That the individual is not available for planned special exposures.

(6) The licensee or registrant shall retain the records on form DRC-05 or equivalent until the Executive Secretary terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing form DRC-05 or equivalent for three years after the record is made.

R313-15-206. Planned Special Exposures.

A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in Section R313-15-201 provided that each of the following conditions is satisfied:

(1) The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical.

(2) The licensee or registrant, and employer if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

(3) Before a planned special exposure, the licensee or registrant ensures that each individual involved is:

(a) Informed of the purpose of the planned operation; and

(b) Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

(c) Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

(4) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by Subsection R313-15-205(2) during the lifetime of the individual for each individual involved.

(5) Subject to Subsection R313-15-201(2), the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

(a) The numerical values of any of the dose limits in Subsection R313-15-201(1) in any year; and

(b) Five times the annual dose limits in Subsection R313-15-201(1) during the individual's lifetime.

(6) The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with Section R313-15-1106 and submits a written report in accordance with Section R313-15-1204.

(7) The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to Subsection R313-15-201(1) but shall be included in evaluations required by Subsections R313-15-206(4) and R313-15-206(5).

R313-15-207. Occupational Dose Limits for Minors.

The annual occupational dose limits for minors are ten percent of the annual occupational dose limits specified for adult workers in Section R313-15-201.

R313-15-208. Dose to an Embryo/Fetus.

(1) The licensee or registrant shall ensure that the dose equivalent to the embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed five mSv (0.5 rem). See Section R313-15-1107 for recordkeeping requirements.

(2) The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in Subsection R313-15-208(1).

(3) The dose equivalent to an embryo/fetus is the sum of:

(a) The dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman; and

(b) The dose equivalent that is most representative of the dose equivalent to the embryo/fetus from external radiation, that is, in the mother's lower torso region.

(i) If multiple measurements have not been made, assignment of the highest deep dose equivalent for the declared pregnant woman shall be the dose equivalent to the embryo/fetus, in accordance with Subsection R313-15-201(3); or

(ii) If multiple measurements have been made, assignment of the deep dose equivalent for the declared pregnant woman from the individual monitoring device which is most representative of the dose equivalent to the embryo/fetus shall be the dose equivalent to the embryo fetus. Assignment of the highest deep dose equivalent for the declared pregnant woman to the embryo/fetus is not required unless that dose equivalent is also the most representative deep dose equivalent for the region of the embryo/fetus.

(4) If the dose equivalent to the embryo/fetus is found to have exceeded five mSv (0.5 rem) or is within 0.5 mSv (0.05 rem) of this dose by the time the woman declares the pregnancy to the licensee or registrant, the licensee or registrant shall be deemed to be in compliance with Subsection R313-15-208(1) if the additional dose equivalent to the embryo/fetus does not exceed 0.50 mSv (0.05 rem) during the remainder of the pregnancy.

R313-15-301. Dose Limits for Individual Members of the Public.

(1) Each licensee or registrant shall conduct operations so that:

(a) Except as provided in Subsection R313-15-301(1)(c), the total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed one mSv (0.1 rem) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Section R313-32-75, from voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with Section R313-15-1003; and

(b) The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with Section R313-32-75, does not exceed 0.02 mSv (0.002 rem) in any one hour; and

(c) The total effective dose equivalent to individual members of the public from infrequent exposure to radiation from radiation machines does not exceed 5 mSv (0.5 rem) in a year.

(2) If the licensee or registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

(3) A licensee, registrant, or an applicant for a license or registration may apply for prior Executive Secretary authorization to operate up to an annual dose limit for an individual member of the public of five mSv (0.5 rem). This application shall include the following information:

(a) Demonstration of the need for and the expected duration of operations in excess of the limit in Subsection R313-15-301(1); and

(b) The licensee's or registrant's program to assess and control dose within the five mSv (0.5 rem) annual limit; and

(c) The procedures to be followed to maintain the dose ALARA.

(4) The Executive Secretary may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.

R313-15-302. Compliance with Dose Limits for Individual Members of the Public.

(1) The licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in Section R313-15-301.

(2) A licensee or registrant shall show compliance with the annual dose limit in Section R313-15-301 by:

(a) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or

(b) Demonstrating that:

(i) The annual average concentrations of radioactive material released in gaseous and liquid

effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B of 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference; and

(ii) If an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (0.002 rem) in an hour and 0.50 mSv (0.05 rem) in a year.

(3) Upon approval from the Executive Secretary, the licensee or registrant may adjust the effluent concentration values in Appendix B, Table II of 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as, aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

R313-15-401. Radiological Criteria for License Termination - General Provisions.

(1) The criteria in Sections R313-15-401 through R313-15-406 apply to the decommissioning of facilities licensed under Rules R313-22 and R313-25, as well as other facilities subject to the Board's jurisdiction under the Act. For low-level waste disposal facilities (Rule R313-25), the criteria apply only to ancillary surface facilities that support radioactive waste disposal activities.

(2) The criteria in Sections R313-15-401 through R313-15-406 do not apply to sites which:

(a) Have been decommissioned prior to the effective date of the rule in accordance with criteria approved by the Executive Secretary;

(b) Have previously submitted and received Executive Secretary approval on a license termination plan or decommissioning plan; or

(c) Submit a sufficient license termination plan or decommissioning plan before the effective date of the rule with criteria approved by the Executive Secretary.

(3) After a site has been decommissioned and the license terminated in accordance with the criteria in Sections R313-15-401 through R313-15-406, the Executive Secretary will require additional cleanup only if, based on new information, the Executive Secretary determines that the criteria in Sections R313-15-401 through R313-15-406 was not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

(4) When calculating the total effective dose equivalent to the average member of the critical group, the licensee shall determine the peak annual total effective dose equivalent dose expected within the first 1000 years after decommissioning.

R313-15-402. Radiological Criteria for Unrestricted Use.

A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a total effective dose equivalent to an average member of the critical group that does not exceed 0.25 mSv (0.025 rem) per year, including no greater than 0.04 mSv (0.004 rem) committed effective dose equivalent or total effective dose equivalent to an average member of the critical group from groundwater sources, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

R313-15-403. Criteria for License Termination Under Restricted Conditions.

A site will be considered acceptable for license termination under restricted conditions if:

(1) The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of Section R313-15-402 would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal; and

(2) The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the total effective dose equivalent from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 0.25 mSv (0.025 rem) per year; and

(3) The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

(a) Funds placed into an account segregated from the licensee's assets outside the licensee's administrative control as described in Subsection R313-22-35(6)(a);

(b) Surety method, insurance, or other guarantee method as described in Subsection R313-22-35(6)(b);

(c) A statement of intent in the case of Federal, State, or local Government licensees, as described in Subsection R313-22-35(6)(d); or

(d) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity; and

(4) The licensee has submitted a decommissioning plan or license termination plan to the Executive Secretary indicating the licensee's intent to decommission in accordance with Subsection R313-22-36(4) and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the license termination plan or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice;

(a) Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:

(i) Whether provisions for institutional controls proposed by the licensee;

(A) Will provide reasonable assurance that the total effective dose equivalent from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 0.25 mSv (0.025 rem) total effective dose equivalent per year;

(B) Will be enforceable; and

(C) Will not impose undue burdens on the local community or other affected parties; and

(ii) Whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities

for any necessary control and maintenance of the site; and

(b) In seeking advice on the issues identified in Subsection R313-15-403(4)(a), the licensee shall provide for:

(i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

(5) Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the total effective dose equivalent from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either:

(a) one mSv (0.1 rem) per year; or

(b) five mSv (0.5 rem) per year provided the licensee:

(i) Demonstrates that further reductions in residual radioactivity necessary to comply with the one mSv (0.1 rem) per year value of Subsection R313-15-403(5)(a) are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(ii) Makes provisions for durable institutional controls; and

(iii) Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every five years to assure that the institutional controls remain in place as necessary to meet the criteria of Subsection R313-15-403(2) and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in Subsection R313-15-403(3).

R313-15-404. Alternate Criteria for License Termination.

(1) The Executive Secretary may terminate a license using alternative criteria greater than the dose criterion of Section R313-15-402, and Subsections R313-15-403(2) and R313-15-403(4)(a)(i)(A), if the licensee:

(a) Provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the one mSv (0.1 rem) per year limit of Subsection R313-15-301(1)(a), by submitting an analysis of possible sources of exposure; and

(b) Has employed, to the extent practical, restrictions on site use according to the provisions of Section R313-15-403 in minimizing exposures at the site; and

(c) Reduces doses to ALARA levels, taking into consideration any detriments such as traffic

accidents expected to potentially result from decontamination and waste disposal; and

(d) Has submitted a decommissioning plan or license termination plan to the Executive Secretary indicating the licensee's intent to decommission in accordance with Subsection R313-22-36(4), and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or license termination plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:

(i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning; and

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.

(2) The use of alternate criteria to terminate a license requires the approval of the Executive Secretary after consideration of recommendations from the Division's staff, comments provided by federal, state and local governments, and any public comments submitted pursuant to Section R313-15-405.

R313-15-405. Public Notification and Public Participation.

Upon the receipt of a license termination plan or decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to Sections R313-15-403 or R313-15-404, or whenever the Executive Secretary deems such notice to be in the public interest, the Executive Secretary shall:

(1) Notify and solicit comments from:

(a) Local and State governments in the vicinity of the site and any Indian Nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and

(b) Federal, state and local governments for cases where the licensee proposes to release a site pursuant to Section R313-15-404.

(2) Publish a notice in a forum, such as local newspapers, letters to State or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

R313-15-406. Minimization of Contamination.

Applicants for licenses, other than renewals, shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of waste.

R313-15-501. Surveys and Monitoring - General.

(1) Each licensee or registrant shall make, or cause to be made, surveys that:

(a) Are necessary for the licensee or registrant to comply with Rule R313-15; and

(b) Are necessary under the circumstances to evaluate:

(i) The magnitude and the extent of radiation levels; and

(ii) Concentrations or quantities of radioactive material; and

(iii) The potential radiological hazards.

(2) The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured, except when a more frequent interval is specified in another applicable part of these rules or a license condition.

(3) All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with Section R313-15-201, with other applicable provisions of these rules, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

(a) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(b) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

(4) The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

R313-15-502. Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.

Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Rule R313-15. As a minimum:

(1) Each licensee or registrant shall monitor occupational exposure to radiation from licensed, unlicensed, and registered radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by:

(a) Adults likely to receive, in one year from sources external to the body, a dose in excess of ten percent of the limits in Subsection R313-15-201(1); and

(b) Minors likely to receive, in one year, from radiation sources external to the body, a deep dose equivalent in excess of one mSv (0.1 rem), a lens dose equivalent in excess of 1.5 mSv (0.15 rem), or a shallow dose equivalent to the skin or to the extremities in excess of five mSv (0.5 rem); and

(c) Declared pregnant women likely to receive during the entire pregnancy, from radiation

sources external to the body, a deep dose equivalent in excess of one mSv (0.1 rem); and

(d) Individuals entering a high or very high radiation area; and

(e) Individuals working with medical fluoroscopic equipment.

(i) An individual monitoring device used for the dose to an embryo/fetus of a declared pregnant woman, pursuant to Subsection R313-15-208(1), shall be located under the protective apron at the waist.

(A) If an individual monitoring device worn by a declared pregnant woman has a monthly reported dose equivalent value in excess of 0.5 mSv (50 mrem), the value to be used for determining the dose to the embryo/fetus, pursuant to Subsection R313-15-208(3)(a) for radiation from medical fluoroscopy, may be the value reported by the individual monitoring device worn at the waist underneath the protective apron which has been corrected for the potential overestimation of dose recorded by the monitoring device because of the overlying tissue of the pregnant individual. This correction shall be performed by a radiation safety officer of an institutional radiation safety committee, a qualified expert approved by the Board, or a representative of the Executive Secretary.

(ii) An individual monitoring device used for lens dose equivalent shall be located at the neck, or an unshielded location closer to the eye, outside the protective apron.

(iii) When only one individual monitoring device is used to determine the effective dose equivalent for external radiation pursuant to Subsection R313-15-201(3)(b), it shall be located at the neck outside the protective apron. When a second individual monitoring device is used, for the same purpose, it shall be located under the protective apron at the waist. Note: The second individual monitoring device is required for a declared pregnant woman.

(iv) A registrant is not required to supply and require the use of individual monitoring devices provided the registrant has conducted a survey, pursuant to Section R313-15-501, that demonstrates that the working environment the individual encounters will not likely result in a dose in excess of ten percent of the limits in Subsection R313-15-201(1), and that the individual is neither a minor nor a declared pregnant woman.

(2) Each licensee or registrant shall monitor, to determine compliance with Section R313-15-204, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(a) Adults likely to receive, in one year, an intake in excess of ten percent of the applicable ALI(s) in Table I, Columns 1 and 2, of Appendix B of 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference; and

(b) Minors likely to receive, in one year, a committed effective dose equivalent in excess of one mSv (0.1 rem); and

(c) Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of one mSv (0.1 rem).

Note: All of the occupational doses in Section R313-15-201 continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded.

R313-15-503. Location of Individual Monitoring Devices.

Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with Subsection R313-15-502(1) wear individual monitoring devices as follows:

- (1) An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar).
- (2) An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman, pursuant to Subsection R313-15-208(1), shall be located at the waist under any protective apron being worn by the woman.
- (3) An individual monitoring device used for monitoring the lens dose equivalent, to demonstrate compliance with Subsection R313-15-201(1)(b)(i), shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye.
- (4) An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with Subsection R313-15-201(1)(b)(ii), shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

R313-15-601. Control of Access to High Radiation Areas.

- (1) The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:
 - (a) A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of one mSv (0.1 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates; or
 - (b) A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or
 - (c) Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.
- (2) In place of the controls required by Subsection R313-15-601(1) for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.
- (3) The licensee or registrant may apply to the Executive Secretary for approval of alternative methods for controlling access to high radiation areas.
- (4) The licensee or registrant shall establish the controls required by Subsections R313-15-601(1) and R313-15-601(3) in a way that does not prevent individuals from leaving a high radiation area.
- (5) The licensee or registrant is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials

prepared for transport and packaged and labeled in accordance with the rules of the U.S. Department of Transportation provided that:

- (a) The packages do not remain in the area longer than three days; and
 - (b) The dose rate at one meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.
- (6) The licensee or registrant is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in Rule R313-15 and to operate within the ALARA provisions of the licensee's or registrant's radiation protection program.
- (7) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in Section R313-15-601 if the registrant has met all the specific requirements for access and control specified in other applicable sections of these rules, such as, Rule R313-36 for industrial radiography, Rule R313-28 for x rays in the healing arts, Rule R313-30 for therapeutic radiation machines, and Rule R313-35 for industrial use of x-ray systems.

R313-15-602. Control of Access to Very High Radiation Areas.

- (1) In addition to the requirements in Section R313-15-601, the licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at five Gy (500 rad) or more in one hour at one meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation, or to non-self-shielded irradiators.
- (2) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in Subsection R313-15-602(1) if the registrant has met all the specific requirements for access and control specified in other applicable sections of these rules, such as, Rule R313-36 for industrial radiography, Rule R313-28 for x rays in the healing arts, Rule R313-30 for therapeutic radiation machines, and Rule R313-35 for industrial use of x-ray systems.

R313-15-603. Control of Access to Very High Radiation Areas -- Irradiators.

- (1) Section R313-15-603 applies to licensees or registrants with sources of radiation in non-self-shielded irradiators. Section R313-15-603 does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create a high levels of radiation in an area that is accessible to any individual.
- (2) Each area in which there may exist radiation levels in excess of five Gy (500 rad) in one hour at one meter from a source of radiation that is used to irradiate materials shall meet the following requirements:
 - (a) Each entrance or access point shall be equipped with entry control devices which:

(i) Function automatically to prevent any individual from inadvertently entering a very high radiation area; and

(ii) Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of one mSv (0.1 rem) in one hour; and

(iii) Prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of one mSv (0.1 rem) in one hour.

(b) Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by Subsection R313-15-603(2)(a):

(i) The radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of one mSv (0.1 rem) in one hour; and

(ii) Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.

(c) The licensee or registrant shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:

(i) The radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of one mSv (0.1 rem) in one hour; and

(ii) Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or registrant or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

(d) When the shield for stored sealed sources is a liquid, the licensee or registrant shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

(e) Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of Subsections R313-15-603(2)(c) and R313-15-603(2)(d).

(f) Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, which shall be installed in the area and which can prevent the source of radiation from being put into operation.

(g) Each area shall be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

- (h) Each area shall be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of one mSv (0.1 rem) in one hour.
- (i) The entry control devices required in Subsection R313-15-603(2)(a) shall be tested for proper functioning. See Section R313-15-1110 for recordkeeping requirements.
- (i) Testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day; and
- (ii) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and
- (iii) The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.
- (j) The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.
- (k) Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and automatically to prevent loose radioactive material from being carried out of the area.
- (3) Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of Subsection R313-15-603(2) which will be used in a variety of positions or in locations, such as open fields or forests, that make it impractical to comply with certain requirements of Subsection R313-15-603(2), such as those for the automatic control of radiation levels, may apply to the Executive Secretary for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in Subsection R313-15-603(2). At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.
- (4) The entry control devices required by Subsections R313-15-603(2) and R313-15-603(3) shall be established in such a way that no individual will be prevented from leaving the area.

R313-15-701. Use of Process or Other Engineering Controls.

The licensee or registrant shall use, to the extent practical, process or other engineering controls, such as, containment, decontamination, or ventilation, to control the concentration of radioactive material in air.

R313-15-702. Use of Other Controls.

- (1) When it is not practical to apply process or other engineering controls to control the concentration of radioactive material in the air to values below those that define an airborne

radioactivity area, the licensee or registrant shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

- (a) Control of access; or
- (b) Limitation of exposure times; or
- (c) Use of respiratory protection equipment; or
- (d) Other controls.

(2) If the licensee or registrant performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee or registrant should also consider the impact of respirator use on workers' industrial health and safety.

R313-15-703. Use of Individual Respiratory Protection Equipment.

If the licensee or registrant uses respiratory protection equipment to limit the intake of radioactive material:

(1) Except as provided in Subsection R313-15-703(2), the licensee or registrant shall use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health.

(2) The licensee or registrant may use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health or for which there is no schedule for testing or certification, provided the licensee or registrant has submitted to the Executive Secretary and the Executive Secretary has approved an application for authorized use of that equipment. The application must include a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

(3) The licensee or registrant shall implement and maintain a respiratory protection program that includes:

- (a) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses; and
- (b) Surveys and bioassays, as necessary, to evaluate actual intakes; and
- (c) Testing of respirators for operability, user seal check for face sealing devices and functional check for others, immediately prior to each use; and
- (d) Written procedures regarding
 - (i) Monitoring, including air sampling and bioassays;
 - (ii) Supervision and training of respirator users;
 - (iii) Fit testing;

- (iv) Respirator selection;
 - (v) Breathing air quality;
 - (vi) Inventory and control;
 - (vii) Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;
 - (viii) Recordkeeping; and
 - (ix) Limitations on periods of respirator use and relief from respirator use; and
- (e) Determination by a physician prior to initial fitting of respirators, before the first field use of non-face sealing respirators, and either every 12 months thereafter or periodically at a frequency determined by a physician, that the individual user is medically fit to use the respiratory protection equipment; and
- (f) Fit testing, with fit factor greater than or equal to ten times the APF for negative pressure devices, and a fit factor greater than or equal to 500 for positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed one year. Fit testing must be performed with the facepiece operating in the negative pressure mode.
- (4) The licensee or registrant shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.
- (5) The licensee or registrant shall also consider limitations appropriate to the type and mode of use. When selecting respiratory devices the licensee shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The licensee or registrant shall use equipment in such a way as not to interfere with the proper operation of the respirator.
- (6) Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.
- (7) Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997 ed. and included in 29 CFR 1910.134(i)(1)(ii)(A) through (E), 2000 ed. Grade D quality air criteria include:
- (a) Oxygen content (v/v) of 19.5 to 23.5%;

- (b) Hydrocarbon (condensed) content of five milligrams per cubic meter of air or less;
- (c) Carbon monoxide (CO) content of ten ppm or less;
- (d) Carbon dioxide content of 1,000 ppm or less; and
- (e) Lack of noticeable odor.

(8) The licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face and facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

(9) In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

R313-15-704. Further Restrictions on the Use of Respiratory Protection Equipment.

The Executive Secretary may impose restrictions in addition to the provisions of Section R313-15-702, Section R313-15-703, and Appendix A of 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference to:

- (1) Ensure that the respiratory protection program of the licensee or registrant is adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and
- (2) Limit the extent to which a licensee or registrant may use respiratory protection equipment instead of process or other engineering controls.

R313-15-705. Application for Use of Higher Assigned Protection Factors.

The licensee or registrant shall obtain authorization from the Executive Secretary before using assigned protection factors in excess of those specified in Appendix A of 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference. The Executive Secretary may authorize a licensee or registrant to use higher assigned protection factors on receipt of an application that:

- (1) Describes the situation for which a need exists for higher protection factors; and
- (2) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

R313-15-801. Security and Control of Licensed or Registered Sources of Radiation.

- (1) The licensee or registrant shall secure licensed or registered radioactive material from unauthorized removal or access.
- (2) The licensee or registrant shall maintain constant surveillance, and use devices or administrative procedures to prevent unauthorized use of licensed or registered radioactive

material that is in an unrestricted area and that is not in storage.

(3) The registrant shall secure registered radiation machines from unauthorized removal.

(4) The registrant shall use devices or administrative procedures to prevent unauthorized use of registered radiation machines.

R313-15-901. Caution Signs.

(1) Standard Radiation Symbol. Unless otherwise authorized by the Executive Secretary, the symbol prescribed by 10 CFR 20.1901, 2001 ed., which is incorporated by reference, shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

(a) Cross-hatched area is to be magenta, or purple, or black, and

(b) The background is to be yellow.

(2) Exception to Color Requirements for Standard Radiation Symbol. Notwithstanding the requirements of 10 CFR 20.1901(a), 2001 ed., which is incorporated by reference, licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

(3) Additional Information on Signs and Labels. In addition to the contents of signs and labels prescribed in Rule R313-15, the licensee or registrant shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

R313-15-902. Posting Requirements.

(1) Posting of Radiation Areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

(2) Posting of High Radiation Areas. The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

(3) Posting of Very High Radiation Areas. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

(4) Posting of Airborne Radioactivity Areas. The licensee or registrant shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

(5) Posting of Areas or Rooms in which Licensed or Registered Material is Used or Stored. The licensee or registrant shall post each area or room in which there is used or stored an amount of licensed or registered material exceeding ten times the quantity of such material specified in Appendix C of 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL."

R313-15-903. Exceptions to Posting Requirements.

(1) A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than eight hours, if each of the following conditions is met:

(a) The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in Rule R313-15; and

(b) The area or room is subject to the licensee's or registrant's control.

(2) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to Section R313-15-902 provided that the patient could be released from licensee control pursuant to Section R313-32-75.

(3) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.05 mSv (0.005 rem) per hour.

