



# State of Utah

## DEPARTMENT OF ENVIRONMENTAL QUALITY DIVISION OF RADIATION CONTROL

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December 22, 1999

M. Linda McLean  
States Agreements Officer  
Nuclear Regulatory Commission  
611 Ryan Plaza Drive, Suite 400  
Arlington, Texas 76011-8064

DEC 28 1999

Dear Ms. McLean:

The Division of Radiation Control (DRC) is proposing changes to the Utah Administrative Code. The proposed changes pertain to: R313-12, "General Provisions;" R313-15, "Standards for Protection Against Radiation;" R313-16, "General Requirements Applicable to the Installation, Registration, Inspection, and Use of Radiation Machines;" R313-22, "Specific Licenses;" and R313-25, "License Requirements for Land Disposal of Radioactive Waste General Provisions." The proposed changes pertain to radiological criteria for license termination.

The proposed rulemaking will provide specific radiological criteria for the decommissioning of lands and structures and is intended to provide a clear and consistent regulatory basis for determining the extent to which lands and structures must be remediated before decommissioning of a site can be considered complete and the license terminated. This criteria will be used by the Division to determine the adequacy of remediation of residual radioactivity resulting from the possession or use of radioactive material. The criteria would apply to decommissioning of nuclear facilities that operate through their normal lifetime and to those that may be shut down prematurely. The rulemaking is necessary to ensure that decommissioning will be carried out without impact on public health and safety and the environment. Also, the proposed rulemaking incorporates a State Law that also exists in R317-6, "Ground Water Quality Protection Regulations," promulgated under the Utah Water Quality Act.

The proposed rules will be transmitted: by electronic mail in WordPerfect, version 6.1 format with ".jrf" as the file extension, and as "hard copy" documents.

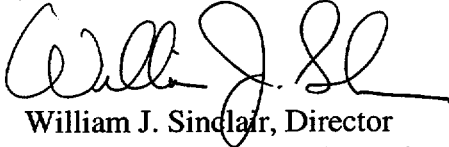
The Utah Radiation Control Board will meet on January 7, 2000. It is anticipated that the Board will approve the proposed rulemaking action so that the rule(s) may be filed with DAR and notice be given to the public. The comment period is anticipated to be from February 1, 2000 to March 2, 2000. The possible effective date of this rulemaking action could be March 10, 2000.

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If you have questions about the rule(s), please contact Julie Felice or Craig Jones at (801) 536-4250.

Sincerely,

A handwritten signature in black ink, appearing to read "William J. Sinclair". The signature is fluid and cursive, with a large initial "W" and a long, sweeping underline.

William J. Sinclair, Director  
Division of Radiation Control

Enclosure(s): As stated

### **R313. Environmental Quality, Radiation Control.**

#### **R313-12. General Provisions.**

##### **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 [~~chapter~~]rule will be found in that [~~chapter~~]rule.

"A<sub>1</sub>" means the maximum activity of special form radioactive material permitted in a Type A package.

"A<sub>2</sub>" 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  $3.7 \times 10^{10}$  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 ( $1000 \text{ mg/cm}^2$ ).

"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.

"Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (300 mg/cm<sup>2</sup>).

"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 could result in an individual receiving a dose equivalent in excess of one mSv (0.1 rem), in one hour at 30 centimeters from a 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 designated 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, thermoluminescent 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.

"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 natural 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.

"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 58-17-1 through 58-17-27.

"Physician" means an individual licensed by this state to practice medicine and surgery in all its branches. See Sections 58-12-26 through 58-12-43.

"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  $2.58 \times 10^{-4}$  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  $\text{cm}^2$ ), 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  $1.3 \times 10^5$  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  $2.58 \times 10^{-4}$  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 Equivalencies**

Type of Radiation	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent
X, gamma, or beta radiation and	1	1

high-speed electrons		
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 Equivalent", the absorbed dose in rad is equal 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 Dose Equivalent for Monoenergetic Neutrons

