



State of Utah

DEPARTMENT OF ENVIRONMENTAL QUALITY
DIVISION OF RADIATION CONTROL

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June 6, 2001

Fred Combs, Deputy Director
Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission

RE: Regulation Assessment Tracking System; RATS Data Sheet ID # 1998-5, RATS Data Sheet ID # 1998-6, and RATS Data Sheet ID # 1999-3.

Dear Mr. Combs:

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"; R313-22, "Specific Licenses"; R313-32, "Medical Use of Radioactive Material"; and R313-34, "Requirements for Irradiators." The proposed changes pertain to minor corrections, clarifying changes, transfer for disposal and manifests, and respiratory protection and controls to restrict internal exposure. In addition, references to the Code of Federal Regulations (CFR) in the above stated Chapters of the Utah Administrative Code were updated to reflect the most recent version of the CFR's. These rulemakings address compatibility matters and should satisfy compatibility requirements.

The proposed rule will be transmitted: by electronic mail in Corel WordPerfect 8 format with "wpd" as the file extension, and as "hard copy" documents.

The Utah Radiation Control Board met on June 1, 2001. The Board approved the proposed rulemaking actions so that the rules may be filed with the Utah Department of Administrative Services, Division of Administrative Rules and notice be given to the public. The comment period is anticipated to be from July 1, 2001 to July 31, 2001. The possible effective date of these rulemaking actions could be August 10, 2001.

If you have questions about the rules, please contact Gwyn Galloway or Craig Jones at (801) 536-4250.

Sincerely,

William J. Sinclair, Director
Division of Radiation Control

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OSP

Enclosures: As stated

DCD (SP07)
Template STP-008

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 rule will be found in that rule.

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

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

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

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

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

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

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

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

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

"Airborne radioactive material" means a radioactive material dispersed in the air in the form of dusts, fumes, particulates,

mists, vapors, or gases.

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

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

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

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

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

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

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

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

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

"Byproduct material" means:

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

(b) the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these

solution extraction operations do not constitute "byproduct material" within this definition.

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

"Calibration" means the determination of:

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

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

"CFR" means Code of Federal Regulations.

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

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

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

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

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

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

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

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

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

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

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

"Department" means the Utah State Department of Environmental

Quality.

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

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

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

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

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

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

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

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

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

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

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

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

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

"External dose" means that portion of the dose equivalent

received from a source of radiation outside the body.

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

~~["Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (300 mg/cm²).~~

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

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

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

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

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

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

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

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

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

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

"Individual" means a human being.

"Individual monitoring" means the assessment of:

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

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

"Individual monitoring devices" means devices ~~[designated]~~ designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these rules, individual monitoring equipment and personnel monitoring equipment

are equivalent terms. Examples of individual monitoring devices are film badges, [thermoluminescent] thermoluminescence dosimeters (TLD's), pocket ionization chambers, and personal air sampling devices.

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

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

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

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

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

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

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

"Licensing state" means a state which has been provisionally or finally designated as such by the Conference of Radiation Control Program Directors, Inc., which reviews state regulations to establish equivalency with the Suggested State Regulations and ascertains whether a State has an effective program for control of 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.

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

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

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

"Personnel monitoring equipment," see individual monitoring devices.

"Pharmacist" means an individual licensed by this state to practice pharmacy. See Sections 58-17a-101 through 58-17a-801.

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

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

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

"Public dose" means the dose received by a member of the public from sources of radiation from licensed or registered operations. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals

administered radioactive material and released in accordance with Section R313-32-75, or from voluntary participation in medical research programs.

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

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

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

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

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

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

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

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

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

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

"Radiobioassay". See "Bioassay".

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

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

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

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

rem equals 0.01 sievert (Sv).

"Research and development" means:

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

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

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

"Roentgen" (R) means the special unit of EXPOSURE. One roentgen equals 2.58×10^{-4} coulombs per kilogram of air. See EXPOSURE.

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

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

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

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

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

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

"Source material" means:

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

(b) ores that contain by weight one-twentieth of one percent (0.05 percent), or more of, uranium, thorium, or any combination of

uranium and thorium. Source material does not include special nuclear material.

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

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

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

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

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

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

"Special nuclear material" means:

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

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

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

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

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

"Test" means the process of verifying compliance with an

applicable rule.

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

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

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

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

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

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

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

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

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

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

"Week" means seven consecutive days starting on Sunday.

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

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

"Working level" (WL), means any combination of short-lived

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

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

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

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

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

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

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

(b) Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram. One rad equals 0.01 Gy.