(4) A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

(5) Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under Section R313-15-902 if:

(a) Access to the room is controlled pursuant to Section R313-32-615; and

(b) Personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in Rule R313-15.

R313-15-904. Labeling Containers and Radiation Machines.

(1) The licensee or registrant shall ensure that each container of licensed or registered material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

(2) Each licensee or registrant shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

(3) Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

R313-15-905. Exemptions to Labeling Requirements.

A licensee or registrant is not required to label:

- (1) Containers holding licensed or registered material in quantities less than the quantities listed in Appendix C of 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference; or
- (2) Containers holding licensed or registered material in concentrations less than those specified in Table III of Appendix B of 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference; or
- (3) Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by Rule R313-15; or
- (4) Containers when they are in transport and packaged and labeled in accordance with the rules of the U.S. Department of Transportation; or
- (5) Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or
- (6) Installed manufacturing or process equipment, such as piping and tanks.

R313-15-906. Procedures for Receiving and Opening Packages.

- (1) Each licensee or registrant who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as used in Section R313-19-100, which incorporates 10 CFR 71.4 by reference, shall make arrangements to receive:
 - (a) The package when the carrier offers it for delivery; or
 - (b) The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.
- (2) Each licensee or registrant shall:
 - (a) Monitor the external surfaces of a labeled package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in Section R313-12-3; and
 - (b) Monitor the external surfaces of a labeled package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as used in Section R313-19- 100, which incorporates 10 CFR 71.4 by reference; and
 - (c) Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.
- (3) The licensee or registrant shall perform the monitoring required by Subsection R313-15-906 (2) as soon as practical after receipt of the package, but not later than three hours after the package is received at the licensee's or registrant's facility if it is received during the licensee's or registrant's normal working hours or if there is evidence of degradation of package integrity, such as a package that is crushed, wet, or damaged. If a package is received after working hours, and has no evidence of degradation of package integrity, the package shall be monitored no later than three hours from the beginning of the next working day.

(4) The licensee or registrant shall immediately notify the final delivery carrier and, by telephone and telegram, mailgram, or facsimile, the Executive Secretary when:

(a) Removable radioactive surface contamination exceeds the limits of Section R313-19-100 which incorporates 10 CFR 71.87(i) by reference; or

(b) External radiation levels exceed the limits of Section R313-19-100 which incorporates 10 CFR 71.47 by reference.

(5) Each licensee or registrant shall:

(a) Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

(b) Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

(6) Licensees or registrants transferring special form sources in vehicles owned or operated by the licensee or registrant to and from a work site are exempt from the contamination monitoring requirements of Subsection R313-15-906(2), but are not exempt from the monitoring requirement in Subsection R313-15-906(2) for measuring radiation levels that ensures that the source is still properly lodged in its shield.

R313-15-1001. Waste Disposal - General Requirements.

(1) A licensee or registrant shall dispose of licensed or registered material only:

(a) By transfer to an authorized recipient as provided in Section R313-15-1006 or in Rules R313-21, R313-22, R313-24, or R313-25, or to the U.S. Department of Energy; or

(b) By decay in storage; or

(c) By release in effluents within the limits in Section R313-15-301; or

(d) As authorized pursuant to Sections R313-15-1002, R313-15-1003, R313-15-1004, or R313-15-1005.

(2) A person shall be specifically licensed or registered to receive waste containing licensed or registered material from other persons for:

(a) Treatment prior to disposal; or

(b) Treatment or disposal by incineration; or

(c) Decay in storage; or

(d) Disposal at a land disposal facility licensed pursuant to Rule R313-25; or

(e) Storage until transferred to a storage or disposal facility authorized to receive the waste.

R313-15-1002. Method for Obtaining Approval of Proposed Disposal Procedures.

A licensee or registrant or applicant for a license or registration may apply to the Executive Secretary for approval of proposed procedures, not otherwise authorized in these rules, to dispose of licensed or registered material generated in the licensee's or registrant's operations. Each application shall include:

- (1) A description of the waste containing licensed or registered material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal; and
- (2) An analysis and evaluation of pertinent information on the nature of the environment; and
- (3) The nature and location of other potentially affected facilities; and
- (4) Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in Rule R313-15.

R313-15-1003. Disposal by Release into Sanitary Sewerage.

(1) A licensee or registrant may discharge licensed or registered material into sanitary sewerage if each of the following conditions is satisfied:

- (a) The material is readily soluble, or is readily dispersible biological material, in water; and
- (b) The quantity of licensed or registered radioactive material that the licensee or registrant releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee or registrant does not exceed the concentration listed in Table III of Appendix B of 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference; and
- (c) If more than one radionuclide is released, the following conditions shall also be satisfied:
 - (i) The licensee or registrant shall determine the fraction of the limit in Table III of Appendix B of 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference, represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee or registrant into the sewer by the concentration of that radionuclide listed in Table III of Appendix B of 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference; and
 - (ii) The sum of the fractions for each radionuclide required by Subsection R313-15-1003(1)(c)(i) does not exceed unity; and
- (d) The total quantity of licensed or registered radioactive material that the licensee or registrant releases into the sanitary sewerage system in a year does not exceed 185 GBq (five Ci) of hydrogen-3, 37 GBq (one Ci) of carbon-14, and 37 GBq (one Ci) of all other radioactive materials combined.

(2) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in Subsection R313-15-1003(1).

R313-15-1004. Treatment or Disposal by Incineration.

A licensee or registrant may treat or dispose of licensed or registered material by incineration only in the form and concentration specified in Section R313-15-1005 or as specifically approved by the Executive Secretary pursuant to Section R313-15-1002.

R313-15-1005. Disposal of Specific Wastes.

(1) A licensee or registrant may dispose of the following licensed or registered material as if it were not radioactive:

(a) 1.85 kBq (0.05 uCi), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

(b) 1.85 kBq (0.05 uCi) or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

(2) A licensee or registrant shall not dispose of tissue pursuant to Subsection R313-15-1005(1) (b) in a manner that would permit its use either as food for humans or as animal feed.

(3) The licensee or registrant shall maintain records in accordance with Section R313-15-1109.

R313-15-1006. Transfer for Disposal and Manifests.

(1) The requirements of Section R313-15-1006 and Appendix G of 10 CFR 20.1001 to 20.2402, 2001 ed., which are incorporated into these rules by reference, are designed to:

(a) control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in Appendix G in 10 CFR 20.1001 to 20.2402, 2001 ed., who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility as defined in Section R313-25-2;

(b) establish a manifest tracking system; and

(c) supplement existing requirements concerning transfers and recordkeeping for those wastes.

(2) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G to 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated into these rules by reference.

(3) Each shipment manifest shall include a certification by the waste generator as specified in Section II of Appendix G to 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference.

(4) Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix G to 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference.

R313-15-1007. Compliance with Environmental and Health Protection Rules.

Nothing in Sections R313-15-1001, R313-15-1002, R313-15-1003, R313-15-1004, R313-15-1005, or R313-15-1006 relieves the licensee or registrant from complying with other applicable Federal, State and local rules governing any other toxic or hazardous properties of materials that may be disposed of pursuant to Sections R313-15-1001, R313-15-1002, R313-15-1003, R313-15-1004, R313-15-1005, or R313-15-1006.

R313-15-1008. Classification and Characteristics of Low-Level Radioactive Waste.

(1) Classification of Radioactive Waste for Land Disposal

(a) Considerations. Determination of the classification of radioactive waste involves two considerations. First, consideration shall be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration shall be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.

(b) Classes of waste.

(i) Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste shall meet the minimum requirements set forth in Subsection R313-15-1008(2)(a). If Class A waste also meets the stability requirements set forth in Subsection R313-15-1008(2)(b), it is not necessary to segregate the waste for disposal.

(ii) Class B waste is waste that shall meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste shall meet both the minimum and stability requirements set forth in Subsection R313-15-1008(2).

(iii) Class C waste is waste that not only shall meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste shall meet both the minimum and stability requirements set forth in Subsection R313-15-1008(2).

(c) Classification determined by long-lived radionuclides. If the radioactive waste contains only radionuclides listed in Table I, classification shall be determined as follows:

(i) If the concentration does not exceed 0.1 times the value in Table I, the waste is Class A.

(ii) If the concentration exceeds 0.1 times the value in Table I, but does not exceed the value in Table I, the waste is Class C.

(iii) If the concentration exceeds the value in Table I, the waste is not generally acceptable for land disposal.

(iv) For wastes containing mixtures of radionuclides listed in Table I, the total concentration shall be determined by the sum of fractions rule described in Subsection R313-15-1008(1)(g).

TABLE I

Concentration

| Radionuclide | Concentration | |
|--------------------------|----------------------|-------------------|
| | curie/cubic meter(1) | nanocurie/gram(2) |
| C-14 | 8 | |
| C-14 in activated metal | 80 | |
| Ni-59 in activated metal | 220 | |

| | |
|---|--------|
| Nb-94 in activated metal | 0.2 |
| Tc-99 | 3 |
| I-129 | 0.08 |
| Alpha emitting transuranic radionuclides with half-life greater than five years | 100 |
| Pu-241 | 3,500 |
| Cm-242 | 20,000 |
| Ra-226 | 100 |

NOTE: (1) To convert the Ci/m³ values to gigabecquerel (GBq)/cubic meter, multiply by 37.

(2) To convert the nCi/g values to becquerel (Bq)/gram, multiply the nCi/g

(d) Classification determined by short-lived radionuclides. If the waste does not contain any of the radionuclides listed in Table I, classification shall be determined based on the concentrations shown in Table II. However, as specified in Subsection R313-15-1008(1)(f), if radioactive waste does not contain any nuclides listed in either Table I or II, it is Class A.

(i) If the concentration does not exceed the value in Column 1, the waste is Class A.

(ii) If the concentration exceeds the value in Column 1 but does not exceed the value in Column 2, the waste is Class B.

(iii) If the concentration exceeds the value in Column 2 but does not exceed the value in Column 3, the waste is Class C.

(iv) If the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.

(v) For wastes containing mixtures of the radionuclides listed in Table II, the total concentration shall be determined by the sum of fractions rule described in Subsection R313-15-1008(1)(g).

TABLE II

| Radionuclide | Concentration, curie/cubic meter(1) | | |
|--|-------------------------------------|----------|----------|
| | Column 1 | Column 2 | Column 3 |
| Total of all radionuclides with less than 5-year half-life | 700 | (2) | (2) |
| H-3 | 40 | (2) | (2) |
| Co-60 | 700 | (2) | (2) |
| Ni-63 | 3.5 | 70 | 700 |
| Ni-63 in activated metal | 35 | 700 | 7000 |
| Sr-90 | 0.04 | 150 | 7000 |
| Cs-137 | 1 | 44 | 4600 |

NOTE: (1) To convert the Ci/m³ value to gigabecquerel (GBq)/cubic meter, multiply by 37.

(2) There are no limits established for these radionuclides in Class B or C as the effects of external radiation and internal heat generation on transportation concentrations for these wastes. These wastes shall be Class B unless the concentr

II determine the waste to be Class C independent of these radionuclides.

(e) Classification determined by both long- and short-lived radionuclides. If the radioactive waste contains a mixture of radionuclides, some of which are listed in Table I and some of which are listed in Table II, classification shall be determined as follows:

(i) If the concentration of a radionuclide listed in Table I is less than 0.1 times the value listed in Table I, the class shall be that determined by the concentration of radionuclides listed in Table II.

(ii) If the concentration of a radionuclide listed in Table I exceeds 0.1 times the value listed in Table I, but does not exceed the value in Table I, the waste shall be Class C, provided the concentration of radionuclides listed in Table II does not exceed the value shown in Column 3 of Table II.

(f) Classification of wastes with radionuclides other than those listed in Tables I and II. If the waste does not contain any radionuclides listed in either Table I or II, it is Class A.

(g) The sum of the fractions rule for mixtures of radionuclides. For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits shall all be taken from the same column of the same table. The sum of the fractions for the column shall be less than 1.0 if the waste class is to be determined by that column. Example: A waste contains Sr-90 in a concentration of 1.85 TBq/m³ (50 Ci/m³) and Cs-137 in a concentration of 814 GBq/m³ (22 Ci/m³). Since the concentrations both exceed the values in Column 1, Table II, they shall be compared to Column 2 values. For Sr-90 fraction, $50/150 = 0.33.$, for Cs-137 fraction, $22/44 = 0.5$; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.

(h) Determination of concentrations in wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as becquerel (nanocurie) per gram.

(2) Radioactive Waste Characteristics

(a) The following are minimum requirements for all classes of waste and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site.

(i) Wastes shall be packaged in conformance with the conditions of the license issued to the site operator to which the waste will be shipped. Where the conditions of the site license are more restrictive than the provisions of Rule R313-15, the site license conditions shall govern.

(ii) Wastes shall not be packaged for disposal in cardboard or fiberboard boxes.

(iii) Liquid waste shall be packaged in sufficient absorbent material to absorb twice the volume of the liquid.

(iv) Solid waste containing liquid shall contain as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed one percent of the volume.

(v) Waste shall not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

(vi) Waste shall not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with Subsection R313-15-1008(2)(a)(viii).

(vii) Waste shall not be pyrophoric. Pyrophoric materials contained in wastes shall be treated, prepared, and packaged to be nonflammable.

(viii) Wastes in a gaseous form shall be packaged at an absolute pressure that does not exceed 1.5 atmospheres at 20 degrees celsius. Total activity shall not exceed 3.7 TBq (100 Ci) per container.

(ix) Wastes containing hazardous, biological, pathogenic, or infectious material shall be treated to reduce to the maximum extent practical the potential hazard from the non-radiological materials.

(b) The following requirements are intended to provide stability of the waste. Stability is intended to ensure that the waste does not degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

(i) Waste shall have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.

(ii) Notwithstanding the provisions in Subsections R313-15-1008(2)(a)(iii) and R313-15-1008(2)(a)(iv), liquid wastes, or wastes containing liquid, shall be converted into a form that contains as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed one percent of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5 percent of the volume of the waste for waste processed to a stable form.

(iii) Void spaces within the waste and between the waste and its package shall be reduced to the extent practical.

(3) Labeling. Each package of waste shall be clearly labeled to identify whether it is Class A, Class B, or Class C waste, in accordance with Subsection R313-15-1008(1).

R313-15-1101. Records - General Provisions.

(1) Each licensee or registrant shall use the SI units becquerel, gray, sievert and coulomb per kilogram, or the special units, curie, rad, rem, and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by Rule R313-15.

(2) Notwithstanding the requirements of Subsection R313-15-1101(1), when recording information on shipment manifests, as required in Subsection R313-15-1006(2), information must be recorded in SI units or in SI units and the special units specified in Subsection R313-15-1101(1).

(3) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by Rule R313-15, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

R313-15-1102. Records of Radiation Protection Programs.

(1) Each licensee or registrant shall maintain records of the radiation protection program, including:

(a) The provisions of the program; and

(b) Audits and other reviews of program content and implementation.

(2) The licensee or registrant shall retain the records required by Subsection R313-15-1102(1)(a) until the Executive Secretary terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by Subsection R313-15-1102(1)(b) for three years after the record is made.

R313-15-1103. Records of Surveys.

(1) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by Section R313-15-501 and Subsection R313-15-906(2). The licensee or registrant shall retain these records for three years after the record is made.

(2) The licensee or registrant shall retain each of the following records until the Executive Secretary terminates each pertinent license or registration requiring the record:

(a) Records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and

(b) Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

(c) Records showing the results of air sampling, surveys, and bioassays required pursuant to Subsections R313-15-703(3)(a) and R313-15-703(3)(b); and

(d) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

R313-15-1104. Records of Tests for Leakage or Contamination of Sealed Sources.

Records of tests for leakage or contamination of sealed sources required by Section R313-15-1401 shall be kept in units of becquerel or microcurie and maintained for inspection by the Executive Secretary for five years after the records are made.

R313-15-1105. Records of Prior Occupational Dose.

For each individual who is likely to receive in a year an occupational dose requiring monitoring pursuant to Section R313-15-502, the licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in Section R313-15-205 on form DRC-05 or

equivalent until the Executive Secretary terminates each pertinent license requiring this record. The licensee or registrant shall retain records used in preparing form DRC-05 or equivalent for three years after the record is made.

R313-15-1106. Records of Planned Special Exposures.

(1) For each use of the provisions of Section R313-15-206 for planned special exposures, the licensee or registrant shall maintain records that describe:

- (a) The exceptional circumstances requiring the use of a planned special exposure; and
- (b) The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and
- (c) What actions were necessary; and
- (d) Why the actions were necessary; and
- (e) What precautions were taken to assure that doses were maintained ALARA; and
- (f) What individual and collective doses were expected to result; and
- (g) The doses actually received in the planned special exposure.

(2) The licensee or registrant shall retain the records until the Executive Secretary terminates each pertinent license or registration requiring these records.

R313-15-1107. Records of Individual Monitoring Results.

(1) Recordkeeping Requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to Section R313-15-502, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before January 1, 1994, need not be changed. These records shall include, when applicable:

- (a) The deep dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and
- (b) The estimated intake of radionuclides, see Section R313-15-202; and
- (c) The committed effective dose equivalent assigned to the intake of radionuclides; and
- (d) The specific information used to calculate the committed effective dose equivalent pursuant to Subsections R313-15-204(1) and R313-15-204(3) and when required by Section R313-15-502; and
- (e) The total effective dose equivalent when required by Section R313-15-202; and
- (f) The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

(2) Recordkeeping Frequency. The licensee or registrant shall make entries of the records

specified in Subsection R313-15-1107(1) at intervals not to exceed one year.

(3) Recordkeeping Format. The licensee or registrant shall maintain the records specified in Subsection R313-15-1107(1) on form DRC-06, in accordance with the instructions for form DRC-06, or in clear and legible records containing all the information required by form DRC-06.

(4) The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

(5) The licensee or registrant shall retain each required form or record until the Executive Secretary terminates each pertinent license or registration requiring the record.

R313-15-1108. Records of Dose to Individual Members of the Public.

(1) Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See Section R313-15-301.

(2) The licensee or registrant shall retain the records required by Subsection R313-15-1108(1) until the Executive Secretary terminates each pertinent license or registration requiring the record. Requirements for disposition of these records, prior to license termination, are located in Section R313-12-51 for activities licensed under these rules.

R313-15-1109. Records of Waste Disposal.

(1) Each licensee or registrant shall maintain records of the disposal of licensed or registered materials made pursuant to Sections R313-15-1002, R313-15-1003, R313-15-1004, R313-15-1005, Rule R313-25, and disposal by burial in soil, including burials authorized before January 28, 1981.

(2) The licensee or registrant shall retain the records required by Subsection R313-15-1109(1) until the Executive Secretary terminates each pertinent license or registration requiring the record.

R313-15-1110. Records of Testing Entry Control Devices for Very High Radiation Areas.

(1) Each licensee or registrant shall maintain records of tests made pursuant to Subsection R313-15-603(2)(i) on entry control devices for very high radiation areas. These records shall include the date, time, and results of each such test of function.

(2) The licensee or registrant shall retain the records required by Subsection R313-15-1110(1) for three years after the record is made.

R313-15-1111. Form of Records.

Each record required by Rule R313-15 shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee shall

maintain adequate safeguards against tampering with and loss of records.

R313-15-1201. Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.

(1) Telephone Reports. Each licensee or registrant shall report to the Executive Secretary by telephone as follows:

(a) Immediately after its occurrence becomes known to the licensee or registrant, stolen, lost, or missing licensed or registered radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C of 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference, under such circumstances that it appears to the licensee or registrant that an exposure could result to individuals in unrestricted areas;

(b) Within 30 days after its occurrence becomes known to the licensee or registrant, lost, stolen, or missing licensed or registered radioactive material in an aggregate quantity greater than ten times the quantity specified in Appendix C of 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference, that is still missing.

(c) Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

(2) Written Reports. Each licensee or registrant required to make a report pursuant to Subsection R313-15-1201(1) shall, within 30 days after making the telephone report, make a written report to the Executive Secretary setting forth the following information:

(a) A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;

(b) A description of the circumstances under which the loss or theft occurred; and

(c) A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and

(d) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

(e) Actions that have been taken, or will be taken, to recover the source of radiation; and

(f) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

(3) Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.

(4) The licensee or registrant shall prepare any report filed with the Executive Secretary pursuant to Section R313-15-1201 so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

R313-15-1202. Notification of Incidents.

(1) Immediate Notification. Notwithstanding other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

(a) An individual to receive:

(i) A total effective dose equivalent of 0.25 Sv (25 rem) or more; or

(ii) A lens dose equivalent of 0.75 Sv (75 rem) or more; or

(iii) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 2.5 Gy (250 rad) or more; or

(b) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot- cells or process enclosures.

(2) Twenty-Four Hour Notification. Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Executive Secretary each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

(a) An individual to receive, in a period of 24 hours:

(i) A total effective dose equivalent exceeding 0.05 Sv (five rem); or

(ii) A lens dose equivalent exceeding 0.15 Sv (15 rem); or

(iii) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 Sv (50 rem); or

(b) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot- cells or process enclosures.

(3) The licensee or registrant shall prepare each report filed with the Executive Secretary pursuant to Section R313-15-1202 so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

(4) Licensees or registrants shall make the reports required by Subsections R313-15-1202(1) and R313- 15-1202(2) to the Executive Secretary by telephone, telegram, mailgram, or facsimile.

(5) The provisions of Section R313-15-1202 do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to Section R313-15-1204.

R313-15-1203. Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits.

(1) Reportable Events. In addition to the notification required by Section R313-15-1202, each

licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:

(a) Incidents for which notification is required by Section R313-15-1202; or

(b) Doses in excess of any of the following:

(i) The occupational dose limits for adults in Section R313-15-201; or

(ii) The occupational dose limits for a minor in Section R313-15-207; or

(iii) The limits for an embryo/fetus of a declared pregnant woman in Section R313-15-208; or

(iv) The limits for an individual member of the public in Section R313-15-301; or

(v) Any applicable limit in the license or registration; or

(vi) The ALARA constraints for air emissions established under Subsection R313-15-101(4); or

(c) Levels of radiation or concentrations of radioactive material in:

(i) A restricted area in excess of applicable limits in the license or registration; or

(ii) An unrestricted area in excess of ten times the applicable limit set forth in Rule R313-15 or in the license or registration, whether or not involving exposure of any individual in excess of the limits in Section R313-15-301; or

(d) For licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

(2) Contents of Reports.

(a) Each report required by Subsection R313-15-1203(1) shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(i) Estimates of each individual's dose; and

(ii) The levels of radiation and concentrations of radioactive material involved; and

(iii) The cause of the elevated exposures, dose rates, or concentrations; and

(iv) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits; ALARA constraints, generally applicable environmental standards, and associated license or registration conditions.

(b) Each report filed pursuant to Subsection R313-15-1203(1) shall include for each occupationally overexposed individual: the name, Social Security account number, and date of birth. With respect to the limit for the embryo/fetus in Section R313-15-208, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

(3) All licensees or registrants who make reports pursuant to Subsection R313-15-1203(1) shall submit the report in writing to the Executive Secretary.