	Neutron Energy MeV	Quality Factor Q	Fluence per Unit Dose Equivalent neutrons cm <sup>-2</sup> rem <sup>-1</sup>	Fluence per Unit Dose Equivalent neutrons cm <sup>-2</sup> Sv <sup>-1</sup>
thermal	2.5 x 10 <sup>-8</sup>	2	980 x 10 <sup>6</sup>	980 x 10 <sup>8</sup>
	1 x 10 <sup>-7</sup>	2	980 x 10 <sup>6</sup>	980 x 10 <sup>8</sup>
	1 x 10 <sup>-6</sup>	2	810 x 10 <sup>6</sup>	810 x 10 <sup>8</sup>
	1 x 10 <sup>-5</sup>	2	810 x 10 <sup>6</sup>	810 x 10 <sup>8</sup>
	1 x 10 <sup>-4</sup>	2	840 x 10 <sup>6</sup>	840 x 10 <sup>8</sup>
	1 x 10 <sup>-3</sup>	2	980 x 10 <sup>6</sup>	980 x 10 <sup>8</sup>
	1 x 10 <sup>-2</sup>	2.5	1010 x 10 <sup>6</sup>	1010 x 10 <sup>8</sup>
	1 x 10 <sup>-1</sup>	7.5	170 x 10 <sup>6</sup>	170 x 10 <sup>8</sup>
	5 x 10 <sup>-1</sup>	11	39 x 10 <sup>6</sup>	39 x 10 <sup>8</sup>
	1	11	27 x 10 <sup>6</sup>	27 x 10 <sup>8</sup>
	2.5	9	29 x 10 <sup>6</sup>	29 x 10 <sup>8</sup>
	5	8	23 x 10 <sup>6</sup>	23 x 10 <sup>8</sup>
	7	7	24 x 10 <sup>6</sup>	24 x 10 <sup>8</sup>
	10	6.5	24 x 10 <sup>6</sup>	24 x 10 <sup>8</sup>
	14	7.5	17 x 10 <sup>6</sup>	17 x 10 <sup>8</sup>
	20	8	16 x 10 <sup>6</sup>	16 x 10 <sup>8</sup>
	40	7	14 x 10 <sup>6</sup>	14 x 10 <sup>8</sup>
	60	5.5	16 x 10 <sup>6</sup>	16 x 10 <sup>8</sup>

$1 \times 10^2$	4	$20 \times 10^6$	$20 \times 10^8$
$2 \times 10^2$	3.5	$19 \times 10^6$	$19 \times 10^8$
$3 \times 10^2$	3.5	$16 \times 10^6$	$16 \times 10^8$
$4 \times 10^2$	3.5	$14 \times 10^6$	$14 \times 10^8$

For the column in Table 2 labeled "Quality Factor", the values of Q are at the point where the dose equivalent is 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 for monoenergetic neutrons incident 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  $3.7 \times 10^{10}$  disintegrations or transformations per second, which equals  $3.7 \times 10^{10}$  becquerel, which equals  $2.22 \times 10^{12}$  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**

**[~~March 12, 1999~~]2000**

**Notice of Continuation March 26, 1997**

**19-3-104**

**19-3-108**

**R313. Environmental Quality, Radiation Control.**

**R313-15. Standards for Protection Against Radiation.**

**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, 1997 ed., which is incorporated by reference.

"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, 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.

"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,

Appendix B, Table II of 10 CFR 20.1001 to 20.2402, 1997 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. 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 R313-15-401(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.]~~

#### **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 4 millirem 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) Radiation levels; and

(ii) Concentrations or quantities of radioactive material;

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 R313-15-401 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 [as the Executive Secretary may specify].

**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 R313-15-401(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**  
**[March 12, 1999]2000** **19-3-104**  
**Notice of Continuation April 30, 1998** **19-3-108**

**R313. Environmental Quality, Radiation Control.**

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

**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.

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

**R313-16-215. Definitions.**

~~["Facility" means the location, building, vehicle, or complex under one administrative control, at which one or more radiation machines are installed, located or used.]~~

"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

- (i) B.S. plus five years health physics, preferably in diagnostic x-ray surveys experience;
- (ii) M.S. in physical sciences plus four years health physics, preferably in diagnostic x-ray surveys experience;
- (iii) M.S. in health physics or medical physics plus 3-1/2 years health physics, preferably in diagnostic x-ray surveys experience;
- (iv) Ph.D. in physical sciences plus 3-1/2 years health physics, preferably in diagnostic x-ray surveys experience; or
- (v) Ph.D. in health physics or medical physics plus three years health physics, preferably in diagnostic x-ray surveys experience.

**KEY: x-ray, inspection**

**[August 13, 1999] 2000**

**19-3-104**

**Notice of Continuation March 26, 1997**

**R313. Environmental Quality, Radiation Control.**

**R313-22. Specific Licenses.**

**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.

~~["Decommission" means to remove, as a facility, safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of license.]~~

"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, [~~1996~~2000 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, 1992 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[7] and R313-22-75, and Rules 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, [1996]2000 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, [1996]2000 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

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, [ <del>1996</del> ]2000 ed., which is incorporated by reference, in unsealed form. For a combination of radionuclides, if R, as defined in <u>Subsection</u> 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:	\$750,000
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, [ <del>1996</del> ]2000 ed., which is incorporated by reference, in unsealed form. For a combination of radionuclides, if R, as defined in <u>Subsection</u> 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:	\$150,000
Greater than $10^{10}$ times the applicable quantities of radioactive material, as defined in Appendix B of 10 CFR 30.1 through 30.72, [ <del>1996</del> ]2000 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:	\$75,000

(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); ~~[-or]~~

(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 ~~[unrestricted release levels]~~ 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([6]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 some other manner] 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 (microroentgen) 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 [so that there is not an undue hazard to public health and safety or the environment] 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 [~~so that there is not an undue hazard to public health and safety or the environment~~] 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 R313-25, 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. 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	<u>150.0 mSv</u> (15 rems) [ <del>(150.0</del> mSv)]
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter	<u>2.0 Sv</u> (200 rems) [ <del>(2.0</del> Sv)]
Other organs	<u>500.0 mSv</u> (50 rems) [ <del>(500.0</del> mSv)]; 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.