R313-15-1204. Reports of Planned Special Exposures.

The licensee or registrant shall submit a written report to the Executive Secretary within 30 days following any planned special exposure conducted in accordance with Section R313-15-206, informing the Executive Secretary that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by Section R313-15-1106.

R313-15-1205. Reports to Individuals of Exceeding Dose Limits.

When a licensee or registrant is required, pursuant to the provisions of Sections R313-15-1203 or R313-15-1204, to report to the Executive Secretary any exposure of an identified occupationally exposed individual, or an identified member of the public, to sources of radiation, the licensee or registrant shall also provide a copy of the report submitted to the Executive Secretary to the individual. This report shall be transmitted at a time no later than the transmittal to the Executive Secretary.

R313-15-1207. Notifications and Reports to Individuals.

(1) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in Rule R313-18.

(2) When a licensee or registrant is required pursuant to Section R313-15-1203 to report to the Executive Secretary any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the Executive Secretary, and shall comply with the provisions of Rule R313-18.

R313-15-1208. Reports of Leaking or Contaminated Sealed Sources.

If the test for leakage or contamination required pursuant to Section R313-15-1401 indicates a sealed source is leaking or contaminated, a report of the test shall be filed within five days with the Executive Secretary describing the equipment involved, the test results and the corrective action taken.

R313-15-1301. Vacating Premises.

Each specific licensee or registrant shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of his activities, notify the Executive Secretary in writing of intent to vacate. When deemed necessary by the Executive Secretary, the licensee shall decontaminate the premises in such a manner that the annual total effective dose equivalent to any individual after the site is released for unrestricted use should not exceed 0.1 mSv (0.01 rem) above background and that the annual total effective dose equivalent from any specific environmental source during decommissioning activities should not exceed 0.1 mSv (0.01 rem) above background.

R313-15-1401. Testing for Leakage or Contamination of Sealed Sources.

(1) The licensee or registrant in possession of any sealed source shall assure that:

(a) Each sealed source, except as specified in Subsection R313-15-1401(2), is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee or registrant has a certificate from the transferor indicating that the sealed source was tested within six months before transfer to the licensee or registrant.

(b) Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed six months or at alternative intervals approved by the Executive Secretary, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission.

(c) Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three months or at alternative intervals approved by the Executive Secretary, an Agreement State, a Licensing State, or the Nuclear Regulatory Commission.

(d) For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee or registrant shall assure that the sealed source is tested for leakage or contamination before further use.

(e) Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of 185 Bq (0.005 uCi) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position.

(f) The test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 37 Bq (0.001 uCi) of radon-222 in a 24 hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume and time.

(g) Tests for contamination from radium daughters shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 185 Bq (0.005 uCi) of a radium daughter which has a half-life greater than four days.

(2) A licensee or registrant need not perform tests for leakage or contamination on the following sealed sources:

(a) Sealed sources containing only radioactive material with a half-life of less than 30 days;

(b) Sealed sources containing only radioactive material as a gas;

(c) Sealed sources containing 3.7 MBq (100 uCi) or less of beta or photon-emitting material or 370 kBq (ten uCi) or less of alpha-emitting material;

(d) Sealed sources containing only hydrogen-3;

(e) Seeds of iridium-192 encased in nylon ribbon; and

(f) Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used and identified as in storage. The licensee or registrant shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless

it has been tested for leakage or contamination within six months before the date of use or transfer.

(3) Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Executive Secretary, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such services.

(4) Test results shall be kept in units of becquerel or microcurie and maintained for inspection by representatives of the Executive Secretary. Records of test results for sealed sources shall be made pursuant to Section R313-15-1104.

(5) The following shall be considered evidence that a sealed source is leaking:

(a) The presence of 185 Bq (0.005 uCi) or more of removable contamination on any test sample.

(b) Leakage of 37 Bq (0.001 uCi) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium.

(c) The presence of removable contamination resulting from the decay of 185 Bq (0.005 uCi) or more of radium.

(6) The licensee or registrant shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with Rule R313-15.

(7) Reports of test results for leaking or contaminated sealed sources shall be made pursuant to Section R313-15-1208.

KEY

radioactive material, contamination, waste disposal, safety

Date of Enactment or Last Substantive Amendment

July 23, 2002

Notice of Continuation

April 30, 1998

Authorizing, Implemented, or Interpreted Law

19-3-104; 19-3-108

Rule converted into HTML by the Division of Administrative Rules.

For questions regarding the *content* or *application* of rules under Title R313, please contact the promulgating agency (Environmental Quality, Radiation Control). A list of agencies with links to their homepages is available at <http://www.utah.gov/government/agencylist.html>.

For questions about the *rulemaking process*, please contact **the Division of Administrative Rules**. *Please Note:* The Division of Administrative Rules is ***not able*** to answer questions about the content or application of these rules.

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**DAR File No. 24052**

This filing was published in the 01/10/2001, issue, Vol. 2001, No.19, of the Utah State Bulletin.

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Environmental Quality, Radiation Control

R313-15-502

Conditions Requiring Individual Monitoring of External and Internal Occupational Dose

NOTICE OF PROPOSED RULE

DAR File No.: 24052

Filed: 09/13/2001, 02:48

Received by: NL

RULE ANALYSIS

Purpose of the rule or reason for the change:

Five separate registrants of X-ray systems have petitioned the Utah Radiation Control Board for an exemption from the requirements of this rule. The Board has approved each request based on a reasoned justification by the registrant. Another four petitions for an exemption from the requirements of Section R313-15-502 have been received and are under consideration. The reason for this change is to allow registrants, who use medical fluoroscopic equipment, an alternative way of demonstrating compliance with the rule. The proposed rule will likely curtail the filing of petitions for exemption.

Summary of the rule or change:

A provision is being added such that a registrant does not need to supply and require the use of personnel monitoring devices if the registrant has conducted tests of the radiation environment in accordance with the provisions of Section R313-15-501. The registrant must demonstrate that the working environment an individual encounters will not likely result in a dose in excess of ten percent of the limits in Subsection R313-15-201(1).

State statutory or constitutional authorization for this rule:

Sections 19-3-104, 19-3-108

Anticipated cost or savings to: the state budget:

Approximately \$500 of staff time and resources of the Radiation Control Board are expended on each petition for an exemption from the requirements in Section R313-15-502. This proposed change will curtail and eliminate this expenditure of resources.

local governments:

There will not be a cost or savings to local government as local government is not affected by this rulemaking.

other persons:

Compliance costs for affected persons are expected to remain the same. This is because the tests of the radiation environment used to justify an exemption from the rule are the same as the tests needed under the proposed change.

Compliance costs for affected persons:

Compliance costs for affected persons are expected to remain the same. This is because the tests of the radiation environment used to justify an exemption from the rule are the same as the tests needed under the proposed change.

Comments by the department head on the fiscal impact the rule may have on businesses:

The fiscal impact of this rule may allow registrants to save financial resources. The tests to evaluate the radiation environment may be completed for under \$100. A registrant may elect to perform these tests if they want to eliminate the use of personnel monitoring devices. The cost savings from eliminating the use of personnel monitors may eventually exceed the cost of performing the tests of the radiation environment.

The full text of this rule may be inspected, during regular business hours, at the Division of Administrative Rules, or at:

*Environmental Quality
Radiation Control
168 N 1950 W
SALT LAKE CITY UT 84116-3085*

Direct questions regarding this rule to:

Craig Jones at the above address, by phone at 801-536-4264, by FAX at 801-533-4097, or by Internet E-mail at cjones@deq.state.ut.us

Interested persons may present their views on this rule by submitting written comments to the address above no later than 5:00 p.m. on:
10/31/2001

This rule may become effective on:
11/09/2001

Authorized by:

William Sinclair, Director

RULE TEXT**R313. Environmental Quality, Radiation Control.****R313-15. Standards for Protection Against Radiation.****R313-15-502. Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.**

Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Rule R313-15. As a minimum:

(1) Each licensee or registrant shall monitor occupational exposure to radiation from licensed, unlicensed, and registered radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by:

(a) Adults likely to receive, in one year from sources external to the body, a dose in excess of ten percent of the limits in Subsection R313-15-201(1); and

(b) Minors likely to receive, in one year, from radiation sources external to the body, a deep dose equivalent in excess of one mSv (0.1 rem), a lens dose equivalent in excess of 1.5 mSv (0.15 rem), or a shallow dose equivalent to the skin or to the extremities in excess of five mSv (0.5 rem); and

(c) Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of one mSv (0.1 rem); and

(d) Individuals entering a high or very high radiation area; and

(e) Individuals working with medical fluoroscopic equipment.

(i) An individual monitoring device used for the dose to an embryo/fetus of a declared pregnant woman, pursuant to Subsection R313-15-208(1), shall be located under the protective apron at the waist.

(A) If an individual monitoring device worn by a declared pregnant woman has a monthly reported dose equivalent value in excess of 0.5 mSv (50 mrem), the value to be used for determining the dose to the embryo/fetus, pursuant to Subsection R313-15-208(3)(a) for radiation from medical fluoroscopy, may be the value reported by the individual monitoring device worn at the waist underneath the protective apron which has been corrected for the potential overestimation of dose recorded by the monitoring device because of the overlying tissue of the pregnant individual. This correction shall be performed by a radiation safety officer of an institutional radiation safety committee, a qualified expert approved by the Board, or a representative of the Executive Secretary.

(ii) An individual monitoring device used for lens dose equivalent shall be located at the neck, or an unshielded location closer to the eye, outside the protective apron.

(iii) When only one individual monitoring device is used to determine the effective dose

equivalent for external radiation pursuant to Subsection R313-15-201(3)(b), it shall be located at the neck outside the protective apron. When a second individual monitoring device is used, for the same purpose, it shall be located under the protective apron at the waist. Note: The second individual monitoring device is required for a declared pregnant woman.

(iv) A registrant is not required to supply and require the use of individual monitoring devices provided the registrant has conducted a survey, pursuant to Section R313-15-501, that demonstrates that the working environment the individual encounters will not likely result in a dose in excess of ten percent of the limits in Subsection R313-15-201(1), and that the individual is neither a minor nor a declared pregnant woman.

(2) Each licensee or registrant shall monitor, to determine compliance with Section R313-15-204, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(a) Adults likely to receive, in one year, an intake in excess of ten percent of the applicable ALI(s) in Table I, Columns 1 and 2, of Appendix B of 10 CFR 20.1001 to 20.2402, 2001 ed., which is incorporated by reference; and

(b) Minors likely to receive, in one year, a committed effective dose equivalent in excess of one mSv (0.1 rem); and

(c) Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of one mSv (0.1 rem).

Note: All of the occupational doses in Section R313-15-201 continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded.

KEY: radioactive material, contamination, waste disposal, safety

2001

Notice of Continuation April 30, 1998

19-3-104

19-3-108

ADDITIONAL INFORMATION

PLEASE NOTE:

- Text to be deleted is struck through and surrounded by brackets (e.g., [~~example~~]). Text to be added is underlined (e.g., example). Some browsers may not depict some or any of these attributes on the screen or when the document is printed.
- Please see the **DISCLAIMER** regarding information available from state web pages.

For questions regarding the *content* or *application* of this rule, please contact Craig Jones at the above address, by phone at 801-536-4264, by FAX at 801-533-4097, or by Internet E-mail at cjones@deq.state.ut.us

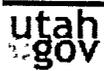
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Rule R313-16. General Requirements Applicable to the Installation, Registration, Inspection, and Use of Radiation Machines.

As in effect on September 1, 2002

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- **Authorizing, Implemented, or Interpreted Law**

R313-16-200. Purpose and Authority.

(1) The purpose of this rule is to prescribe requirements governing the installation, registration, inspection, and use of sources of electronically produced ionizing radiation. This rule provides for the registration of individuals providing inspection services to a facility where one or more radiation machines are installed or located.

(2) The rules set forth herein are adopted pursuant to the provisions of Subsections 19-3-104(3) and 19-3-104(8)(a).

R313-16-215. Definitions.

"Qualified expert" means an individual having the knowledge and training to measure regulatory parameters on radiation machines, to evaluate radiation safety programs, to evaluate radiation levels, and to give advice on radiation protection needs while conducting inspections of radiation machine facilities registered with the Department. Qualified experts are not considered employees or representatives of the Division of Radiation Control or the State.

"Sorting Center" means a facility in which radiation machines are in storage until they are shipped out of state.

"Storage" means a condition in which a radiation machine is not being used for an extended period of time, and has been made inoperable.

R313-16-220. Exemptions.

(1) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of Rule R313-16, providing the dose equivalent rate averaged over an area of ten square centimeters does not exceed 0.5 mrem (5.0 uSv) per hour at five centimeters from accessible surfaces of the equipment.

(2) Radiation machines while in transit are exempt from the requirements of Section R313-16-230. See Section R313-16-250 for other applicable requirements.

(3) Television receivers are exempt from the requirements of Rule R313-16.

(4) Radiation machines while in the possession of a manufacturer, assembler, or a sorting center are exempt from the requirements of Section R313-16-230.

(5) Radiation machines owned by an agency of the Federal Government are exempt from the requirements of Rule R313-16.

R313-16-225. Responsibility for Radiation Safety Program.

(1) The registrant shall be ultimately responsible for radiation safety, but may designate another person to implement the radiation safety program. When, in the Executive Secretary's opinion, neither the registrant nor the registrant's designee is sufficiently qualified to insure safe use of the machine; the Executive Secretary may order the registrant to designate another individual who has adequate qualifications.

(2) The registrant or the registrant's designee shall:

(a) develop a detailed program of radiation safety that assures compliance with the applicable requirements of these rules, including Section R313-15-101;

(b) have instructions given concerning radiation hazards and radiation safety practices to individuals who may be occupationally exposed;

(c) have surveys made and other procedures carried out as required by these rules; and

(d) keep a copy of all reports, records, and written policies and procedures required by these rules.

R313-16-230. Registration of Radiation Machines.

(1) Ionizing radiation producing machines not exempted by Section R313-16-220 shall be registered with the Executive Secretary.

(2) Registration renewal shall be required annually. The registration interval is July 1 through June 30 of the following year. The annual registration anniversary date shall be July 1. Renewal application will be considered late and late fees may be assessed if not received by the last day of August.

(3) Registration for the facility is achieved when the Executive Secretary receives the following:

(a) a current and complete application form DRC-10 for registration of radiation machines; and

(b) annual registration fees.

(4) Registration for the current fiscal year shall be acknowledged by the Executive Secretary through receipts for the remittance of the registration fee.

R313-16-231. Additional Requirements for the Issuance of a Registration for Particle Accelerators Excluding Therapeutic Radiation Machines (See Rule R313-30).

(1) In addition to the requirements of Section R313-16-230, a registrant who proposes to use a particle accelerator shall submit an application to the Executive Secretary containing the following:

(a) information demonstrating that the applicant, by reason of training and experience, is qualified to use the accelerator in question for the purpose requested in a manner that will minimize danger to public health and safety or the environment;

(b) a discussion which demonstrates that the applicant's equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or the environment;

(c) the name and qualifications of the individual, appointed by the applicant, to serve as radiation safety officer pursuant to Section R313-35-140;

(d) a description of the applicant's or the staff's experience in the use of particle accelerators and radiation safety training; and

(e) a description of the radiation safety training the applicant will provide to particle accelerator operators.

(2) Registrants who possess and use a particle accelerator that has been registered with the Department prior to January 1, 1999 shall submit a registration application that contains the information in Subsections R313-16-231(1)(a) through (e). The application shall be submitted by July 1, 1999.

R313-16-233. Notification of Intent to Provide Servicing and Services.

(1) Persons engaged in the business of installing or offering to install radiation machines or engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this State shall notify the Executive Secretary of the intent to provide these services within 30 days following the effective date of this rule or, thereafter, prior to furnishing or offering to furnish these services.

(2) The notification shall specify:

(a) that the applicable requirements of these rules have been read and understood;

(b) the services which will be provided;

(c) the training and experience that qualify for the discharge of the services; and

(d) the type of measurement instrument to be used, frequency of calibration, and source of calibration.

(3) For the purpose of Section R313-16-233, services may include but shall not be limited to:

(a) installation or servicing of radiation machines and associated radiation machine components; and

(b) calibration of radiation machines or radiation measurement instruments or devices.

(4) Individuals shall not perform the services listed in Subsection R313-16-233(3) unless they are specifically stated for that individual on the notification of intent required in Subsection R313-16-233(1) and the complete information required by Subsection R313-16-233(2) has been received by the Executive Secretary.

R313-16-235. Designation of Registrant.

The owner or lessee of a radiation machine is the registrant. The registrant shall be responsible for penalties imposed under the Executive Secretary's escalated enforcement authority, see Rule R313-14.

R313-16-240. Reciprocal Recognition of Registration or License.

Radiation machines from jurisdictions other than the State of Utah may be operated in this state for a period of less than 30 days providing that the requirements of Section R313-16-280 have been met and providing they are properly registered or licensed with the State Agency having jurisdiction over the office directing the activities of the individuals operating the radiation machines. Radiation machines operating under reciprocity may be inspected pursuant to Section

R313-16-290.

R313-16-250. Report of Changes.

The registrant shall send written notification within 14 working days to the Executive Secretary when:

- (1) there are changes in location or ownership of a radiation machine;
- (2) radiation machines are retired from service;
- (3) radiation machines are put in storage or returned to service from storage; or
- (4) modifications in facility or equipment are made that might reasonably be expected to effect compliance under the terms of these rules.

R313-16-260. Approval Not Implied.

Registration does not constitute approval of activities performed under the registration and no person shall state or imply that activities under the registration have been approved by the Executive Secretary.

R313-16-270. Transferor, Assembler, or Installer Obligation.

(1) Persons who sell, lease, transfer, lend, dispose, assemble, or install a radiation machine in this state shall notify the Executive Secretary within 14 working days of the following:

- (a) the name and address of the person who received the machine and also the name and address of the new registrant of the machine if not the same;
- (b) the manufacturer, model, and serial number of the master control of the radiation machine and the number of x-ray tubes transferred; and
- (c) the date of transfer of the radiation machine.

(2) Radiation machine equipment or accessories shall not be installed if the equipment will not meet the requirements of these rules when installation is completed.

(3) Reporting Compliance. Assemblers who install one or more components into a radiation machine system or subsystem, shall certify that the equipment meets the standards of these rules. A copy of this certification shall be transmitted to the purchaser and to the Executive Secretary within 14 working days following the completion of the installation.

(4) Certification can be accomplished by providing the following in conjunction with the information required by Section R313-16-250 and Subsection R313-16-270(1):

- (a) the full name and address of the assembler and the date of assembly or installation;
- (b) a statement as to whether the equipment is a replacement for other equipment, in addition to other equipment, or new equipment in a new facility;
- (c) an affirmation that the applicable rules have been met;

(d) a statement of the type and intended use of the radiation machine system or subsystem, for example "radiographic-stationary general purpose x-ray;" and

(e) a list of the components which were assembled or installed into the radiation machine system or subsystem, identifying the components by type, manufacturer, model number, and serial number.

R313-16-275. Obligation of Equipment Registrant or Recipient of New Equipment.

The registrant of a radiation machine shall not allow the equipment to be put into operation until it has been determined that the facility in which it is installed meets the shielding and design requirements of Rule R313- 28; see Sections R313-28-32, R313-28-200 and R313-28-450.

R313-16-280. Out-of-State Radiation Machines.

(1) Whenever a radiation machine is to be brought into the state, for either temporary or extended use, the person proposing to bring the machine into the state shall give written notice to the Executive Secretary at least three working days before the machine is to be used in the state. The notice shall include the type of radiation machine; the manufacturer model and serial number of the master control; the nature, duration, and scope of use; and the exact location where the radiation machine is to be used. If, for a specific case, the three working-day period would impose an undue hardship, the person may, upon application to the Executive Secretary, obtain permission to proceed sooner.

(2) In addition, the out-of-state person shall:

(a) comply with the applicable portions of these rules;

(b) supply the Executive Secretary other information as the Executive Secretary requests.

R313-16-290. Inspection of Radiation Machines and Facilities.

(1) Registrants shall assure that radiation machines registered pursuant to Section R313-16-230 are compliant with these rules. Radiation machines, facilities, and radiation safety programs are subject to inspection to assure compliance with these rules and to assist in lowering radiation exposure to as low as reasonably achievable levels, see Section R313-15-101. Inspections may be performed by representatives of the Executive Secretary or by independent qualified experts.

(2) Inspections may, at the Executive Secretary's discretion, be done after the installation of equipment, or after a change in the facility or equipment which might cause a significant change in radiation output or hazards. Inspections may be completed in accordance with the schedule as defined in Table I.

TABLE I

| FACILITY TYPE | MAXIMUM TIME BETWEEN INSPECTIONS |
|---|----------------------------------|
| Hospital or Radiation Therapy Facility | one year |
| Medical Facility using Fluoroscopic or Computed Tomography (CT) Units | one year |
| Medical Facility Using General Radiographic Devices | two years |
| Chiropractic | two years |
| Dental | five years |

| | |
|---|-------------------|
| Podiatry | five years |
| Veterinary | five years |
| Industrial Facility with High or Very High Radiation Areas Accessible to Individuals | one year |
| Industrial Facility Using Cabinet X-Ray Units or Units Designed for Other Industrial Purposes | five years |
| Other | one to five years |

(3) The registrant, in a timely manner, shall pay the appropriate inspection fee after completion of the inspection.

(4) Ionizing radiation producing machines which have been officially placed in storage are exempt from inspection fees but are subject to visual verification of their status by representatives of the Executive Secretary.

R313-16-291. Inspection Services.

Registrants shall only utilize qualified experts who have been registered by the Executive Secretary in accordance with Section R313-16-293. Registrants may also utilize inspectors from the Division of Radiation Control in lieu of registered qualified experts.

R313-16-292. Minimum Qualifications for Registration of Inspection Services.

A qualified expert who is engaged in the business of furnishing or offering to furnish inspection services at facilities shall meet the training and experience criteria developed by the Department. At a minimum, the training and experience shall include:

(1) Bachelor's degree in health physics, chemistry, biology, physical or environmental science plus one year full-time paid professional related experience, such as performing radiation safety evaluations in a hospital.

(a) An advanced degree in a related field may be substituted for one year of required experience; or

(2) Five years full-time paid professional, directly related work experience.

R313-16-293. Application for Registration of Inspection Services.

(1) Each qualified expert who is providing or offering to provide inspection services at facilities registered with the Executive Secretary shall complete an application for registration on a form prescribed by the Executive Secretary and shall submit all information required by the Executive Secretary as indicated on the form. A qualified expert must complete the registration process prior to providing services.

(2) Individuals applying for registration under Section R313-16-293 shall personally sign and submit to the Executive Secretary an attestation statement:

(a) that they have read and understand the requirements of these rules; and

(b) that they will document inspection items defined by the Executive Secretary on a form

prescribed by the Executive Secretary; and

(c) that they will follow guidelines for the evaluation of x-ray equipment defined by the Executive Secretary; and

(d) that, except for those facilities where a registered qualified expert is a full-time employee, they will limit inspections to facilities with which they have no direct conflict of interest; and

(e) that radiation exposure measurements and peak tube potential measurements will be made with instruments which have been calibrated biennially by the manufacturer of the instrument or by a calibration laboratory accredited in x-ray calibration procedures by the American Association of Physicians in Medicine, American Association for Laboratory Accreditation, Conference of Radiation Control Program Directors, Health Physics Society or the National Voluntary Laboratory Accreditation Program; and

(f) that the calibration of radiation exposure measuring and peak tube potential measuring instruments used to evaluate compliance of x-ray systems with the requirements of these rules will include at least secondary level traceability to a National Institute of Standards and Technology, or similar international agency, transfer standard instrument or transfer standard source; and

(g) that they will make available to representatives of the Executive Secretary documents concerning the calibration of any radiation exposure measuring or peak tube potential measuring instrument used to evaluate compliance of x-ray systems; and

(h) that they or the registrant will submit to the Executive Secretary, within 30 calendar days after completion of an inspection, a written report of compliance or noncompliance; and

(i) that reports of items of noncompliance will include:

(i) the name of the facility inspected, and

(ii) the date of the inspection, and

(iii) the manufacturer, model number, and serial number or Utah identification number of the control unit for the radiation machine, and

(iv) the requirements of the rule where compliance was not achieved, and

(v) the manner in which the facility or radiation machine failed to meet the requirements, and

(vi) a signed commitment from the registrant of the radiation machine facility that the problem will be fixed within 30 days of the date the written report of noncompliance is submitted to the Executive Secretary; and

(vii) that all reports of compliance or noncompliance will contain a statement signed by the qualified expert acknowledging under penalties of law that all information contained in the report is truthful, accurate, and complete; and

(viii) that they acknowledge that they are subject to the provisions of Section R313-16-300.

R313-16-294. Issuance of Registration Certificate for Inspection Services.

Upon a determination that an applicant meets the requirements of these rules, the Executive Secretary shall issue a registration certificate for inspection services.

R313-16-295. Expiration of Registration Certificates for Inspection Services.

A registration certificate for inspection services shall expire at the end of the day on the date stated therein.

R313-16-296. Renewal of Registration Certificate for Inspection Services.

(1) Qualified experts shall file an application for renewal of a registration certificate for inspection services 30 days in advance of the registration certificate expiration date and in accordance with Section R313- 16-293.

(2) Applicants shall document that they performed a minimum of two inspections in Utah under these rules each year the previous registration certificate was in effect.

R313-16-297. Revocation of Registration Certificate for Inspection Services.

A registration certificate for inspection services may be revoked by the Executive Secretary for any matter of deliberate misconduct pursuant to Section R313-16-300 or for misfeasance, malfeasance or nonfeasance.

R313-13-16-300. Deliberate Misconduct.

(1) Any registrant, applicant for registration, employee of a registrant or applicant; or any contractor, including a supplier or consultant, subcontractor, employee of a contractor or subcontractor of any registrant or applicant for registration, who knowingly provides to any registrant, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a registrant's, or applicant's activities in these rules, may not:

(a) Engage in deliberate misconduct that causes or would have caused, if not detected, a registrant or applicant to be in violation of any rule or order; or any term, condition, or limitation of any registration issued by the Executive Secretary; or

(b) Deliberately submit to the Executive Secretary, a registrant, an applicant, or a registrant's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Executive Secretary.

(2) A person who violates Subsections R313-16-300(1)(a) or (b) may be subject to enforcement action in accordance with Rule R313-14.

(3) For the purposes of Subsection R313-16-300(1)(a), deliberate misconduct by a person means an intentional act or omission that the person knows:

(a) Would cause a registrant or applicant to be in violation of any rule or order; or any term, condition, or limitation, of any registration issued by the Executive Secretary; or

(b) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a registrant, applicant, contractor, or subcontractor.

KEY

x-ray, inspection

Date of Enactment or Last Substantive Amendment

December 14, 2001

Notice of Continuation

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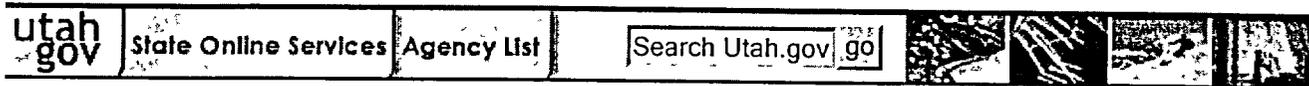
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Rule R313-17. Administrative Procedures.

As in effect on September 1, 2002

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R313-17-1. Application of Rule.

This rule applies to proceedings under Title 19, Chapter 3 (Radiation Control Act).

R313-17-2. Public Notice and Public Comment Period.

(1) The Executive Secretary shall give public notice of, and an opportunity to comment on the following actions:

(a) Proposed licensing action for license categories 4a, b, c, d and 6 identified in R313-70-7 or a proposed approval or denial of a significant radioactive materials license, license amendment, or license renewal.

- (b) The initial proposed registration of an ionizing radiation producing machine which operates at a kilovoltage potential (kVp) greater than 200 in an open beam configuration. R313-17-2(1)(b) does not apply to use in the healing arts.
- (c) Board activities that may have significant public interest and the Board requests the Executive Secretary to take public comment on those proposed activities.
- (2) Public notice shall allow at least 30 days for public comment.
- (3) Public notice may describe more than one action listed in R313-17-2(1) and may combine notice of a public hearing with notice of the proposed action.
- (4) Public notice shall be given by publication in a newspaper of general circulation in the area affected by the proposed action. Notice shall also be given to persons on a mailing list developed by the Executive Secretary and those who request in writing to be notified.

R313-17-3. Public Comments, Response to Comments and Requests for Public Hearings.

- (1) During the public comment period provided under R313-17-2, any interested person may submit written comments on the proposed action and may request a public hearing, if no hearing has already been scheduled.
- (2) A request for a public hearing shall be in writing and shall state the nature of the issues proposed to be raised in the hearing.
- (3) Comments received during the public comment period and during any hearing shall be considered in making the final decision.
- (4) At the time of the final decision, the Executive Secretary shall issue a response to comments, which shall include:
- (a) Specific provisions, if any, that have been changed in the final action and the reasons for the change; and
- (b) A brief description and response to all significant comments raised during the public comment period or during any hearing.
- (5) The Executive Secretary's response to public comments shall be available to the public.

R313-17-4. Public Hearings.

- (1) This section applies to hearings for public comment on proposed actions specified in R313-17-2. This section does not govern adjudicative proceedings.
- (2) The Executive Secretary shall hold a public hearing whenever he finds, on the basis of requests, a significant degree of public interest in the proposed action.
- (3) The Executive Secretary may also hold a public hearing at his discretion, whenever, for instance, a hearing might clarify one or more issues involved in the proposed action.
- (4) The Executive Secretary shall hold a public hearing whenever he receives written notice of opposition to a proposed action and a request for a hearing within 30 days of public notice under

R313-17-2.

(5)(a) Public notice of the hearing shall be given as specified in R313-17-2.

(b) The public comment period under R313-17-2 shall automatically be extended to the close of any public hearing under this section. The hearing officer may also extend the comment period by so stating at the hearing.

(c) Whenever possible the Executive Secretary shall schedule a hearing under this section at a time and location convenient to the parties involved.

(d) Any person at the hearing may submit oral or written statements and data concerning the proposed action. Reasonable limits may be set upon the time allowed for oral statements and the submission of statements in writing may be required.

(e) A tape recording or written transcript of the hearing shall be made available to the public.

R313-17-5. Administrative Procedures General Provisions.

(1) PURPOSE AND SCOPE

R313-17-5 through R313-17-13 set out procedures for conducting formal adjudicative proceedings in accordance with the Utah Administrative Procedures Act (UAPA), Section 63-46b-1 et seq. and govern:

(a) the contest of the validity of initial order or notice of violation as described in R313-17- 5(2);

(b) the contest of proposed imposition of civil penalties under Section 19-3-109; and

(c) other formal adjudicative proceedings before the Radiation Control Board.

(2) INITIAL PROCEEDINGS EXEMPT FROM UAPA

Proceedings that culminate in the issuance of an initial order or a notice of violation under the Utah Radiation Control Act are not governed by UAPA as specified in Section 63-46b-1(2)(k). This includes, but is not limited to, initial proceedings regarding:

(a) approval, amendment, denial, termination, transfer, revocation, or renewal of licenses;

(b) requests for variances, exemptions, and other approvals;

(c) notices of violation and orders associated with notices of violation;

(d) orders to comply and orders to cease and desist;

(e) impoundment of radioactive material;

(f) orders for decommissioning;

(g) declaratory orders; and

(h) orders for surveying, monitoring, sampling, or information;

(3) DESIGNATION OF PROCEEDINGS

(a) Contest of an initial order or notice of violation or proposed imposition of civil penalties shall be conducted as a formal proceeding.

(b) The Board in accordance with Section 63-46b-4(3) may convert proceedings which are designated to be formal to informal, and proceedings which are designated as informal to formal if conversion is in the public interest and rights of all parties are not unfairly prejudiced.

(c) Unless otherwise stated in R313, informal adjudicative proceedings shall be conducted in accordance with Section 63-46b-5.

(4) APPEARANCES AND REPRESENTATION

(a) An individual who is a participant to a proceeding, or an officer designated by a partnership, corporation, association, or governmental entity which is a participant to a proceeding, may represent his, her, or its interest in the proceeding.

(b) Any participant may be represented by legal counsel.

(5) COMPUTATION OF TIME

Time shall be computed as provided in Rule 6(a) of the Utah Rules of Civil Procedure except that no additional time shall be allowed for service by mail.

R313-17-6. Commencing a Formal Adjudicative Proceeding.

(1) Except as otherwise permitted by emergency orders as described in Section 63-46b-20, all adjudicative proceedings shall be commenced by either:

(a) a Notice of Agency Action in accordance with Section 63-46b-3, if proceedings are commenced by the Board; or

(b) a Request for Agency Action in accordance with R313-17-6(2), if proceedings are commenced by a person other than the Board.

(2)(a) The validity of initial orders, notices of violation and proposed imposition of civil penalties, as described in R313-17-5(1) and (2), may be contested by filing a written Request for Agency Action with the Board and submitted to:

Executive Secretary, Utah Radiation Control Board

Division of Radiation Control

168 North 1950 West

PO Box 144850

Salt Lake City, Utah 84114-4850.

(b) Any such request is governed by and shall comply with the requirements of Section 63-46b-3 (3) and shall be received for filing within 30 days of the issuance of the Executive Secretary's

order or notice of violation.

(c)(i) All initial orders or notices of violation are effective upon issuance and shall become final if not contested within 30 days after the date issued.

(ii) Issuance of such orders or notices of violation means the time a signed order is mailed by certified mail to the recipient's most current address or hand delivered to the recipient.

(iii) If delivery by certified mail is refused, the issued order or notice shall be sent by regular first class mail.

(d) Failure to timely contest an initial order or notice of violation waives any right of administrative contest, reconsideration, review or judicial appeal.

(3) RESPONSE TO REQUEST FOR AGENCY ACTION

In accordance with Section 63-46b-3(3)(d) and (e), notice of the time and place for a hearing shall be provided in the response to a request for agency action, or shall be provided promptly after the hearing is scheduled.

(4) PRE-HEARING RECORD

The Executive Secretary shall compile an administrative record prior to a scheduled hearing and give any party the opportunity to supplement the record. The pre-hearing record shall also consist of pleadings or other documents filed prior to the hearing.

R313-17-7. Parties and Intervention.

(1) DETERMINATION OF A PARTY.

The following persons are Parties to a formal proceeding governed by these rules:

(a) The person to whom an initial order or notice of violation is directed, such as a person who submitted a license application that was approved or disapproved by order of the Executive Secretary;

(b) The Executive Secretary of the Radiation Control Board; and

(c) All persons whose legal rights or interests are substantially affected by the proceeding, who have standing to participate in the proceeding, and to whom the Board has granted intervention under R313-17-7(2).

(2) INTERVENTION

A petition for intervention may be filed by a petitioner to commence an adjudicative proceeding in accordance with R313-17-6(2) or to intervene after a notice of agency action or request for agency action has been filed. A petitioner for intervention shall meet the following requirements:

(a)(i) The request for agency action is timely filed in accordance with R313-17-6(2); or

(ii) The Petition to Intervene in a proceeding commenced by a party other than the Petitioner for Intervention is filed with the Board, with a copy to all parties, within 20 days from the date of the

Notice of Agency Action or Request for Agency Action.

(b) The Petition to Intervene:

(i) Identifies the proceedings in which intervention is sought;

(ii) Contains a statement of facts demonstrating that the petitioner's legal rights or interests are substantially affected by the formal adjudicative proceeding and the petitioner qualifies as an Intervenor under Section 63-46b-9; and

(iii) Includes a statement of relief sought from the Board, including the basis thereof.

(c) Unless modified by the Presiding Officer, any party may respond to a Petition for Intervention during the period allowed for responsive pleadings under Section 63-46b-6. The Chair of the Radiation Control Board may act as Presiding Officer for purposes of this paragraph.

(d) Intervention may only be granted by order of the Board to a petitioner who meets the requirements of R313-17-7(2)(a) and (b).

(3) DESIGNATION OF PARTIES

Unless otherwise designed by the Hearing Officer:

(a) The person filing a Request for Agency Action shall be the Petitioner and the Executive Secretary shall be the Respondent.

(b) In a proceeding requested by a Petitioner for Intervention, the person granted Intervenor status shall be the Petitioner. The Executive Secretary and the person to whom the challenged order or notice is directed shall be the Respondents.

(4) AMICUS CURIAE (Friend of the Court)

Persons may be permitted by the Presiding Officer(s) to enter an appearance as Amicus Curiae (Friend of the Court), subject to conditions established by the Presiding Officer(s).

R313-17-8. Conduct of Proceedings.

(1) ROLE OF BOARD

(a) The Board is the "agency head" as that term is used in Section 63-46b. The Board is also the "presiding officer," as that term is used in Section 63-46b, except:

(i) The Chair of the Board shall be considered the Presiding Officer to the extent that these rules allow; and

(ii) The Board may by order appoint one or more Presiding Officers to preside over all or a portion of the proceedings.

(b) The Chair of the Board may delegate his or her authority as specified in this Rule to another Board member.

(2) APPOINTED PRESIDING OFFICERS

Unless otherwise explicitly provided in an order of appointment, any appointment of a Presiding Officer shall be for the purpose of conducting all aspects of an adjudicative proceeding, except grant of intervention, stays of orders and issuance of the final order. As used in these rules, the term Presiding Officer shall mean Presiding Officers if more than one Presiding Officer is appointed by the Board.

(3) PRE-HEARING CONFERENCES

The Presiding Officer may direct the Parties to appear at a specified time and place for pre-hearing conferences for the purposes of clarifying the issues, simplifying the evidence, facilitating discovery, expediting proceedings, or encouraging settlement.

(4) BRIEFS

(a) Unless otherwise directed by the Presiding Officer, parties to the proceeding may submit a pre-hearing brief at least five business days before the hearing. Post-hearing briefs will be allowed only as authorized by the Presiding Officer.

(b) Response briefs may not be filed unless permitted by the Presiding Officer.

(5) SCHEDULES

(a) The Presiding Officer shall establish schedules for discovery and other pre-hearing proceedings, for the hearing, and for any post-hearing proceedings.

(b) The parties are encouraged to prepare a joint proposed schedule. If the parties cannot agree on a joint proposed schedule, the Presiding Officer may consider proposals by any party.

(6) EXTENSIONS OF TIME

Except as otherwise provided by statute, the Presiding Officer may approve extensions of time limits established by this rule, and may extend time limits adopted in schedules established under R313-17-8(5). The Presiding Officer may also postpone hearings. The Chair of the Board may act as Presiding Officer for purposes of this paragraph.

(7) MOTIONS

All motions shall be filed a minimum of 12 days before a scheduled hearing, unless otherwise directed by the Presiding Officer. A memorandum in opposition to a motion may be filed within ten days of the filing of the motion, or at least one day before any scheduled hearing, whichever is earlier. Memoranda in support of or in opposition to motions may not exceed 15 pages unless otherwise provided by the Presiding Officer.

(8) FILING AND COPIES OF SUBMISSIONS

The original of any motion, brief, petition for intervention, or other submission shall be filed with the Executive Secretary. In addition, the submitter shall provide a copy to each Presiding Officer and to all parties or their counsel of record.

R313-17-9. Hearings.

(1) CONDUCT OF HEARING

The Presiding Officer shall govern the conduct of a hearing, and may establish reasonable limits on the length of witness testimony, cross-examination, oral arguments or opening and closing statements.

(2) ORDER OF PRESENTATION

Unless otherwise directed by the Presiding Officer, the Executive Secretary shall present its case first, followed by the Petitioner and any other party, then the Executive Secretary, and other parties if appropriate, shall have the opportunity for rebuttal.

R313-17-10. Orders.

(1) PROPOSED ORDERS BY PARTIES

Unless otherwise directed by the Presiding Officer, each party may provide proposed orders for the Presiding Officer within ten days of the conclusion of the hearing.

(2) DRAFT ORDERS OF APPOINTED PRESIDING OFFICERS

(a) The appointed Officer presiding over the adjudicative proceeding shall prepare a recommended order, provide a copy of the order to the Board and mail a copy of the order to all parties or their counsel of record.

(b) The Board shall review the recommended order and hearing record.

(c) The Board may give each party the opportunity to make a presentation to the Board specific to the recommended order.

(d) After deliberation, the Board shall determine whether to accept, reject or modify the recommended order. The Board may remand part or all of the matter to the Presiding Officer for further proceedings.

(e) The Board may modify this procedure with notice to all parties.

(3) FINAL ORDERS

The Board shall issue a final order which shall include the information required by Sections 63-46b-10 or 63-46b-5(1)(i).

R313-17-11. Stays of Orders.

(1) STAY OF ORDERS PENDING ADMINISTRATIVE ADJUDICATION

(a) A party seeking a stay of a challenged order during an adjudicative proceeding shall file a motion with the Board. If granted, a stay would suspend the challenged Order for the period as directed by the Board.

(b) The Board may order a stay of the Order that is the subject of the formal adjudicative proceeding if the party seeking the Stay demonstrates the following:

(i) The party seeking the Stay will suffer irreparable harm unless the stay issues;

- (ii) The threatened injury to the party seeking the Stay outweighs whatever damage the proposed stay is likely to cause the party restrained or enjoined;
- (iii) The Stay, if issued, would not be adverse to the public interest; and
- (iv) There is substantial likelihood that the party seeking the Stay will prevail on the merits of the underlying claim, or the case presents serious issues on the merits which should be the subject of further adjudication.

(2) STAY OF THE ORDER PENDING JUDICIAL REVIEW

- (a) A party seeking a stay of the Board's final order during judicial review shall file a motion with the Board.
- (b) The Board as Presiding Officer may grant a stay of its order during the pendency of judicial review if the standards of R317-17-11(1)(b) are met.

R313-17-12. Reconsideration.

No agency review under Section 63-46b-12 is available. A party may request reconsideration of an order of the Presiding Officer as provided in Section 63-46b-13.

R313-17-13. Disqualification of Presiding Officer(s).

(1) DISQUALIFICATION OF PRESIDING OFFICER

- (a) A member of the Board or other Presiding Officer shall disqualify himself or herself from performing the functions of the Presiding Officer regarding any matter in which he or she, or his or her spouse, or a person within the third degree of relationship to either of them, or the spouse of such person:
 - (i) Is a party to the proceeding, or an officer, director, or trustee of a party;
 - (ii) Has acted as an attorney in the proceeding or served as an attorney for, or otherwise represented a party concerning the matter in controversy;
 - (iii) Knows that he or she has an financial interest, either individually or as a fiduciary, in the subject matter in controversy or in a party to the proceeding;
 - (iv) Knows that he or she has any other interest that could be substantially affected by the outcome of the proceeding; or
 - (v) Is likely to be a material witness in the proceeding.
- (b) A member of the Board or other Presiding Officer is also subject to disqualification under principles of due process and administrative law.

(2) MOTIONS FOR DISQUALIFICATION

A motion for disqualification shall be made first to the Presiding Officer. If the Presiding Officer is appointed, any determination of the Presiding Officer upon a motion for disqualification may be appealed to the Board.

R313-17-14. Other Forms of Address.

Nothing in these rules shall prevent any person from requesting an opportunity to address the Board as a member of the public, rather than as a party. An opportunity to address the Board shall be granted at the discretion of the Board. However, addressing the Board in this manner does not constitute a request for agency action under R313-17- 6.

R313-17-15. Requests for Records.

Requests for records under the Utah Government Record Access and Management Act, Title 63, Chapter 2, Utah Code Ann., are not governed by R313. See R305-1.

KEY

administrative procedures, public comment, public hearings, orders

Date of Enactment or Last Substantive Amendment

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Notice of Continuation

July 23, 2001

Authorizing, Implemented, or Interpreted Law

19-3-103.5; 19-3-104

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Rule R313-18. Notices, Instructions and Reports to Workers by Licensees or Registrants-- Inspections.

As in effect on September 1, 2002

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R313-18-1. Purpose and Authority.

(1) The purpose of this rule is to establish requirements for notices, instructions and reports by licensees or registrants to individuals engaged in work under a license or registration and options available to such individuals in connection with inspections of licensees or registrants.

(2) The rules set forth herein are adopted pursuant to the provisions of Sections 19-3-104(3) and 19-3-104(6).

R313-18-2. General.

The rules of R313-18 shall apply to all persons who receive, possess, use, own or transfer a source of radiation licensed by or registered with the Department pursuant to the rules in R313-16, R313-19 or R313-22.

R313-18-11. Posting of Notices to Workers.

- (1) Licensees or registrants shall post current copies of the following documents:
 - (a) the rules in R313-15 and R313-18;
 - (b) the license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;
 - (c) the operating procedures applicable to work under the license or registration; and
 - (d) a notice of violation involving radiological working conditions, proposed imposition of civil penalty, order issued pursuant to R313-14, or any response from the licensee or registrant.
- (2) If posting of a document specified in R313-18-11(1)(a), (b), or (c) is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.
- (3) DRC-04 "Notice to Employees," shall be posted by licensees or registrants wherever individuals work in or frequent a portion of a restricted area.
- (4) Documents from the Executive Secretary which are posted pursuant to R313-18-11(1)(d) shall be posted within five working days after receipt of the documents from the Executive Secretary; the licensee's or registrant's response, if there is one, shall be posted for a minimum of five working days after dispatch from the licensee or registrant. The documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.
- (5) Documents, notices or forms posted pursuant to R313-18-11 shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

R313-18-12. Instructions to Workers.

- (1) All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 1.0 mSv (100 mrem):
 - (a) shall be kept informed of the storage, transfer, or use of sources of radiation in the licensee's or registrant's workplace;
 - (b) shall be instructed in the health protection considerations associated with exposure to radiation or radioactive material to the individual and potential offspring, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;
 - (c) shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of these rules and licenses for the protection of personnel from exposure to radiation or radioactive material;
 - (d) shall be instructed as to their responsibility to report promptly to the licensee or registrant a condition which may constitute, lead to, or cause a violation of the Act, these rules, or a condition of the licensee's license or unnecessary exposure to radiation or radioactive material;

(e) shall be instructed in the appropriate response to warnings made in the event of an unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and

(f) shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to R313-18-13.