(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, 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, 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 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([4]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([4]5) or its equivalent:

(A) a copy of the general license contained in Subsection R313-21-21([4]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([4]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([4]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([4]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([4]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([4]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;

(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([4]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([4]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	.001	9
(20 mg)		
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 an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Section R313-22-90 exceeds one.

(2) Waste packaged in Type B containers does not require an emergency plan.

R313-22-100. Limits for Broad Licenses. Refer to Section R313-22-50.

TABLE

RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II CURIES
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	1	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1
Cesium-134m	100	1
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1
Chromium-51	100	1
Cobalt-57	10	0.1
Cobalt-58m	100	1
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 (9.2h)	10	0.1
Europium-152 (13y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1

Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
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, [~~1996~~2000 ed. or equivalent regulations of an Agreement State.

**KEY: specific licenses, decommissioning, broad scope, radioactive material**

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(b) that additional requirements resulting from new information developed during the institutional control period have been met;

(c) that permanent monuments or markers warning against intrusion have been installed; and

(d) that records required by R313-25-33(4) and (5) have been sent to the party responsible for institutional control of the disposal site and a copy has been sent to the Executive Secretary immediately prior to license termination.

**R313-25-18. General Requirement.**

Land disposal facilities shall be sited, designed, operated, closed, and controlled after closure so that reasonable assurance exists that exposures to individuals do not exceed the limits stated in R313-25-19 and 25-22.

**R313-25-19. Protection of the General Population from Releases of Radioactivity.**

Concentrations of radioactive material which may be released to the general environment in ground water, surface water, air, soil, plants or animals shall not result in an annual dose exceeding an equivalent of 0.25 mSv (0.025 rem) [25 millirems (0.25 mSv)] to the whole body, 0.75 mSv (0.075 rem) [75 millirems (0.75 mSv)] to the thyroid, and 0.25 mSv (0.025 rem) [25 millirems (0.25 mSv)] to any other organ of any member of the public. No greater than 0.04 mSv (0.004 rem) committed effective dose equivalent or total effective dose equivalent to any member of the public shall come from groundwater. Reasonable efforts should be made to maintain releases of radioactivity in effluents to the general environment as low as is reasonably achievable.

**R313-25-20. Protection of Individuals from Inadvertent Intrusion.**

Design, operation, and closure of the land disposal facility shall ensure protection of any individuals inadvertently intruding into the disposal site and occupying the site or contacting the waste after active institutional controls over the disposal site are removed.

**R313-25-21. Protection of Individuals During Operations.**

Operations at the land disposal facility shall be conducted in compliance with the standards for radiation protection set out in R313-15 of these rules, except for release of radioactivity in effluents from the land disposal facility, which shall be governed by R313-25-19. Every reasonable effort should be made to maintain radiation exposures as low as is reasonably achievable, ALARA.

**R313-25-22. Stability of the Disposal Site After Closure.**

The disposal facility shall be sited, designed, used, operated, and closed to achieve long-term stability of the disposal site and to eliminate, to the extent practicable, the need for ongoing active maintenance of the disposal site following closure so that only surveillance, monitoring, or minor custodial care are

and consignee certifications; and

(ii) that information required in R313-25-33(5).

(b) As specified in facility license conditions, the licensee shall report the stored information, or subsets of this information, on a computer-readable medium.

**R313-25-34. Tests on Land Disposal Facilities.**

Licensees shall perform, or permit the Executive Secretary to perform, any tests the Executive Secretary deems appropriate or necessary for the administration of the rules in R313-25, including, but not limited to, tests of;

- (1) wastes;
- (2) facilities used for the receipt, storage, treatment, handling or disposal of wastes;
- (3) radiation detection and monitoring instruments; or
- (4) other equipment and devices used in connection with the receipt, possession, handling, treatment, storage, or disposal of waste.

**R313-25-35. Executive Secretary Inspections of Land Disposal Facilities.**

(1) Licensees shall afford to the Executive Secretary, at reasonable times, opportunity to inspect waste not yet disposed of, and the premises, equipment, operations, and facilities in which wastes are received, possessed, handled, treated, stored, or disposed of.

(2) Licensees shall make available to the Executive Secretary for inspection, upon reasonable notice, records kept by it pursuant to these rules. Authorized representatives of the Executive Secretary may copy and take away copies of, for the Executive Secretary's use, any records required to be kept pursuant to R313-25.

**KEY: radiation, radioactive waste disposal**

**[~~January 23, 1998~~2000]**

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