(2) In determining those individuals subject to the requirements of R313-18-12(1), licensees must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation or radioactive material which can reasonably be expected to occur during the life of a licensed facility. The extent of these instructions shall be commensurate with potential radiological health protection considerations for the workplace.

R313-18-13. Notifications and Reports to Individuals.

(1) Radiation exposure data for an individual and the results of measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in R313-18-13. The information reported shall include data and results obtained pursuant to these rules, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to R313-15-1107. Notifications and reports shall:

(a) be in writing;

(b) include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number, preferably social security number;

(c) include the individual's exposure information; and

(d) contain the following statement:

"This report is furnished to you under the provisions of the Utah Administrative Code Section R313-18- 13. You should preserve this report for further reference."

(2) Licensees or registrants shall furnish to each worker annually a written report of the worker's dose as shown in records maintained by the licensee or registrant pursuant to R313-15-1107.

(3) Licensees or registrants shall furnish a written report of the worker's exposure to sources of radiation at the request of a worker formerly engaged in activities controlled by the licensee or registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to R313-15-502. The report shall be furnished within 30 days from the date of the request, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

(4) When a licensee or registrant is required pursuant to R313-15-1202, R313-15-1203, or R313-15-1204 to report to the Executive Secretary an exposure of an individual to sources of radiation, the licensee or the registrant shall also provide the individual a written report on the exposure data included therein. Reports shall be transmitted at a time not later than the transmittal to the Executive Secretary.

(5) At the request of a worker who is terminating employment with the licensee or registrant in

work involving exposure to radiation or radioactive material, during the current year, the licensee or registrant shall provide at termination to the worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

R313-18-14. Presence of Representatives of Licensees or Registrants and Workers During Inspection.

- (1) Licensees or registrants shall afford representatives of the Board or the Executive Secretary, at reasonable times, the opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these rules.
- (2) During an inspection, representatives of the Board or the Executive Secretary may consult privately with workers as specified in R313-18-15. The licensee or registrant may accompany representatives during other phases of an inspection.
- (3) If, at the time of inspection, an individual has been authorized by the workers to represent them during Department inspections, the licensee or registrant shall notify the representatives of the Board or the Executive Secretary of the authorization and shall give the workers' representative an opportunity to accompany the representatives during the inspection of physical working conditions.
- (4) The workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in R313-18-12.
- (5) Different representatives of licensees or registrants and workers may accompany the representatives of the Board or the Executive Secretary during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the representatives of the Board or the Executive Secretary.
- (6) With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany representatives of the Board or the Executive Secretary during the inspection of physical working conditions.
- (7) Notwithstanding the other provisions of R313-18-14, representatives of the Board or the Executive Secretary are authorized to refuse to permit accompaniment by an individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an Agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to areas containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

R313-18-15. Consultation with Workers During Inspections.

- (1) Representatives of the Board or the Executive Secretary may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of these rules and licenses to the extent the representatives deem necessary for the

conduct of an effective and thorough inspection.

(2) During the course of an inspection, workers may bring privately to the attention of the representatives of the Board or the Executive Secretary, either orally or in writing, a past or present condition which the worker has reason to believe may have contributed to or caused a violation of the Act, these rules, or license condition, or an unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. A notice in writing shall comply with the requirements of R313-18-16(1).

(3) The provisions of R313-18-15(2) shall not be interpreted as authorization to disregard instructions pursuant to R313-18-12.

R313-18-16. Request by Workers for Inspections.

(1) A worker or representative of workers believing that a violation of the Act, these rules, or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Executive Secretary. The notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by representatives of the Board or the Executive Secretary no later than at the time of inspection except that, upon the request of the worker giving the notice, his name and the name of individuals referred to therein shall not appear in a copy or on a record published, released, or made available by the Department except for good cause shown.

(2) If, upon receipt of the notice, representatives of the Board or the Executive Secretary, determine that the complaint meets the requirements set forth in R313-18-16(1), and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if the alleged violation exists or has occurred. Inspections pursuant to R313-18-16 need not be limited to matters referred to in the complaint.

(3) A licensee, registrant or contractor or subcontractor of a licensee or registrant shall not discharge or discriminate against a worker because that worker has filed a complaint or instituted or caused to be instituted a proceeding under these rules or has testified or is about to testify in a proceeding or because of the exercise by the worker on behalf of the worker or others of an option afforded by R313-18.

R313-18-17. Inspections Not Warranted -- Informal Review.

(1)(a) If the representatives of the Board or the Executive Secretary determine, with respect to a complaint under Section R313-18-16, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Executive Secretary shall notify the complainant in writing of that determination. The complainant may obtain review of the determination by submitting a written statement of position with the Executive Secretary. The Executive Secretary will provide the licensee or registrant with a copy of the statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the Executive Secretary. The Executive Secretary will provide the complainant with a copy of the statement by certified mail.

(b) Upon the request of the complainant, the Board may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant.

After considering written and oral views presented, the Board shall affirm, modify, or reverse the determination of the representatives of the Board or the Executive Secretary and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefor.

(2) If the Executive Secretary determines that an inspection is not warranted because the requirements of R313-18-16(1) have not been met, the complainant shall be notified in writing of the determination. The determination shall be without prejudice to the filing of a new complaint meeting the requirements of R313-18-16(1).

KEY

radioactive material, inspection, radiation safety, licensing

Date of Enactment or Last Substantive Amendment

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Notice of Continuation

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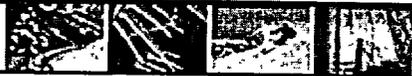
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Rule R313-19. Requirements of General Applicability to Licensing of Radioactive Material.

As in effect on September 1, 2002

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R313-19-1. Purpose and Authority.

(1) The purpose of this rule is to prescribe requirements governing the licensing of radioactive material. This rule also gives notice to all persons who knowingly provide to any licensee, applicant, certificate of registration holder, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's, applicant's or certificate of registration holder's activities subject to these rules, that they may be individually subject to Executive Secretary enforcement action for violation of Section R313-19-5.

(2) The rules set forth herein are adopted pursuant to the provisions of Sections 19-3-104(3) and 19-3-104(6).

R313-19-2. General.

(1) A person shall not receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license issued pursuant to Rules R313-21 or R313-22 or as otherwise provided in Rule R313-19.

(2) In addition to the requirements of Rules R313-19, R313-21 or R313-22, all licensees are subject to the requirements of Rules R313-12, R313-15, and R313-18. Licensees authorized to use sealed sources containing radioactive materials in panoramic irradiators with dry or wet storage of radioactive sealed sources, underwater irradiators, or irradiators with high dose rates from radioactive sealed sources are subject to the requirements of Rule R313-34, licensees engaged in industrial radiographic operations are subject to the requirements of Rule R313-36, licensees using radionuclides in the healing arts are subject to the requirements of Rule R313-32, licensees engaged in land disposal of radioactive material are subject to the requirements of Rule R313-25, and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of Rule R313-38.

R313-19-5. Deliberate Misconduct.

(1) Any licensee, certificate of registration holder, applicant for a license or certificate of registration, employee of a licensee, certificate of registration holder or applicant; or any contractor, including a supplier or consultant, subcontractor, employee of a contractor or subcontractor of any licensee or certificate of registration holder or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, certificate holder, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's or applicant's activities in these rules, may not:

(a) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate of registration holder, or applicant to be in violation of any rule or order; or any term, condition, or limitation of any license issued by the Executive Secretary; or

(b) Deliberately submit to the Executive Secretary, a licensee, certificate of registration holder, an applicant, or a licensee's, certificate holder's or applicant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Executive Secretary.

(2) A person who violates Subsections R313-19-5(1)(a) or (b) may be subject to enforcement action in accordance with Rule R313-14.

(3) For the purposes of Subsection R313-19-5(1)(a), deliberate misconduct by a person means an intentional act or omission that the person knows:

(a) Would cause a licensee, certificate of registration holder or applicant to be in violation of any rule or order; or any term, condition, or limitation, of any license issued by the Executive Secretary; or

(b) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate of registration holder, applicant, contractor, or subcontractor.

R313-19-13. Exemptions.

(1) Source material.

(a) A person is exempt from Rules R313-19, R313-21, and R313-22 to the extent that the person receives, possesses, uses, owns, or transfers source material in a chemical mixture, compound,

solution or alloy in which the source material is by weight less than 1/20 of one percent (0.05 percent) of the mixture, compound, solution, or alloy.

(b) A person is exempt from Rules R313-19, R313-21, and R313-22 to the extent that the person receives, possesses, uses or transfers unrefined and unprocessed ore containing source material; provided, that, except as authorized in a specific license, such person shall not refine or process the ore.

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

(i) any quantities of thorium contained in:

(A) incandescent gas mantles,

(B) vacuum tubes,

(C) welding rods,

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

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

(F) rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these, or

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

(ii) source material contained in the following products:

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

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

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

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

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

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

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

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

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

(D) The requirements specified in Subsections R313-19-13(1)(c)(v)(B) and (C) need not be met by counterweights manufactured prior to December 31, 1969, provided that such counterweights are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM", as previously required by the rules, and

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

(vi) natural or depleted uranium metal used as shielding constituting part of a shipping container which is conspicuously and legibly impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM" and the uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of one eighth inch (3.2 mm);

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

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

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

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

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

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

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

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

(2) Radioactive material other than source material.

(a) Exempt concentrations.

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

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

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

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

(b) Exempt quantities.

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

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

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

(iv) A person who possesses radioactive material received or acquired prior to September 25, 1971, under the general license formerly provided in 10 C.F.R. Part 31.5 is exempt from the requirements for a license set forth in Rule R313-19 to the extent that the person possesses, uses, transfers or owns the radioactive material. This exemption does not apply for radium-226.

(c) Exempt items.

(i) Certain items containing radioactive material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, a person is exempt from these rules to the extent that person receives, possesses, uses, transfers, owns or acquires the following products:

(A) Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:

(I) 25 millicuries (925.0 MBq) of tritium per timepiece;

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

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

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

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

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

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

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

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

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

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

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

(C) Precision balances containing not more than one millicurie (37.0 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part.

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

(E) Marine compasses containing not more than 750 millicuries (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas.

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

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

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

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

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

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

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

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

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

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

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

(I) each source contains no more than one exempt quantity set forth in Section R313-19-71; and

(II) each instrument contains no more than ten exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of exempt quantities in Section R313-19-71, provided that the sum of the fractions shall not exceed unity;

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

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

(ii) Self-luminous products containing radioactive material.

(A) Tritium, krypton-85 or promethium-147. Except for persons who manufacture, process or produce self-luminous products containing tritium, krypton-85 or promethium-147, a person is exempt from these rules to the extent that the person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 C.F.R. Part 32.22, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in Subsection R313-19-13(2)(c)(ii) does not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.

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

(iii) Gas and aerosol detectors containing radioactive material.

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

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

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

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

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

(B) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to Rule R313-32.

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

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

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

D.C. 20555.

R313-19-20. Types of Licenses.

Licenses for radioactive materials are of two types: general and specific.

(1) General licenses provided in Rule R313-21 are effective without the filing of applications with the Executive Secretary or the issuance of licensing documents to the particular persons, although the filing of a registration certificate with the Executive Secretary may be required by the particular general license. The general licensee is subject to the other applicable portions of these rules and limitations of the general license.

(2) Specific licenses require the submission of an application to the Executive Secretary and the issuance of a licensing document by the Executive Secretary. The licensee is subject to applicable portions of these rules as well as limitations specified in the licensing document.

R313-19-25. Prelicensing Inspection.

The Executive Secretary may verify information contained in applications and secure additional information deemed necessary to make a reasonable determination as to whether to issue a license and whether special conditions should be attached thereto by visiting the facility or location where radioactive materials would be possessed or used, and by discussing details of the proposed possession or use of the radioactive materials with the applicant or representatives designated by the applicant. Such visits may be made by representatives of the Board or the Executive Secretary.

R313-19-30. Reciprocal Recognition of Licenses.

(1) Subject to these rules, a person who holds a specific license from the U.S. Nuclear Regulatory Commission, an Agreement State, or Licensing State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in the licensing document within this state, except in areas of exclusive federal jurisdiction, for a period not in excess of 180 days in a calendar year provided that:

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

(b) the out-of-state licensee notifies the Executive Secretary in writing at least three days prior to engaging in such activity. Notifications shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Executive Secretary, obtain permission to proceed sooner. The Executive Secretary may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in Subsection R313-19-30(1);

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

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

and

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

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

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

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

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

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

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

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

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

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 Executive Secretary.

(2) 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 Executive Secretary 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 Executive Secretary, and

shall give his consent in writing.

(3) Persons licensed by the Executive Secretary 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 Executive Secretary 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 Executive Secretary in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11, Bankruptcy, of the United States Code by or against:

(a) the licensee;

(b) an entity, as that term is defined in 11 U.S.C.101(14), controlling the licensee or listing the license or licensee as property of the estate; or

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

(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 Executive Secretary. The licensee may change the approved plan without the Executive Secretary's approval only if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the Executive Secretary 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 Executive Secretary.

R313-19-41. Transfer of Material.

(1) Licensees shall not transfer radioactive material except as authorized pursuant to Section R313- 19-41.

(2) Except as otherwise provided in the license and subject to the provisions of Subsections R313-19- 41(3) and (4), licensees may transfer radioactive material:

(a) to the Executive Secretary, if prior approval from the Executive Secretary has been received;

(b) to the U.S. Department of Energy;

(c) to persons exempt from the rules in Rule R313-19 to the extent permitted under the exemption;

(d) to persons authorized to receive the material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Executive

Secretary, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, or to a person otherwise authorized to receive the material by the federal government or an agency thereof, the Executive Secretary, an Agreement State or a Licensing State; or

(e) as otherwise authorized by the Executive Secretary in writing.

(3) Before transferring radioactive material to a specific licensee of the Executive Secretary, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, or to a general licensee who is required to register with the Executive Secretary, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

(4) The following methods for the verification required by Subsection R313-19-41(3) are acceptable:

(a) the transferor may possess, and read a current copy of the transferee's specific license or registration certificate;

(b) the transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;

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

(d) the transferor may obtain other information compiled by a reporting service from official records of the Executive Secretary, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State regarding the identity of licensees and the scope and expiration dates of licenses and registration; or

(e) when none of the methods of verification described in Subsection R313-19-41(4) are readily available or when a transferor desires to verify that information received by one of the methods is correct or up-to-date, the transferor may obtain and record confirmation from the Executive Secretary, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State that the transferee is licensed to receive the radioactive material.

(5) Shipment and transport of radioactive material shall be in accordance with the provisions of Section R313-19-100.

R313-19-50. Reporting Requirements.

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

(2) The following events involving licensed material require notification of the Executive Secretary

by the licensee within 24 hours:

(a) an unplanned contamination event that:

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

(ii) involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of 10 CFR 20.1001 through 20.2402 (2000), which is incorporated by reference, for the material; and

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

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

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

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

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

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

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

(i) the quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of 10 CFR 20.1001 through 20.2402 (2000), which is incorporated by reference, for the material; and

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

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

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

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

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

(iii) the exact location of the event;

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

(v) available personnel radiation exposure data.

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

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

(ii) the exact location of the event;

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

(iv) date and time of the event;

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

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

R313-19-61. Modification, Revocation, and Termination of Licenses.

(1) The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Act, or by reason of rules, and orders issued by the Executive Secretary.

(2) Licenses may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act, or because of conditions revealed by the application or statement of fact or any report, record, or inspection or other means which would warrant the Executive Secretary to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rule, or order of the Executive Secretary.

(3) Administrative reviews, modifications, revocations or terminations of licenses will be in accordance with Title 19, Chapter 3.

(4) The Executive Secretary may terminate a specific license upon written request submitted by the licensee to the Executive Secretary.

R313-19-70. Exempt Concentrations of Radioactive Materials.

Refer to Subsection R313-19-13(2)(a)

TABLE

| Element (Atomic Number) | Column I Concentration Material | | Column II Concentration |
|-------------------------------|---------------------------------------|-----------------|----------------------------------|
| | Normally Used Radionuclide | As Gas (uCi/ml) | Liquid (uCi/ml) Solid (uCi/g) |
| | | | |

| | | | |
|-----------------|-------------|-------|-------|
| Antimony (51) | Sb-122 | | 3 E-4 |
| | Sb-124 | | 2 E-4 |
| | Sb-125 | | 1 E-3 |
| Argon (18) | Ar-37 | 1 E-3 | |
| | Ar-41 | 4 E-7 | |
| Arsenic (33) | As-73 | | 5 E-3 |
| | As-74 | | 5 E-4 |
| | As-76 | | 2 E-4 |
| | As-77 | | 8 E-4 |
| Barium (56) | Ba-131 | | 2 E-3 |
| | Ba-140 | | 3 E-4 |
| Beryllium (4) | Be-7 | | 2 E-2 |
| Bismuth (83) | Bi-206 | | 4 E-4 |
| Bromine (35) | Br-82 | 4 E-7 | 3 E-3 |
| Cadmium (48) | Cd-109 | | 2 E-3 |
| | Cd-115m | | 3 E-4 |
| | Cd-115 | | 3 E-4 |
| Calcium (20) | Ca-45 | | 9 E-5 |
| | Ca-47 | | 5 E-4 |
| | C-14 | 1 E-6 | 8 E-3 |
| Cerium (58) | Ce-141 | | 9 E-4 |
| | Ce-143 | | 4 E-4 |
| | Ce-144 | | 1 E-4 |
| Cesium (55) | Cs-131 | | 2 E-2 |
| | Cs-134m | | 6 E-2 |
| | Cs-134 | | 9 E-5 |
| Chlorine (17) | Cl-38 | 9 E-7 | 4 E-3 |
| Chromium (24) | Cr-51 | | 2 E-2 |
| Cobalt (27) | Co-57 | | 5 E-3 |
| | Co-58 | | 1 E-3 |
| | Co-60 | | 5 E-4 |
| Copper (29) | Cu-64 | | 3 E-3 |
| Dysprosium (66) | Dy-165 | | 4 E-3 |
| | Dy-166 | | 4 E-4 |
| Erbium (68) | Er-169 | | 9 E-4 |
| Europium (63) | Er-171 | | 1 E-3 |
| | Eu-152 | | 6 E-4 |
| | (T = 9.2 h) | | |
| Fluorine (9) | Eu-155 | | 2 E-3 |
| | F-18 | 2 E-6 | 8 E-3 |
| Gadolinium (64) | Gd-153 | | 2 E-3 |
| | Gd-159 | | 8 E-4 |
| Gallium (31) | Ga-72 | | 4 E-4 |
| Germanium (32) | Ge-71 | | 2 E-2 |
| Gold (79) | Au-196 | | 2 E-3 |
| | Au-198 | | 5 E-4 |
| | Au-199 | | 2 E-3 |
| Hafnium (72) | Hf-181 | | 7 E-4 |
| Hydrogen (1) | H-3 | 5 E-6 | 3 E-2 |
| Indium (49) | In-113m | | 1 E-2 |
| | In-114m | | 2 E-4 |
| Iodine (53) | I-126 | 3 E-9 | 2 E-5 |
| | I-131 | 3 E-9 | 2 E-5 |
| | I-132 | 8 E-8 | 6 E-4 |
| | I-133 | 1 E-8 | 7 E-5 |
| | I-134 | 2 E-7 | 1 E-3 |
| Iridium (77) | Ir-190 | | 2 E-3 |
| | Ir-192 | | 4 E-4 |
| | Ir-194 | | 3 E-4 |

| | | | |
|-------------------|---------|-------|-------|
| Iron (26) | Fe-55 | | 8 E-3 |
| | Fe-59 | | 6 E-4 |
| Krypton (36) | Kr-85m | 1 E-6 | |
| | Kr-85 | 3 E-6 | |
| Lanthanum (57) | La-140 | | 2 E-4 |
| Lead (82) | Pb-203 | | 4 E-3 |
| Lutetium (71) | Lu-177 | | 1 E-3 |
| Manganese (25) | Mn-52 | | 3 E-4 |
| | Mn-54 | | 1 E-3 |
| | Mn-56 | | 1 E-3 |
| Mercury (80) | Hg-197m | | 2 E-3 |
| | Hg-197 | | 3 E-3 |
| | Hg-203 | | 2 E-4 |
| Molybdenum (42) | Mo-99 | | 2 E-3 |
| Neodymium (60) | Nd-147 | | 6 E-4 |
| | Nd-149 | | 3 E-3 |
| Nickel (28) | Ni-65 | | 1 E-3 |
| Niobium | Nb-95 | | 1 E-3 |
| (Columbium) (41) | Nb-97 | | 9 E-3 |
| Osmium (76) | Os-185 | | 7 E-4 |
| | Os-191m | | 3 E-2 |
| | Os-191 | | 2 E-3 |
| | Os-193 | | 6 E-4 |
| Palladium (46) | Pd-103 | | 3 E-3 |
| | Pd-109 | | 9 E-4 |
| Phosphorus (15) | P-32 | | 2 E-4 |
| Platinum (78) | Pt-191 | | 1 E-3 |
| | Pt-193m | | 1 E-2 |
| | Pt-197m | | 1 E-2 |
| | Pt-197 | | 1 E-3 |
| Potassium (19) | K-42 | | 3 E-3 |
| Praseodymium (59) | Pr-142 | | 3 E-4 |
| | Pr-143 | | 5 E-4 |
| Promethium (61) | Pm-147 | | 2 E-3 |
| | Pm-149 | | 4 E-3 |
| Rhenium (75) | Re-183 | | 6 E-4 |
| | Re-186 | | 9 E-3 |
| | Re-188 | | 6 E-4 |
| Rhodium (45) | Rh-103m | | 1 E-1 |
| | Rh-105 | | 1 E-3 |
| Rubidium (37) | Rb-86 | | 7 E-4 |
| Ruthenium (44) | Ru-97 | | 4 E-4 |
| | Ru-103 | | 8 E-4 |
| | Ru-105 | | 1 E-3 |
| | Ru-106 | | 1 E-4 |
| Samarium (62) | Sm-153 | | 8 E-4 |
| Scandium (21) | Sc-46 | | 4 E-4 |
| | Sc-47 | | 9 E-4 |
| | Sc-48 | | 3 E-4 |
| Selenium (34) | Se-75 | | 3 E-3 |
| Silicon (14) | Si-31 | | 9 E-3 |
| Silver (47) | Ag-105 | | 1 E-3 |
| | Ag-110m | | 3 E-4 |
| | Ag-111 | | 4 E-4 |
| Sodium (11) | Na-24 | | 2 E-3 |
| Strontium (38) | Sr-85 | | 1 E-4 |
| | Sr-89 | | 1 E-4 |
| | Sr-91 | | 7 E-4 |
| | Sr-92 | | 7 E-4 |

| | | | |
|---|---------|--------|-------|
| Sulfur (16) | S-35 | 9 E-8 | 6 E-4 |
| Tantalum (73) | Ta-182 | | 4 E-4 |
| Technetium (43) | Tc-96m | | 1 E-1 |
| | Tc-96 | | 1 E-3 |
| Tellurium (52) | Te-125m | | 2 E-3 |
| | Te-127m | | 6 E-4 |
| | Te-127 | | 3 E-3 |
| | Te-129m | | 3 E-4 |
| | Te-131m | | 6 E-4 |
| | Te-132 | | 3 E-4 |
| Terbium (65) | Tb-160 | | 4 E-4 |
| Thallium (81) | Tl-200 | | 4 E-3 |
| | Tl-201 | | 3 E-3 |
| | Tl-202 | | 1 E-3 |
| | Tl-204 | | 1 E-3 |
| Thulium (69) | Tm-170 | | 5 E-4 |
| | Tm-171 | | 5 E-3 |
| Tin (50) | Sn-113 | | 9 E-4 |
| | Sn-125 | | 2 E-4 |
| | Sn-125 | | 2 E-4 |
| Tungsten (Wolfram) (74) | W-181 | | 4 E-3 |
| | W-187 | | 7 E-4 |
| Vanadium (23) | V-48 | | 3 E-4 |
| Xenon (54) | Xe-131m | 4 E-6 | |
| | Xe-133 | 3 E-6 | |
| | Xe-135 | 1 E-6 | |
| Ytterbium (70) | Yb-175 | | 1 E-3 |
| Yttrium (39) | Y-90 | | 2 E-4 |
| | Y-91m | | 3 E-2 |
| | Y-91 | | 3 E-4 |
| | Y-92 | | 6 E-4 |
| | Y-93 | | 3 E-4 |
| | Y-93 | | 3 E-4 |
| Zinc (30) | Zn-65 | | 1 E-3 |
| | Zn-69m | | 7 E-4 |
| | Zn-69 | | 2 E-2 |
| Zirconium (40) | Zr-95 | | 6 E-4 |
| | Zr-97 | | 2 E-4 |
| Beta or gamma emitting radioactive material not listed above with half-life less than 3 years | | 1 E-10 | 1 E-6 |

(1) In expressing the concentrations in Section R313-19-70, the activity stated and takes into account the radioactive decay products, because many radionuclides are also radioactive.

(2) For purposes of Subsection R313-19-13(2)(a) where there is involved a combination should be derived as follows: Determine for each radionuclide in the radioactivity concentration present in the product and the exempt radioactivity concentration for the specific radionuclide when not in combination. The sum of the ratios

(3) To convert microcuries (uCi) to SI units of kilobecquerels (kBq), multiply

R313-19-71. Exempt Quantities of Radioactive Materials.

Refer to Subsection R313-19-13(2)(b)

TABLE

| RADIOACTIVE MATERIAL | MICROCURIES |
|-----------------------------|-------------|
| Antimony-122 (Sb-122) | 100 |
| Antimony-124 (Sb-124) | 10 |
| Antimony-125 (Sb-125) | 10 |
| Arsenic-73 (As-73) | 100 |
| Arsenic-74 (As-74) | 10 |
| Arsenic-76 (As-76) | 10 |
| Arsenic-77 (As-77) | 100 |
| Barium-131 (Ba-131) | 10 |
| Barium-133 (Ba-133) | 10 |
| Barium-140 (Ba-140) | 10 |
| Bismuth-210 (Bi-210) | 1 |
| Bromine-82 (Br-82) | 10 |
| Cadmium-109 (Cd-109) | 10 |
| Cadmium-115m (Cd-115m) | 10 |
| Cadmium-115 (Cd-115) | 100 |
| Calcium-45 (Ca-45) | 10 |
| Calcium-47 (Ca-47) | 10 |
| Carbon-14 (C-14) | 100 |
| Cerium-141 (Ce-141) | 100 |
| Cerium-143 (Ce-143) | 100 |
| Cerium-144 (Ce-144) | 1 |
| Cesium-129 (Cs-129) | 100 |
| Cesium-131 (Cs-131) | 1,000 |
| Cesium-134m (Cs-134m) | 100 |
| Cesium-134 (Cs-134) | 1 |
| Cesium-135 (Cs-135) | 10 |
| Cesium-136 (Cs-136) | 10 |
| Cesium-137 (Cs-137) | 10 |
| Chlorine-36 (Cl-36) | 10 |
| Chlorine-38 (Cl-38) | 10 |
| Chromium-51 (Cr-51) | 1,000 |
| Cobalt-57 (Co-57) | 100 |
| Cobalt-58m (Co-58m) | 10 |
| Cobalt-58 (Co-58) | 10 |
| Cobalt-60 (Co-60) | 1 |
| Copper-64 (Cu-64) | 100 |
| Dysprosium-165 (Dy-165) | 10 |
| Dysprosium-166 (Dy-166) | 100 |
| Erbium-169 (Er-169) | 100 |
| Erbium-171 (Er-171) | 100 |
| Europium-152 (Eu-152) 9.2h | 100 |
| Europium-152 (Eu-152) 13 yr | 1 |
| Europium-154 (Eu-154) | 1 |
| Europium-155 (Eu-155) | 10 |
| Fluorine-18 (F-18) | 1,000 |
| Gadolinium-153 (Gd-153) | 10 |
| Gadolinium-159 (Gd-159) | 100 |
| Gallium-67 (Ga-67) | 100 |
| Gallium-72 (Ga-72) | 10 |
| Germanium-68 (Ge-68) | 10 |
| Germanium-71 (Ge-71) | 100 |
| Gold-195 (Au 195) | 10 |
| Gold-198 (Au-198) | 100 |
| Gold-199 (Au-199) | 100 |
| Hafnium-181 (Hf-181) | 10 |

| | |
|---------------------------|-------|
| Holmium-166 (Ho-166) | 100 |
| Hydrogen-3 (H-3) | 1,000 |
| Indium-111 (In-111) | 100 |
| Indium-113m (In-113m) | 100 |
| Indium-114m (In-114m) | 10 |
| Indium-115m (In-115m) | 100 |
| Indium-115 (In-115) | 10 |
| Iodine-123 (I-123) | 100 |
| Iodine-125 (I-125) | 1 |
| Iodine-126 (I-126) | 1 |
| Iodine-129 (I-129) | 0.1 |
| Iodine-131 (I-131) | 1 |
| Iodine-132 (I-132) | 10 |
| Iodine-133 (I-133) | 1 |
| Iodine-134 (I-134) | 10 |
| Iodine-135 (I-135) | 10 |
| Iridium-192 (Ir-192) | 10 |
| Iridium-194 (Ir-194) | 100 |
| Iron-52 (Fe-52) | 10 |
| Iron-55 (Fe-55) | 100 |
| Iron-59 (Fe-59) | 10 |
| Krypton-85 (Kr-85) | 100 |
| Krypton-87 (Kr-87) | 10 |
| Lanthanum-140 (La-140) | 10 |
| Lutetium-177 (Lu-177) | 100 |
| Manganese-52 (Mn-52) | 10 |
| Manganese-54 (Mn-54) | 10 |
| Manganese-56 (Mn-56) | 10 |
| Mercury-197m (Hg-197m) | 100 |
| Mercury-197 (Hg-197) | 100 |
| Mercury-203 (Hg-203) | 10 |
| Molybdenum-99 (Mo-99) | 100 |
| Neodymium-147 (Nd-147) | 100 |
| Neodymium-149 (Nd-149) | 100 |
| Nickel-59 (Ni-59) | 100 |
| Nickel-63 (Ni-63) | 10 |
| Nickel-65 (Ni-65) | 100 |
| Niobium-93m (Nb-93m) | 10 |
| Niobium-95 (Nb-95) | 10 |
| Niobium-97 (Nb-97) | 10 |
| Osmium-185 (Os-185) | 10 |
| Osmium-191m (Os-191m) | 100 |
| Osmium-191 (Os-191) | 100 |
| Osmium-193 (Os-193) | 100 |
| Palladium-103 (Pd-103) | 100 |
| Palladium-109 (Pd-109) | 100 |
| Phosphorus-32 (P-32) | 10 |
| Platinum-191 (Pt-191) | 100 |
| Platinum-193m (Pt-193m) | 100 |
| Platinum-193 (Pt-193) | 100 |
| Platinum-197m (Pt-197m) | 100 |
| Platinum-197 (Pt-197) | 100 |
| Polonium-210 (Po-210) | 0.1 |
| Potassium-42 (K-42) | 10 |
| Potassium-43 (K-43) | 10 |
| Praseodymium-142 (Pr-142) | 100 |
| Praseodymium-143 (Pr-143) | 100 |
| Promethium-147 (Pm-147) | 10 |
| Promethium-149 (Pm-149) | 10 |

| | |
|--------------------------|-------|
| Rhenium-186 (Re-186) | 100 |
| Rhenium-188 (Re-188) | 100 |
| Rhodium-103m (Rh-103m) | 100 |
| Rhodium-105 (Rh-105) | 100 |
| Rubidium-81 (Rb-81) | 10 |
| Rubidium-86 (Rb-86) | 10 |
| Rubidium-87 (Rb-87) | 10 |
| Ruthenium-97 (Ru-97) | 100 |
| Ruthenium-103 (Ru-103) | 10 |
| Ruthenium-105 (Ru-105) | 10 |
| Ruthenium-106 (Ru-106) | 1 |
| Samarium-151 (Sm-151) | 10 |
| Samarium-153 (Sm-153) | 100 |
| Scandium-46 (Sc-46) | 10 |
| Scandium-47 (Sc-47) | 100 |
| Scandium-48 (Sc-48) | 10 |
| Selenium-75 (Se-75) | 10 |
| Silicon-31 (Si-31) | 100 |
| Silver-105 (Ag-105) | 10 |
| Silver-110m (Ag-110m) | 1 |
| Silver-111 (Ag-111) | 100 |
| Sodium-22 (Na-22) | 10 |
| Sodium-24 (Na-24) | 10 |
| Strontium-85 (Sr-85) | 10 |
| Strontium-89 (Sr-89) | 1 |
| Strontium-90 (Sr-90) | 0.1 |
| Strontium-91 (Sr-91) | 10 |
| Strontium-92 (Sr-92) | 10 |
| Sulfur-35 (S-35) | 100 |
| Tantalum-182 (Ta-182) | 10 |
| Technetium-96 (Tc-96) | 10 |
| Technetium-97m (Tc-97m) | 100 |
| Technetium-97 (Tc-97) | 100 |
| Technetium-99m (Tc-99m) | 100 |
| Technetium-99 (Tc-99) | 10 |
| Tellurium-125m (Te-125m) | 10 |
| Tellurium-127m (Te-127m) | 10 |
| Tellurium-127 (Te-127) | 100 |
| Tellurium-129m (Te-129m) | 10 |
| Tellurium-129 (Te-129) | 100 |
| Tellurium 131m (Te-131m) | 10 |
| Tellurium-132 (Te-132) | 10 |
| Terbium-160 (Tb-160) | 10 |
| Thallium-200 (Tl-200) | 100 |
| Thallium-201 (Tl-201) | 100 |
| Thallium-202 (Tl-202) | 100 |
| Thallium-204 (Tl-204) | 10 |
| Thulium-170 (Tm-170) | 10 |
| Thulium-171 (Tm-171) | 10 |
| Tin-113 (Sn-113) | 10 |
| Tin-125 (Sn-125) | 10 |
| Tungsten-181 (W-181) | 10 |
| Tungsten-185 (W-185) | 10 |
| Tungsten-187 (W-187) | 100 |
| Vanadium-48 (V-48) | 10 |
| Xenon-131m (Xe-131m) | 1,000 |
| Xenon-133 (Xe-133) | 100 |
| Xenon-135 (Xe-135) | 100 |
| Ytterbium-175 (Yb-175) | 100 |

| | |
|---|-------|
| Yttrium-87 (Y-87) | 10 |
| Yttrium-88 (Y-88) | 10 |
| Yttrium-90 (Y-90) | 10 |
| Yttrium-91 (Y-91) | 10 |
| Yttrium-92 (Y-92) | 100 |
| Yttrium-93 (Y-93) | 100 |
| Zinc-65 (Zn-65) | 10 |
| Zinc-69m (Zn-69m) | 100 |
| Zinc-69 (Zn-69) | 1,000 |
| Zirconium-93 (Zr-93) | 10 |
| Zirconium-95 (Zr-95) | 10 |
| Zirconium-97 (Zr-97) | 10 |
| Any radioactive material not listed above other than alpha emitting radioactive material. | 0.1 |

(1) To convert microcuries (uCi) to SI units of kilobecquerels (kBq), multipl

R313-19-100. Transportation.

For purposes of Section R313-19-100, 10 CFR 71.4, 71.10, 71.12, 71.13(a) and (b) through 71.16, 71.47, 71.81, 71.85 through 71.89, 71.97 (1998), and Appendix A to part 71 are incorporated by reference with the following clarifications or exceptions:

(1) The substitution of the following:

- (a) "Issued by the Executive Secretary" for reference to "issued by the Commission" in 10 CFR 71.4;
- (b) "Licensee" for reference to "licensee of the Commission";
- (c) "Subsection R313-19-100(3)" for reference to "10 CFR 71.5";
- (d) "Subsection R313-15-906(5)" for reference to "10 CFR 20.1906(e)";
- (e) "Section R313-15-502" for reference to "10 CFR 20.1502"; and
- (f) "Utah" for reference to "the United States" in 10 CFR 71.10(b)(3);

(2) The exclusion of the following:

- (a) "close reflection by water" and "optimum interspersed hydrogenous moderation" in 10 CFR 71.4;
- (b) "10 CFR 71.12(b)", "10 CFR 71.14(b)", and "10 CFR 71.16(b)"; and
- (c) "subpart H" in 10 CFR 71.12(c)(2), 71.14(c)(2), 71.16(d)(2), and 71.81;

(3) Transportation of licensed material.

- (a) Each licensee who transports licensed material outside the site of usage, as specified in the

license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the U.S. Department of Transportation (DOT) regulations in 49 CFR 170 through 189 (1998) appropriate to the mode of transport.

(i) The licensee shall particularly note DOT regulations in the following areas:

(A) Packaging--49 CFR 173.1 through 173.13, 173.21 through 173.40, and 173.401 through 173.476;

(B) Marking and labeling--49 CFR 172.300 through 172.338, 172.400 through 172.407, 172.436 through 172.440, and 172.400 through 172.450;

(C) Placarding--49 CFR 172.500 through 172.560 and Appendices B and C;

(D) Accident reporting--49 CFR 171.15 and 171.16;

(E) Shipping papers and emergency information--49 CFR 172.200 through 172.205 and 172.600 through 172.606;

(F) Hazardous material employee training--49 CFR 172.700 through 172.704; and

(G) Hazardous material shipper/carrier registration--49 CFR 107.601 through 107.620.

(ii) The licensee shall also note DOT regulations pertaining to the following modes of transportation:

(A) Rail--49 CFR 174.1 through 174.86 and 174.700 through 174.750;

(B) Air--49 CFR 175;

(C) Vessel--49 CFR 176.1 through 176.99 and 176.700 through 176.715; and

(D) Public Highway--49 CFR 177 and 390 through 397.

(b) If DOT regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the DOT specified in paragraph (a) of this section to the same extent as if the shipment or transportation were subject to DOT regulations. A request for modification, waiver, or exemption from those requirements, and any notification referred to in those requirements, must be filed with, or made to, the Executive Secretary.

KEY

license, reciprocity, transportation, exemptions

Date of Enactment or Last Substantive Amendment

January 26, 2001

Notice of Continuation

October 10, 2001

Authorizing, Implemented, or Interpreted Law

19-3-104; 19-3-108

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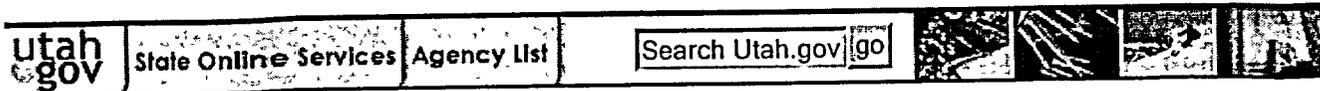
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Rule R313-21. General Licenses.

As in effect on September 1, 2002

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- **R313-21-21. General Licenses--Source Material.**
- **R313-21-22. General Licenses*--Radioactive Material Other Than Source Material.**
- **KEY**
- **Date of Enactment or Last Substantive Amendment**
- **Notice of Continuation**
- **Authorizing, Implemented, or Interpreted Law**

R313-21-1. Purpose and Scope.

(1) R313-21 establishes general licenses for the possession and use of radioactive material contained in certain items and a general license for ownership of radioactive material.

(2) The rules set forth herein are adopted pursuant to the provisions of Sections 19-3-104(3) and 19-3-104(6).

R313-21-21. General Licenses--Source Material.

(1) A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local government agencies to use and transfer not more than 15 pounds (6.82 kg) of source material at any one time for research, development, educational, commercial, or operational purposes. A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of 150 pounds (68.2 kg) of source material in any one calendar year.

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

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

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

(5) Depleted uranium in industrial products and devices.

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

(b) The general license in R313-21-21(5)(a) applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to R313-22-75(12) or in accordance with a specific license issued to the manufacturer by a Licensing State, the Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the Nuclear Regulatory Commission or an Agreement State.

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

(A) name and address of the registrant;

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

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

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

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

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

(ii) shall not abandon depleted uranium;

(iii) shall transfer or dispose of depleted uranium only by transfer in accordance with the provisions of R313-19-41. In the case where the transferee receives the depleted uranium pursuant to the general license established by R313-21-21(5)(a), the transferor shall furnish the transferee a copy of this rule and a copy of form DRC-12. In the case where the transferee

receives the depleted uranium pursuant to a general license contained in the Nuclear Regulatory Commission's or Agreement State's regulation equivalent to R313-21-21(5)(a), the transferor shall furnish the transferee a copy of this rule and a copy of form DRC-12 accompanied by a note explaining that use of the product or device is regulated by the Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in this rule;

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

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

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

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

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

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

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

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

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

(2) RESERVED.

(3) RESERVED.

(4) Certain measuring, gauging or controlling devices.

(a) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, acquire, receive, possess, use or transfer, in accordance with the provisions of R313-21-22(4)(b), (c) and (d), radioactive material excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized

atmosphere.

(b) The general license in R313-21-22(4)(a) applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the Executive Secretary pursuant to R313-22-75 (4) or in accordance with specific license issued by the Nuclear Regulatory Commission, an Agreement State or a Licensing State, which authorizes distribution of devices to persons generally licensed by the Nuclear Regulatory Commission, an Agreement State or Licensing State.*

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

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

(i) shall register all devices by submitting form DRC-13, "Registration Form - Radioactive Material in Certain Measuring, Gauging or Controlling Devices Under General License," to the Executive Secretary within 30 days after the first receipt or acquisition of a device, however:

(A) devices containing no more than ten millicuries of polonium-210 and used for producing an ionized atmosphere need not be registered; and

(B) devices containing hydrogen-3 (tritium) and used for producing light need not be registered;

(ii) shall furnish on form DRC-13 the following information and other information as may be required by that form:

(A) name and address of the registrant;

(B) a statement that the registrant has developed and will maintain procedures designed to establish physical control over the device described in R313-21-22(4)(a) and designed to prevent transfer of the device other than to a specific licensee authorized to receive it or to another general licensee only as authorized by R313-21-22(4)(c)(xii); and

(C) name or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising and maintaining the procedures identified in R313-21-22(4)(c)(ii)(B);

(iii) shall report in writing to the Executive Secretary any changes in information previously furnished on form DRC-13. The information shall be submitted within 30 days after the effective date of a change;

(iv) other than those persons using less than ten millicuries polonium-210 or hydrogen-3 (tritium) for producing light or an ionized atmosphere, shall submit the appropriate fee as required by R313-70-7(11) within 30 days after the first receipt or acquisition of the device.

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

(vi) shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at other

intervals as are specified in the label, however:

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

(B) devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta or gamma emitting material or 10 microcuries (0.37 MBq) of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested;

(vii) shall assure that the tests required by R313-21-22(4)(c)(vi) and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

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

(B) by a person holding a specific license from the Executive Secretary, a Licensing State, the Nuclear Regulatory Commission or an Agreement State which authorizes the activities in R313-21-22(4)(c)(vii);

(viii) shall maintain records showing compliance with the requirements of R313-21-22(4)(c)(vi) and (vii). The records shall show the results of tests. The records also shall show the dates of performance and the names of persons performing, testing, installing, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by R313-21-22(4)(c)(vi) shall be maintained for three years after the next required leak test is performed or the sealed source is transferred or disposed of. Records of tests of the on-off mechanism and indicator required by R313-21-22(4)(c)(vi) shall be maintained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of. Records which are required by R313-21-22(4)(c)(vii) shall be maintained for a period of two years from the date of the recorded event or until the device is transferred or disposed of;

(ix) upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding a specific license from the Executive Secretary, a Licensing State, the Nuclear Regulatory Commission, or an Agreement State to repair the devices, or disposed of by transfer to a person authorized by a specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the Executive Secretary a report containing a brief description of the event and the remedial action taken;

(x) shall not abandon any device containing radioactive material;

(xi) except as provided in R313-21-22(4)(c)(xii), shall transfer or dispose of the device containing radioactive material only by transfer to a person holding a specific license of the Executive Secretary, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State whose specific license authorizes the person to receive the device and within 30 days after transfer of a device to a specific licensee shall furnish to the Executive Secretary a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;

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

(A) where the device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of R313-21-22(4) and any safety documents identified in the label of the device and within 30 days of the transfer, report to the Executive Secretary the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name or position of an individual who may constitute a point of contact between the Executive Secretary and the transferee; or

(B) where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee;

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

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

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

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

(5) Luminous safety devices for aircraft.

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

(i) each device contains not more than 10 curies (370.0 GBq) of tritium or 300 millicuries (11.1 GBq) of promethium-147; and

(ii) each device has been manufactured, assembled or imported in accordance with a specific license issued by the Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the Executive Secretary or an Agreement State to the manufacturer or assembler of the device pursuant to licensing requirements equivalent to those in 10 CFR 32.53.

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

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

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

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

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

use of radioactive material.

(7) Calibration and reference sources.

(a) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use and transfer, in accordance with the provisions of R313-21-22(7)(d) and (e), americium-241 in the form of calibration or reference sources:

(i) any person who holds a specific license issued by the Executive Secretary which authorizes that person to receive, possess, use and transfer radioactive material; and

(ii) any person who holds a specific license issued by the Nuclear Regulatory Commission which authorizes that person to receive, possess, use and transfer special nuclear material.

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

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

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

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

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

(ii) shall not receive, possess, use or transfer a source unless the source, or the storage container, bears a label which includes one of the following statements or a substantially similar statement which contains the information called for in one of the following statements, as appropriate:

(A) The receipt, possession, use and transfer of this source, Model No., Serial No., are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL

THIS SOURCE CONTAINS (AMERICIUM-241)(PLUTONIUM)*

DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

.....

Typed or printed name of the manufacturer or importer

NOTE: *Show the name of the appropriate material.

(B) The receipt, possession, use and transfer of this source, Model No....., Serial No....., are subject to a general license and the regulations of a Licensing State. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL

THIS SOURCE CONTAINS RADIUM-226

DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

.....

Typed or printed name of the manufacturer or importer

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

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

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

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

(8) RESERVED.

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

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

(a) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for the following stated tests, in accordance with the provisions of R313-21-22(9) (b), (c), (d), (e), and (f) the following radioactive materials in prepackaged units for use in in-vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

- (i) iodine-125, in units not exceeding 10 microcuries (370.0 kBq) each;
- (ii) iodine-131, in units not exceeding 10 microcuries (370.0 kBq) each;
- (iii) carbon-14, in units not exceeding 10 microcuries (370.0 kBq) each;
- (iv) hydrogen-3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each;
- (v) iron-59, in units not exceeding 20 microcuries (740.0 kBq) each;
- (vi) cobalt-57, in units not exceeding 10 microcuries (370.0 kBq) each;
- (vii) selenium-75, in units not to exceed 10 microcuries (370.0 kBq) each; or
- (viii) mock iodine-125, reference or calibration sources, in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185.0 Bq) of americium-241 each.

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

- (i) name and address of the physician, veterinarian, clinical laboratory or hospital;
- (ii) the location of use; and
- (iii) a statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in R313-21-22(9)(a) and that the tests will be performed only by personnel competent in the use of radiation measuring instruments and in the handling of the radioactive material.

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

- (i) The general licensee shall not possess at any one time, pursuant to the general license in R313-21-22(9)(a) at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59 and cobalt-57, or any combination, in excess of 200 microcuries (7.4 MBq).
- (ii) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.
- (iii) The general licensee shall use the radioactive material only for the uses authorized by R313-21-22(9)(a).
- (iv) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Executive Secretary, the Nuclear

Regulatory Commission, an Agreement State or Licensing State, nor transfer the radioactive material in a manner other than in the unopened, labeled shipping container as received from the supplier.

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

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

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

(i) Except as prepackaged units which are labeled in accordance with the provision of an applicable specific license issued pursuant to R313-22-75(8) or in accordance with the provisions of a specific license issued by the Nuclear Regulatory Commission, an Agreement State or Licensing State which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3(tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under R313-21-22(9) or its equivalent, and

(ii) Unless 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 prepackaged units or appears in a leaflet or brochure which accompanies the package:

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

.....

Name of Manufacturer"

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

(f) Any person using radioactive material pursuant to the general license of R313-21-22(9)(a) is exempt from the requirements of R313-15 and R313-18 with respect to radioactive material

covered by that general license, except that persons using the Mock Iodine-125 described in R313-21-22(9)(a)(viii) shall comply with the provisions of R313-15-1001, R313-15-1201 and R313-15-1202.

(10) Ice Detection Devices.

(a) A general license is hereby issued to own, receive, acquire, possess, use and transfer strontium-90 contained in ice detection devices, provided each device contains no more than 50 microcuries (1.85 MBq) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the Executive Secretary or an Agreement State to the manufacturer of the device pursuant to licensing requirements equivalent to those in 10 CFR 32.61.

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

(i) shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from over-heating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the Nuclear Regulatory Commission or an Agreement State to manufacture or service the device; or shall dispose of the device pursuant to the provisions of these rules;

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

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

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

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

KEY

radioactive material, general licenses, source material

Date of Enactment or Last Substantive Amendment

July 18, 1997

Notice of Continuation

January 25, 1999

Authorizing, Implemented, or Interpreted Law

19-3-104

Rule converted into HTML by the Division of Administrative Rules.

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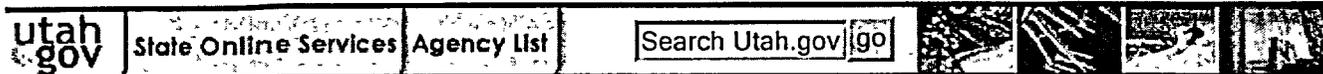
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Rule R313-22. Specific Licenses.

As in effect on September 1, 2002

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R313-22-1. Purpose and Authority.

- (1) The purpose of this rule is to prescribe the requirements for the issuance of specific licenses.
- (2) The rules set forth herein are adopted pursuant to the provisions of Subsections 19-3-104(3) and 19-3-104(6).

R313-22-2. General.

The provisions and requirements of Rule R313-22 are in addition to, and not in substitution for,

other requirements of these rules. In particular the provisions of Rule R313-19 apply to applications and licenses subject to Rule R313-22.

R313-22-4. Definitions.

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

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

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

R313-22-30. Specific License by Rule.

A license by rule is issued in the following circumstances, without the necessity of filing an application for a specific license as required by Subsection R313-22-32(1), and the licensee shall be subject to the applicable provisions of Sections R313-22-33, R313-22-34, R313-22-35, R313-22-36 and R313-22-37:

- (1) When a site must be timely remediated of contamination by radioactive materials that are subject to licensing under these rules but are unlicensed;
- (2) When radioactive materials existing as a result of improper handling, spillage, accidental contamination, or unregulated or illegal possession, transfer, or receipt, must be stored and those materials have not been licensed under these rules.

R313-22-32. Filing Application for Specific Licenses.

- (1) Applications for specific licenses shall be filed on a form prescribed by the Executive Secretary.
- (2) The Executive Secretary may, after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Executive Secretary to determine whether the application should be granted or denied or whether a license should be modified or revoked.
- (3) Applications shall be signed by the applicant or licensee or a person duly authorized to act for and on the applicant's behalf.
- (4) An application for a license may include a request for a license authorizing one or more activities.
- (5) In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Executive Secretary, provided the references are clear and specific.
- (6) An application for a specific license to use radioactive material in the form of a sealed source

or in a device that contains the sealed source shall identify the source or device by manufacturer and model number as registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210, 2001 ed. or the equivalent regulations of an Agreement State.

(7) As provided by Section R313-22-35, certain applications for specific licenses filed under these rules shall contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning. In the case of renewal applications submitted before January 1, 1995, this submittal may follow the renewal application but shall be submitted on or before January 1, 1995.

(8)(a) Applications to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in Section R313-22-90, "Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release", shall contain either:

(i) An evaluation showing that the maximum dose to a individual off-site due to a release of radioactive materials would not exceed one rem effective dose equivalent or five rems to the thyroid; or

(ii) An emergency plan for responding to a release of radioactive material.

(b) One or more of the following factors may be used to support an evaluation submitted under Subsection R313-22-32(8)(a)(i):

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

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

(iii) The release fraction in the respirable size range would be lower than the release fraction shown in Section R313-22-90 due to the chemical or physical form of the material;

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

(v) Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Section R313-22-90;

(vi) Operating restrictions or procedures would prevent a release fraction as large as that shown in Section R313-22-90; or

(vii) Other factors appropriate for the specific facility.

(c) An emergency plan for responding to a release of radioactive material submitted under Subsection R313-22-32(8)(a)(ii) shall include the following information:

(i) Facility description. A brief description of the licensee's facility and area near the site.

(ii) Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.

(iii) Classification of accidents. A classification system for classifying accidents as alerts or site

area emergencies.

(iv) Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

(v) Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers on-site, and a description of the program for maintaining equipment.

(vi) Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

(vii) Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying off-site response organizations and the Executive Secretary; also responsibilities for developing, maintaining, and updating the plan.

(viii) Notification and coordination. A commitment to and a brief description of the means to promptly notify off-site response organizations and request off-site assistance, including medical assistance for the treatment of contaminated injured on-site workers when appropriate. A control point shall be established. The notification and coordination shall be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the Executive Secretary immediately after notification of the appropriate off-site response organizations and not later than one hour after the licensee declares an emergency.

NOTE: These reporting requirements do not supersede or release licensees of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499 or other state or federal reporting requirements, including 40 CFR 302, 2000 ed.

(ix) Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to off-site response organizations and to the Executive Secretary.

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

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

(xii) Exercises. Provisions for conducting quarterly communications checks with off-site response organizations and biennial on-site exercises to test response to simulated emergencies. Quarterly communications checks with off-site response organizations shall include the check and update of all necessary telephone numbers. The licensee shall invite off-site response organizations to participate in the biennial exercises. Participation of off-site response organizations in biennial exercises although recommended is not required. Exercises shall use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most

exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises shall evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques shall be corrected.

(xiii) Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

(d) The licensee shall allow the off-site response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the Executive Secretary. The licensee shall provide any comments received within the 60 days to the Executive Secretary with the emergency plan.

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

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

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

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

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

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

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

(f) in the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, or for the conduct of other activities which the Executive Secretary determines will significantly affect the quality of the environment, the Executive Secretary, before commencement of construction of the plant or facility in which the activity will be conducted, has concluded, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. The Executive Secretary shall respond to the application within 60 days. Commencement of construction prior to a response and conclusion shall be grounds for denial of a license to receive and possess radioactive material in the plant or facility. As used in this paragraph the term "commencement of construction" means clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

R313-22-34. Issuance of Specific Licenses.

(1) Upon a determination that an application meets the requirements of the Act and the rules of

the Board, the Executive Secretary will issue a specific license authorizing the proposed activity in a form and containing conditions and limitations as the Executive Secretary deems appropriate or necessary.

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

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

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

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

R313-22-35. Financial Assurance and Recordkeeping for Decommissioning.

(1) Applicants for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in Appendix B of 10 CFR 30.1 through 30.72, 2001 ed., which is incorporated by reference, shall submit a decommissioning funding plan as described in Subsection R313-22-35(5). The decommissioning funding plan shall also be submitted when a combination of radionuclides is involved if R divided by 10^5 is greater than one, where R is defined here as the sum of the ratios of the quantity of each radionuclide to the applicable value in Appendix B of 10 CFR 30.1 through 30.72, 2001 ed., which is incorporated by reference.

(2) Applicants for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in Subsection R313-22-35(4) shall either:

(a) submit a decommissioning funding plan as described in Subsection R313-22-35(5); or

(b) submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by Subsection R313-22-35(4) using one of the methods described in Subsection R313-22-35(6). For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but before the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of Subsection R313-22-35(6) shall be submitted to the Executive Secretary before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the Executive Secretary, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements in Subsection R313-22-35(6).

(3)(a) Holders of a specific license issued on or after January 1, 1995, which is of a type described in Subsections R313-22-35(1) or (2) shall provide financial assurance for decommissioning in accordance with the criteria set forth in Section R313-22-35.

(b) Holders of a specific license issued before January 1, 1995, and of a type described in Subsection R313-22-35(1) shall submit, on or before January 1, 1995, a decommissioning funding plan as described in Subsection R313-22-35(5) or a certification of financial assurance for decommissioning in an amount at least equal to \$750,000 in accordance with the criteria set forth in Section R313-22-35. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan, the licensee shall include a decommissioning funding plan in any

application for license renewal.

(c) Holders of a specific license issued before January 1, 1995, and of a type described in Subsection R313-22-35(2) shall submit, on or before January 1, 1995, a decommissioning funding plan as described in Subsection R313-22-35(5) or a certification of financial assurance for decommissioning in accordance with the criteria set forth in Section R313-22-35.

(d) A licensee who has submitted an application before January 1, 1995, for renewal of license in accordance with Section R313-22-37 shall provide financial assurance for decommissioning in accordance with Subsections R313-22-35(1) and (2). This assurance shall be submitted before January 1, 1997.

(4) Table of required amounts of financial assurance for decommissioning by quantity of material:

TABLE

| | |
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| <p>Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of radioactive material, as defined in Appendix B of 10 CFR 30.1 through 30.72, 2001 ed., which is incorporated by reference, in unsealed form. For a combination of radionuclides, if R, as defined in Subsection R313-22-35(1) divided by 10^4 is greater than one but R divided by 10^5 is less than or equal to one:</p> | <p>\$750,000</p> |
| <p>Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of radioactive material, as defined in Appendix B of 10 CFR 30.1 through 30.72, 2001 ed., which is incorporated by reference, in unsealed form. For a combination of radionuclides, if R, as defined in Subsection R313-22-35(1) divided by 10^3 is greater than one but R divided by 10^4 is less than or equal to one:</p> | <p>\$150,000</p> |
| <p>Greater than 10^{10} times the applicable quantities of radioactive material, as defined in Appendix B of 10 CFR 30.1 through 30.72, 2001 ed., which is incorporated by reference, in sealed sources or plated foils. For combination of radionuclides, if R, as defined in R313-22-35(1), divided by 10^{10} is greater than one:</p> | <p>\$75,000</p> |

(5) A decommissioning funding plan shall contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from Subsection R313-22-35(6), including means for adjusting cost estimates and associated funding levels periodically over the life of the facility. The decommissioning funding plan shall also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of Subsection R313-22-35(6).

(6) Financial assurance for decommissioning shall be provided by one or more of the following methods:

(a) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets so that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities;

(b) A surety method, insurance, or other guarantee method. These methods shall guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Subsection R313-22-35(8). A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of Section R313-22-35. A guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Subsection R313-22-35(9). A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of Section R313-22-35 or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. A surety method or insurance used to provide financial assurance for decommissioning shall contain the following conditions:

(i) the surety method or insurance shall be open-ended or, if written for a specified term, such as five years, shall be renewed automatically unless 90 days or more prior to the renewal date the issuer notifies the Executive Secretary, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance shall also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Executive Secretary within 30 days after receipt of notification of cancellation,

(ii) the surety method or insurance shall be payable to a trust established for decommissioning costs. The trustee and trust shall be acceptable to the Executive Secretary. An acceptable trustee includes an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency, and

(iii) the surety method or insurance shall remain in effect until the Executive Secretary has terminated the license;

(c) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions shall be as stated in Subsection R313-22-35(6)(b);

(d) In the case of Federal, State or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in Subsection R313-22-35(4) and indicating that funds for decommissioning will be obtained when necessary; or

(e) When a governmental entity is assuming custody and ownership of a site, an arrangement

that is deemed acceptable by such governmental entity.

(7) Persons licensed under Rule R313-22 shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with Subsection R313-19-34(2), licensees shall transfer all records described in Subsections R313-22-35(7)(a) through (d) to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the Executive Secretary considers important to decommissioning consists of the following:

(a) records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records shall include any known information on identification of involved nuclides, quantities, forms, and concentrations;

(b) as-built drawings and modification of structures and equipment in restricted areas where radioactive materials are used or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations;

(c) except for areas containing only sealed sources, provided the sources have not leaked or no contamination remains after a leak, or radioactive materials having only half-lives of less than 65 days, a list contained in a single document and updated every two years, including all of the following:

(i) all areas designated and formerly designated as restricted areas as defined under Section R313-12-3;

(ii) all areas outside of restricted areas that require documentation under Subsection R313-22-35(7)(a);

(iii) all areas outside of restricted areas where current and previous wastes have been buried as documented under Section R313-15-1109; and

(iv) all areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in Sections R313-15-401 through R313-15-406, or apply for approval for disposal under Section R313-15-1002; and

(d) records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

(8) Criteria relating to use of financial tests and parent company guarantees for providing reasonable assurance of funds for decommissioning.

(a) To pass the financial test referred to in Subsection R313-22-35(6)(b), the parent company

shall meet one of the following criteria:

(i) The parent company shall have all of the following:

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

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

(C) Tangible net worth of at least \$10 million; and

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

(ii) The parent company shall have all of the following:

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

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

(C) Tangible net worth of at least \$10 million; and

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

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

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

(ii) If the parent company no longer meets the requirements of Subsection R313-22-35(8)(a) the licensee shall send notice to the Executive Secretary of intent to establish alternative financial assurance as specified in Section R313-22-35. The notice shall be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee shall provide alternate financial assurance within 120 days after the end of such fiscal year.

(d) The terms of a parent company guarantee which an applicant or licensee obtains shall provide that:

(i) The parent company guarantee will remain in force unless the guarantor sends notice of

cancellation by certified mail to the licensee and the Executive Secretary. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Executive Secretary, as evidenced by the return receipts.

(ii) If the licensee fails to provide alternate financial assurance as specified in Section R313-22-35 within 90 days after receipt by the licensee and Executive Secretary of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

(iii) The parent company guarantee and financial test provisions shall remain in effect until the Executive Secretary has terminated the license.

(iv) If a trust is established for decommissioning costs, the trustee and trust shall be acceptable to the Executive Secretary. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(9) Criteria relating to use of financial tests and self guarantees for providing reasonable assurance of funds for decommissioning.

(a) To pass the financial test referred to in Subsection R313-22-35(6)(b), a company shall meet all of the following criteria:

(i) Tangible net worth at least ten times the total current decommissioning cost estimate, or the current amount required if certification is used, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor;

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

(iii) A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poor's, or Aaa, Aa, or A as issued by Moody's.

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

(i) The company shall have at least one class of equity securities registered under the Securities Exchange Act of 1934;

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

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

(c) If the licensee no longer meets the requirements of Subsection R313-22-35(9)(a), the licensee shall send immediate notice to the Executive Secretary of its intent to establish alternate

financial assurance as specified in Section R313-22-35 within 120 days of such notice.

(d) The terms of a self-guarantee which an applicant or licensee furnishes shall provide that:

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

(ii) The licensee shall provide alternative financial assurance as specified in Section R313-22-35 within 90 days following receipt by the Executive Secretary of a notice of a cancellation of the guarantee.

(iii) The guarantee and financial test provisions shall remain in effect until the Executive Secretary has terminated the license or until another financial assurance method acceptable to the Executive Secretary has been put in effect by the licensee.

(iv) The licensee shall promptly forward to the Executive Secretary and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

(v) If, at any time, the licensee's most recent bond issuance ceases to be rated in a category of "A" or above by either Standard and Poor's or Moody's, the licensee shall provide notice in writing of such fact to the Executive Secretary within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poor's and Moody's, the licensee no longer meets the requirements of Subsection R313-22-35(9)(a).

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

R313-22-36. Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas.

(1) A specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under Section R313-22-37 no less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days prior to the expiration date stated in the existing license, the existing license expires at the end of the day on which the Executive Secretary makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(2) A specific license revoked by the Executive Secretary expires at the end of the day on the date of the Executive Secretary's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by an Order issued by the Executive Secretary.

(3) A specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the Executive Secretary notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

- (a) limit actions involving radioactive material to those related to decommissioning; and
- (b) continue to control entry to restricted areas until they are suitable for release so that there is not an undue hazard to public health and safety or the environment.
- (4) Within 60 days of the occurrence of any of the following, a licensee shall provide notification to the Executive Secretary in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release so that there is not an undue hazard to public health and safety or the environment, or submit within 12 months of notification a decommissioning plan, if required by Subsection R313-22-36(7), and begin decommissioning upon approval of that plan if:
- (a) the license has expired pursuant to Subsections R313-22-36(1) or (2); or
- (b) the licensee has decided to permanently cease principal activities at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release because of an undue hazard to public health and safety or the environment; or
- (c) no principal activities under the license have been conducted for a period of 24 months; or
- (d) no principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release because of an undue hazard to public health and safety or the environment.
- (5) Coincident with the notification required by Subsection R313-22-36(4), the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to Section R313-22-35 in conjunction with a license issuance or renewal or as required by Section R313-22-36. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to Subsection R313-22-36(7)(d)(v).
- (a) A licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so on or before August 15, 1997.
- (b) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Executive Secretary.
- (6) The Executive Secretary may grant a request to extend the time periods established in Subsection R313-22-36(4) if the Executive Secretary determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to Subsection R313-22-36(4). The schedule for decommissioning set forth in Subsection R313-22-36(4) may not commence until the Executive Secretary has made a determination on the request.
- (7)(a) A decommissioning plan shall be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Executive Secretary and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

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

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

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

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

(b) The Executive Secretary may approve an alternate schedule for submittal of a decommissioning plan required pursuant to Subsection R313-22-36(4) if the Executive Secretary determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(c) Procedures such as those listed in Subsection R313-22-36(7)(a) with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

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

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

(ii) a description of planned decommissioning activities;

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

(iv) a description of the planned final radiation survey; and

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

(vi) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in Subsection R313-22-36(8).

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

(8)(a) Except as provided in Subsection R313-22-36(9), licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practical but no later than 24 months following the initiation of decommissioning.

(b) Except as provided in Subsection R313-22-36(9), when decommissioning involves the entire site, the licensee shall request license termination as soon as practical but no later than 24 months following the initiation of decommissioning.

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

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

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

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

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

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

(10) As the final step in decommissioning, the licensee shall:

(a) certify the disposition of all licensed material, including accumulated wastes, by submitting a completed Form DRC-14 or equivalent information; and

(b) conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in Sections R313-15-401 through R313-15-406. The licensee shall, as appropriate:

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

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

(11) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Executive Secretary determines that:

(a) radioactive material has been properly disposed;

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

(c) documentation is provided to the Executive Secretary that:

(i) a radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in Sections R313-15-401 through R313-15-406; or

(ii) other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in Sections R313-15-401 through R313-15-406.

R313-22-37. Renewal of Licenses.

Application for renewal of a specific license shall be filed on a form prescribed by the Executive Secretary and in accordance with Section R313-22-32.

R313-22-38. Amendment of Licenses at Request of Licensee.

Applications for amendment of a license shall be filed in accordance with Section R313-22-32 and shall specify the respects in which the licensee desires the license to be amended and the grounds for the amendment.

R313-22-39. Executive Secretary Action on Applications to Renew or Amend.

In considering an application by a licensee to renew or amend the license, the Executive Secretary will use the criteria set forth in Sections R313-22-33, R313-22-50, and R313-22-75 and in Rules R313-24, R313-25, R313-32, R313-34, R313-36, or R313-38, as applicable.

R313-22-50. Special Requirements for Specific Licenses of Broad Scope.

Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity or other product containing byproduct material whose subsequent possession, use, transfer and disposal by all other persons who are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(1) The different types of broad licenses are set forth below:

(a) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

(b) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Section R313-22-100 for any authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Section R313-22-100, Column I. If two or more radionuclides are possessed thereunder, the possession limits are determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Section R313-22-100, Column I, for that radionuclide. The sum of the ratios for the radionuclides possessed under the license shall not exceed unity.

(c) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Section R313-22-100, for any authorized purpose. The possession limit for a Type C

broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Section R313-22-100, Column II. If two or more radionuclides are possessed thereunder, the possession limits are determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Section R313-22-100, Column II, for that radionuclide. The sum of the ratios for the radionuclides possessed under the license shall not exceed unity.

(2) An application for a Type A specific license of broad scope shall be approved if all of the following are complied with:

- (a) the applicant satisfies the general requirements specified in Section R313-22-33;
- (b) the applicant has engaged in a reasonable number of activities involving the use of radioactive material; and
- (c) the applicant has established administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control and accounting, and management review that are necessary to assure safe operations, including:
 - (i) the establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;
 - (ii) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and
 - (iii) the establishment of appropriate administrative procedures to assure:
 - (A) control of procurement and use of radioactive material,
 - (B) completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures, and
 - (C) review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with Subsection R313-22-50(2)(c)(iii)(B) prior to use of the radioactive material.

(3) An application for a Type B specific license of broad scope shall be approved if all of the following are complied with:

- (a) the applicant satisfies the general requirements specified in Section R313-22-33;
- (b) the applicant has established administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control and accounting, and management review that are necessary to assure safe operations, including:
 - (i) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and
 - (ii) the establishment of appropriate administrative procedures to assure:

(A) control of procurement and use of radioactive material,

(B) completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures, and

(C) review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with Subsection R313-22-50(3)(b)(iii)(B) prior to use of the radioactive material.

(4) An application for a Type C specific license of broad scope shall be approved, if:

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

(b) the applicant submits a statement that radioactive material will be used only by, or under the direct supervision of individuals, who have received:

(i) a college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

(ii) at least forty hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

(c) the applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, recordkeeping, material control and accounting, and management review necessary to assure safe operations.

(5) Specific licenses of broad scope are subject to the following conditions:

(a) unless specifically authorized by the Executive Secretary, persons licensed pursuant to this section shall not:

(i) conduct tracer studies in the environment involving direct release of radioactive material;

(ii) receive, acquire, own, possess, use, or transfer devices containing 100,000 curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;

(iii) conduct activities for which a specific license issued by the Executive Secretary under Section R313-22-75, and Rules R313-25, R313-32 or R313-36 is required; or

(iv) add or cause the addition of radioactive material to a food, beverage, cosmetic, drug or other product designed for ingestion or inhalation by, or application to, a human being.

(b) Type A specific licenses of broad scope issued under Rule R313-22 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(c) Type B specific license of broad scope issued under Rule R313-22 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

(d) Type C specific license of broad scope issued under Rule R313-22 shall be subject to the condition that radioactive material possessed under the license may only be used, by or under the direct supervision of, individuals who satisfy the requirements of Subsection R313-22-50(4).

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 into products in exempt concentrations.

(a) In addition to the requirements set forth in Section R313-22-33, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under Subsection R313-19-13(2)

(a) will be issued if:

(i) the applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and

(ii) the applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Section R313-19-70, that reconcentration of the radioactive material in concentrations exceeding those in Section R313-19-70 is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to a human being.

(b) Persons licensed under Subsection R313-22-75(1) shall file an annual report with the Executive Secretary which shall identify the type and quantity of products or materials into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product and material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into the product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to Subsection R313-22-75(1) during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within thirty days thereafter.

(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 U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(a) An application for a specific license to distribute naturally occurring and accelerator-produced radioactive material (NARM) to persons exempted from these rules pursuant to Subsection R313-19-13(2)(b) will be approved if:

(i) the radioactive material is not contained in a food, beverage, cosmetic, drug or other commodity designed for ingestion or inhalation by, or application to, a human being;

(ii) the radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into a manufactured or assembled commodity, product, or device intended for commercial distribution; and

(iii) the applicant submits copies of prototype labels and brochures and the Executive Secretary approves the labels and brochures;

(b) The license issued under Subsection R313-22-75(2)(a) is subject to the following conditions:

(i) No more than ten exempt quantities shall be sold or transferred in a single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantities provided the sum of the fractions shall not exceed unity.

(ii) Exempt quantities shall be separated and individually packaged. No more than ten packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to Subsection R313-19-13(2)(b). The outer package shall not allow the dose rate at the external surface of the package to exceed 0.5 millirem (5.0 uSv) per hour.

(iii) The immediate container of a quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

(A) identifies the radionuclide and the quantity of radioactivity; and

(B) bears the words "Radioactive Material."

(iv) In addition to the labeling information required by Subsection R313-22-75(2)(b)(iii), the label affixed to the immediate container, or an accompanying brochure, shall:

(A) state that the contents are exempt from Licensing State requirements;

(B) bear the words "Radioactive Material - Not for Human Use - Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited - Exempt Quantities Should Not Be Combined;" and

(C) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage and disposal of the radioactive material.

(c) Persons licensed under Subsection R313-22-75(2) shall maintain records identifying, by name and address, persons to whom radioactive material is transferred for use under Subsection R313-19-13(2)(b) or the equivalent regulations of a Licensing State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of radionuclides transferred under the specific license shall be filed with the Executive Secretary. Reports shall cover the year ending June 30, and shall be filed within thirty days thereafter. If no transfers of radioactive material have been made pursuant to Subsection R313-22-75(2) during the reporting period, the report shall so indicate.

(3) Licensing the incorporation of naturally occurring and accelerator-produced radioactive material (NARM) into gas and aerosol detectors. An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under Subsection R313-19-13(2)(c)(iii) will be approved if the application satisfies requirements equivalent to those contained in 10 CFR 32.26, 2001 ed. The maximum quantity of radium-226 in

each device shall not exceed 0.1 microcurie (3.7 kBq).

(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 U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State will be approved if:

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

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

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

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

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

TABLE

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

(iii) each device bears a durable, legible, clearly visible label or labels approved by the Executive Secretary, 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 U.S. Nuclear Regulatory Commission or a state with which the U.S. 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.

(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 Executive Secretary 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 U.S. 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) Persons licensed under Subsection R313-22-75(4) to distribute devices to generally licensed persons shall:

(i) furnish a copy of the general license contained in Subsection R313-21-22(4) to each person to whom the person directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in Subsection R313-21-22(4);

(ii) furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's, Agreement State's, or Licensing State's regulation equivalent to Subsection R313-21-22(4), or alternatively, furnish a copy of the general license contained in Subsection R313-21-22(4) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission, the Agreement State or the Licensing State. If a copy of the general license in Subsection R313-21-22(4) is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the U.S. Nuclear Regulatory Commission, Agreement State or Licensing State under requirements substantially the same as those in Subsection R313-21-22(4);

(iii) report to the Executive Secretary all transfers of such devices to persons for use under the general license in Subsection R313-21-22(4). The reports shall identify the general licensee by name and address, an individual by name or position who may constitute a point of contact between the Executive Secretary and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under Subsection R313- 21-22(4) during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within thirty days thereafter;

(iv) furnish reports to other agencies.

(A) Report to the U.S. Nuclear Regulatory Commission all transfers of those devices to persons for use under the U.S. Nuclear Regulatory Commission general license in 10 CFR 31.5, 2001 ed.

(B) Report to the responsible State agency all transfers of devices manufactured and distributed pursuant to Subsection R313-22-75(4) for use under a general license in that State's regulations equivalent to Subsection R313-21-22(4).

(C) The 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 responsible agency and general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the

intended user. The report shall be submitted within thirty days after the end of each calendar quarter in which a device is transferred to the generally licensed person.

(D) If transfers have not been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.

(E) If transfers have not been made to general licensees within a particular state during the reporting period, this information shall be reported to the responsible state agency upon request of that agency; and

(v) keep records showing the name, address and the point of contact for each general licensee to whom the person directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in Subsection R313-21-22(4), or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. The records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of intermediate persons, and compliance with the report requirements of Subsection R313-22-75(4).

(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 and 32.101, 2001 ed, or their equivalent.

(6) Special requirements for license to manufacture 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, 32.102 and 10 CFR 70.39, 2001 ed., 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 ten microcuries (370.0 kBq) each;

(ii) iodine-131 in units not exceeding ten microcuries (370.0 kBq) each;

(iii) carbon-14 in units not exceeding ten microcuries (370.0 kBq) each;

(iv) hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each;

(v) iron-59 in units not exceeding 20 microcuries (740.0 kBq) each;

(vi) cobalt-57 in units not exceeding ten microcuries (370.0 kBq) each;

(vii) selenium-75 in units not exceeding ten microcuries (370.0 kBq) each; or

(viii) mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185.0 Bq) 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 ten microcuries (370.0 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740.0 kBq) of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcuries (1.85 kBq) of iodine-129 and 0.005 microcurie (185.0 Bq) 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 U.S. Nuclear Regulatory Commission or of a state with which the U.S. 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, 32.103, 2001 ed. are met.

(9) Manufacture and distribution of radiopharmaceuticals containing radioactive material for medical use under group licenses.

(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 or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;

(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.

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

(iv) the applicant satisfies the following labeling requirements:

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

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

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

(i) May prepare radioactive drugs for medical use, as defined in Section R313-32-2, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in Subsections R313-22- 75(9)(b)(ii) and (iii), or an individual under the supervision of an

authorized nuclear pharmacist as specified in Section R313-32-25.

(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 Section R313-32- 2;

(B) this individual meets the requirements specified in Subsection R313-32-980(2) and Section R313- 32-972 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)(iii).

(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 Section R313-32-2, as an authorized nuclear pharmacist if the individual is identified as of January 1, 1997 as an "authorized user" on a nuclear pharmacy license issued by the Executive Secretary under Subsection R313-22-75(9).

(v) Shall provide to the Executive Secretary a copy of each individual's certification by the Board of Pharmaceutical Specialties, the U.S. Nuclear Regulatory Commission or Agreement State license, or the permit issued by a licensee of broad scope, and 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 (B), the individual to work as an authorized nuclear pharmacist.

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

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

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

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

(10) Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Section R313-32-18 for use as a calibration or reference source or for the uses listed in Sections R313-32-400 and R313-32-500 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 Executive Secretary for distribution to persons licensed pursuant to Sections R313-32-18, R313-32-400, and R313-32-500 or under equivalent regulations of the U.S. 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) 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
- (e) in determining the acceptable interval for test of leakage of radioactive material, the Executive Secretary shall consider information that includes, but is not limited to:
- (i) primary containment or source capsule,
 - (ii) protection of primary containment,
 - (iii) method of sealing containment,
 - (iv) containment construction materials,
 - (v) form of contained radioactive material,
 - (vi) maximum temperature withstood during prototype tests,

(vii) maximum pressure withstood during prototype tests,

(viii) maximum quantity of contained radioactive material,

(ix) radiotoxicity of contained radioactive material, and

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

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

(a) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to Subsection R313-21-21(5) or equivalent regulations of the U.S. 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 Executive Secretary 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 Executive Secretary 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 U.S. Nuclear Regulatory Commission or an Agreement State;

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

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

(A) a copy of the general license contained in Subsection R313-21-21(5) and a copy of form DRC-12; or

(B) a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to Subsection R313-21-21(5) and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in Subsection R313-21-21(5) and a copy of form DRC-12 with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in Subsection R313-21-21(5);

(v) report to the Executive Secretary all transfers of industrial products or devices to persons for use under the general license in Subsection R313-21-21(5). 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 Executive Secretary and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within thirty days after the end of the calendar quarter in which the product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under Subsection R313-21-21(5) during the reporting period, the report shall so indicate;

(vi) provide certain other reports as follows:

(A) report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in 10 CFR 40.25, 2001 ed.;

(B) report to the responsible state agency all transfers of devices manufactured and distributed pursuant to Subsection R313-22-75(11) for use under a general license in that state's regulations equivalent to Subsection R313-21-21(5),

(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 U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission, and

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

(vii) records shall be kept showing the name, address and point of contact for each general licensee to whom the person transfers depleted uranium in industrial products or devices for use

pursuant to the general license provided in Subsection R313-21-21(5) or equivalent regulations of the U.S. 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).

R313-22-90. Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release. Refer to Subsection R313-22-32 (8).

TABLE

| Radioactive Material(1) | Release Fraction | Quantity (curies) |
|----------------------------|------------------|-------------------|
| Actinium-228 | 0.001 | 4,000 |
| Americium-241 | .001 | 2 |
| Americium-242 | .001 | 2 |
| Americium-243 | .001 | 2 |
| Antimony-124 | .01 | 4,000 |
| Antimony-126 | .01 | 6,000 |
| Barium-133 | .01 | 10,000 |
| Barium-140 | .01 | 30,000 |
| Bismuth-207 | .01 | 5,000 |
| Bismuth-210 | .01 | 600 |
| Cadmium-109 | .01 | 1,000 |
| Cadmium-113 | .01 | 80 |
| Calcium-45 | .01 | 20,000 |
| Californium-252 (20 mg) | .001 | 9 |
| Carbon-14 | .01 | 50,000 |
| | Non CO | |
| Cerium-141 | .01 | 10,000 |
| Cerium-144 | .01 | 300 |
| Cesium-134 | .01 | 2,000 |
| Cesium-137 | .01 | 3,000 |
| Chlorine-36 | .5 | 100 |
| Chromium-51 | .01 | 300,000 |
| Cobalt-60 | .001 | 5,000 |
| Copper-64 | .01 | 200,000 |
| Curium-242 | .001 | 60 |
| Curium-243 | .001 | 3 |
| Curium-244 | .001 | 4 |
| Curium-245 | .001 | 2 |
| Europium-152 | .01 | 500 |
| Europium-154 | .01 | 400 |
| Europium-155 | .01 | 3,000 |
| Germanium-68 | .01 | 2,000 |
| Gadolinium-153 | .01 | 5,000 |
| Gold-198 | .01 | 30,000 |
| Hafnium-172 | .01 | 400 |
| Hafnium-181 | .01 | 7,000 |
| Holmium-166m | .01 | 100 |
| Hydrogen-3 | .5 | 20,000 |
| Iodine-125 | .5 | 10 |
| Iodine-131 | .5 | 10 |
| Indium-114m | .01 | 1,000 |
| Iridium-192 | .001 | 40,000 |

| | | |
|-------------------------------------|-------|-----------|
| Iron-55 | .01 | 40,000 |
| Iron-59 | .01 | 7,000 |
| Krypton-85 | 1.0 | 6,000,000 |
| Lead-210 | .01 | 8 |
| Manganese-56 | .01 | 60,000 |
| Mercury-203 | .01 | 10,000 |
| Molybdenum-99 | .01 | 30,000 |
| Neptunium-237 | .001 | 2 |
| Nickel-63 | .01 | 20,000 |
| Niobium-94 | .01 | 300 |
| Phosphorus-32 | .5 | 100 |
| Phosphorus-33 | .5 | 1,000 |
| Polonium-210 | .01 | 10 |
| Potassium-42 | .01 | 9,000 |
| Promethium-145 | .01 | 4,000 |
| Promethium-147 | .01 | 4,000 |
| Ruthenium-106 | .01 | 200 |
| Samarium-151 | .01 | 4,000 |
| Scandium-46 | .01 | 3,000 |
| Selenium-75 | .01 | 10,000 |
| Silver-110m | .01 | 1,000 |
| Sodium-22 | .01 | 9,000 |
| Sodium-24 | .01 | 10,000 |
| Strontium-89 | .01 | 3,000 |
| Strontium-90 | .01 | 90 |
| Sulfur-35 | .5 | 900 |
| Technetium-99 | .01 | 10,000 |
| Technetium-99m | .01 | 400,000 |
| Tellurium-127m | .01 | 5,000 |
| Tellurium-129m | .01 | 5,000 |
| Terbium-160 | .01 | 4,000 |
| Thulium-170 | .01 | 4,000 |
| Tin-113 | .01 | 10,000 |
| Tin-123 | .01 | 3,000 |
| Tin-126 | .01 | 1,000 |
| Titanium-44 | .01 | 100 |
| Vanadium-48 | .01 | 7,000 |
| Xenon-133 | 1.0 | 900,000 |
| Yttrium-91 | .01 | 2,000 |
| Zinc-65 | .01 | 5,000 |
| Zirconium-93 | .01 | 400 |
| Zirconium-95 | .01 | 5,000 |
| Any other beta-gamma emitter | .01 | 10,000 |
| Mixed fission products | .01 | 1,000 |
| Mixed corrosion products | .01 | 10,000 |
| Contaminated equipment, beta-gamma | .001 | 10,000 |
| Irradiated material, any form | | |
| other than solid noncombustible | .01 | 1,000 |
| Irradiated material, solid | | |
| noncombustible | .001 | 10,000 |
| Mixed radioactive waste, beta-gamma | .01 | 1,000 |
| Packaged mixed waste, beta-gamma(2) | .001 | 10,000 |
| Any other alpha emitter | .001 | 2 |
| Contaminated equipment, alpha | .0001 | 20 |
| Packaged waste, alpha(2) | .0001 | 20 |
| Combinations of radioactive | | |
| materials listed above(1) | ----- | ----- |

(1) For combinations of radioactive materials, consideration of the need for

| | | |
|------------------|------|--------|
| Germanium-71 | 100 | 1 |
| Gold-198 | 10 | 0.1 |
| Gold-199 | 10 | 0.1 |
| Hafnium-181 | 1 | 0.01 |
| Holmium-166 | 10 | 0.1 |
| Hydrogen-3 | 100 | 1 |
| Indium-113m | 100 | 1 |
| Indium-114m | 1 | 0.01 |
| Indium-115m | 100 | 1 |
| Indium-115 | 1 | 0.01 |
| Iodine-125 | 0.1 | 0.001 |
| Iodine-126 | 0.1 | 0.001 |
| Iodine-129 | 0.1 | 0.01 |
| Iodine-131 | 0.1 | 0.001 |
| Iodine-132 | 10 | 0.1 |
| Iodine-133 | 1 | 0.01 |
| Iodine-134 | 10 | 0.1 |
| Iodine-135 | 1 | 0.01 |
| Iridium-192 | 1 | 0.01 |
| Iridium-194 | 10 | 0.1 |
| Iron-55 | 10 | 0.1 |
| Iron-59 | 1 | 0.01 |
| Krypton-85 | 100 | 1 |
| Krypton-87 | 10 | 0.1 |
| Lanthanum-140 | 1 | 0.01 |
| Lutetium-177 | 10 | 0.1 |
| Manganese-52 | 1 | 0.01 |
| Manganese-54 | 1 | 0.01 |
| Manganese-56 | 10 | 0.1 |
| Mercury-197m | 10 | 0.1 |
| Mercury-197 | 10 | 0.1 |
| Mercury-203 | 1 | 0.01 |
| Molybdenum-99 | 10 | 0.1 |
| Neodymium-147 | 10 | 0.1 |
| Neodymium-149 | 10 | 0.1 |
| Nickel-59 | 10 | 0.1 |
| Nickel-63 | 1 | 0.01 |
| Nickel-65 | 10 | 0.1 |
| Niobium-93m | 1 | 0.01 |
| Niobium-95 | 1 | 0.01 |
| Niobium-97 | 100 | 1 |
| Osmium-185 | 1 | 0.01 |
| Osmium-191m | 100 | 1 |
| Osmium-191 | 10 | 0.1 |
| Osmium-193 | 10 | 0.1 |
| Palladium-103 | 10 | 0.1 |
| Palladium-109 | 10 | 0.1 |
| Phosphorus-32 | 1 | 0.01 |
| Platinum-191 | 10 | 0.1 |
| Platinum-193m | 100 | 1 |
| Platinum-193 | 10 | 0.1 |
| Platinum-197m | 100 | 1 |
| Platinum-197 | 10 | 0.1 |
| Polonium-210 | 0.01 | 0.0001 |
| Potassium-42 | 1 | 0.01 |
| Praseodymium-142 | 10 | 0.1 |
| Praseodymium-143 | 10 | 0.1 |
| Promethium-147 | 1 | 0.01 |
| Promethium-149 | 10 | 0.1 |

| | | |
|----------------|-------|--------|
| Radium-226 | 0.01 | 0.0001 |
| Rhenium-186 | 10 | 0.1 |
| Rhenium-188 | 10 | 0.1 |
| Rhodium-103m | 1,000 | 10 |
| Rhodium-105 | 10 | 0.1 |
| Rubidium-86 | 1 | 0.01 |
| Rubidium-87 | 1 | 0.01 |
| Ruthenium-97 | 100 | 1 |
| Ruthenium-103 | 1 | 0.01 |
| Ruthenium-105 | 10 | 0.1 |
| Ruthenium-106 | 0.1 | 0.001 |
| Samarium-151 | 1 | 0.01 |
| Samarium-153 | 10 | 0.1 |
| Scandium-46 | 1 | 0.01 |
| Scandium-47 | 10 | 0.1 |
| Scandium-48 | 1 | 0.01 |
| Selenium-75 | 1 | 0.01 |
| Silicon-31 | 10 | 0.1 |
| Silver-105 | 1 | 0.01 |
| Silver-110m | 0.1 | 0.001 |
| Silver-111 | 10 | 0.1 |
| Sodium-22 | 0.1 | 0.001 |
| Sodium-24 | 1 | 0.01 |
| Strontium-85m | 1,000 | 10 |
| Strontium-85 | 1 | 0.01 |
| Strontium-89 | 1 | 0.01 |
| Strontium-90 | 0.01 | 0.0001 |
| Strontium-91 | 10 | 0.1 |
| Strontium-92 | 10 | 0.1 |
| Sulphur-35 | 10 | 0.1 |
| Tantalum-182 | 1 | 0.01 |
| Technetium-96 | 10 | 0.1 |
| Technetium-97m | 10 | 0.1 |
| Technetium-97 | 10 | 0.1 |
| Technetium-99m | 100 | 1 |
| Technetium-99 | 1 | 0.01 |
| Tellurium-125m | 1 | 0.01 |
| Tellurium-127m | 1 | 0.01 |
| Tellurium-127 | 10 | 0.1 |
| Tellurium-129m | 1 | 0.01 |
| Tellurium-129 | 100 | 1 |
| Tellurium-131m | 10 | 0.1 |
| Tellurium-132 | 1 | 0.01 |
| Terbium-160 | 1 | 0.01 |
| Thallium-200 | 10 | 0.1 |
| Thallium-201 | 10 | 0.1 |
| Thallium-202 | 10 | 0.1 |
| Thallium-204 | 1 | 0.01 |
| Thulium-170 | 1 | 0.01 |
| Thulium-171 | 1 | 0.01 |
| Tin-113 | 1 | 0.01 |
| Tin-125 | 1 | 0.01 |
| Tungsten-181 | 1 | 0.01 |
| Tungsten-185 | 1 | 0.01 |
| Tungsten-187 | 10 | 0.1 |
| Vanadium-48 | 1 | 0.01 |
| Xenon-131m | 1,000 | 10 |
| Xenon-133 | 100 | 1 |
| Xenon-135 | 100 | 1 |

| | | |
|--|-----|-------|
| Ytterbium-175 | 10 | 0.1 |
| Yttrium-90 | 1 | 0.01 |
| Yttrium-91 | 1 | 0.01 |
| Yttrium-92 | 10 | 0.1 |
| Yttrium-93 | 1 | 0.01 |
| Zinc-65 | 1 | 0.01 |
| Zinc-69m | 10 | 0.1 |
| Zinc-69 | 100 | 1 |
| Zirconium-93 | 1 | 0.01 |
| Zirconium-95 | 1 | 0.01 |
| Zirconium-97 | 1 | 0.01 |
| Any radioactive material other than source material, special nuclear material, or alpha-emitting radioactive material not listed above | 0.1 | 0.001 |

R313-22-210. Registration of Product Information.

Licensees who manufacture or initially distribute a sealed source or device containing a sealed source whose product is intended for use under a specific license or general license are deemed to have provided reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and the environment if the sealed source or device has been evaluated in accordance with 10 CFR 32.210, 2001 ed. or equivalent regulations of an Agreement State.

KEY

specific licenses, decommissioning, broad scope, radioactive materials

Date of Enactment or Last Substantive Amendment

July 23, 2002

Notice of Continuation

October 10, 2001

Authorizing, Implemented, or Interpreted Law

19-3-104; 19-3-108

Rule converted into HTML by the Division of Administrative Rules.

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