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

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

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

TABLE 1

Quality Factors and Absorbed Dose Equivalencies

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

Neutrons of unknown energy	10	0.1
High energy protons	10	0.1

For the column in Table 1 labeled "Absorbed Dose Equal to a Unit Dose 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 ⁻² rem ⁻¹	Fluence per Unit Dose Equivalent neutrons cm ⁻² Sv ⁻¹
thermal	2.5 x 10 ⁻⁸	2	980 x 10 ⁶	980 x 10 ⁸
	1 x 10 ⁻⁷	2	980 x 10 ⁶	980 x 10 ⁸
	1 x 10 ⁻⁶	2	810 x 10 ⁶	810 x 10 ⁸
	1 x 10 ⁻⁵	2	810 x 10 ⁶	810 x 10 ⁸
	1 x 10 ⁻⁴	2	840 x 10 ⁶	840 x 10 ⁸
	1 x 10 ⁻³	2	980 x 10 ⁶	980 x 10 ⁸
	1 x 10 ⁻²	2.5	1010 x 10 ⁶	1010 x 10 ⁸
	1 x 10 ⁻¹	7.5	170 x 10 ⁶	170 x 10 ⁸
	5 x 10 ⁻¹	11	39 x 10 ⁶	39 x 10 ⁸
	1	11	27 x 10 ⁶	27 x 10 ⁸
	2.5	9	29 x 10 ⁶	29 x 10 ⁸
	5	8	23 x 10 ⁶	23 x 10 ⁸
	7	7	24 x 10 ⁶	24 x 10 ⁸
	10	6.5	24 x 10 ⁶	24 x 10 ⁸
	14	7.5	17 x 10 ⁶	17 x 10 ⁸
	20	8	16 x 10 ⁶	16 x 10 ⁸
	40	7	14 x 10 ⁶	14 x 10 ⁸
	60	5.5	16 x 10 ⁶	16 x 10 ⁸
	1 x 10 ²	4	20 x 10 ⁶	20 x 10 ⁸
	2 x 10 ²	3.5	19 x 10 ⁶	19 x 10 ⁸
	3 x 10 ²	3.5	16 x 10 ⁶	16 x 10 ⁸
	4 x 10 ²	3.5	14 x 10 ⁶	14 x 10 ⁸

For the column in Table 2 labeled "Quality Factor", the values of Q are at the 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 3.7×10^{10} disintegrations or transformations per second, which equals 3.7×10^{10} becquerel, which equals 2.22×10^{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

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19-3-104

19-3-108

~~[R313. Environmental Quality, Radiation Control.~~

~~R313-38. Radiation Safety Requirements for Wireline Service Operation and Subsurface Tracer Studies.~~

~~R313-38-1. Purpose and Authority.~~

~~R313-38 establishes radiation safety requirements for persons using sources of radiation for wireline service operations including mineral logging, radioactive markers, and subsurface tracer studies. The requirements of R313-38 are in addition to, and not in substitution for, the requirements of R313-12, R313-15, R313-16, R313-18 and R313-19. The rules in R313-38 apply to all licensees or registrants who use sources of radiation for wireline service operations including mineral logging, radioactive markers, or subsurface tracer studies.~~

~~R313-38-2. Definitions.~~

~~As used in R313-38:~~

~~"Field station" means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary job sites.~~

~~"Fresh water aquifer" means a geologic formation that is capable of yielding fresh water to a well or spring.~~

~~"Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.~~

~~"Irretrievable well logging source" means a sealed source containing licensed material that is pulled off or not connected to the wireline that suspends the source in the well and for which all reasonable effort at recovery has been expended.~~

~~"Logging assistant" means an individual who, under the personal supervision of a logging supervisor, handles sources of radiation or tracers that are not in logging tools or shipping containers or who performs surveys required by R313-38-67.~~

~~"Logging supervisor" means an individual who uses sources of radiation or provides personal supervision in the use of sources of radiation at a temporary job site and who is responsible to the licensee or registrant for assuring compliance with the Utah Radiation Control Rules and the conditions of the license.~~

~~"Logging tool" means a device used subsurface to perform well logging.~~

~~"Personal supervision" means guidance and instruction by a logging supervisor, who is physically present at a temporary job site, who is in personal contact with logging assistants, and who can give immediate assistance.~~

~~"Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation. For purposes of R313-38, this term includes radioactive collar markers and radioactive iron nails.~~

~~"Safety review" means a periodic review provided by the licensee for its employees on radiation safety aspects of well logging. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, accidents or errors that have been observed, and opportunities for employees to ask safety questions.~~

~~"Source holder" means a housing or assembly into which a sealed source is placed to facilitate the handling and use of the source in well logging.~~

~~"Subsurface tracer study" means the release of unsealed licensed material or a substance labeled with licensed material in a single well for the purpose of tracing the movement or position of the material or substance in the well or adjacent formation.~~

~~"Surface casing for protecting fresh water aquifers" means a pipe or tube used as a lining in a well to isolate fresh water aquifers from the well.~~

~~"Uranium sinker bar" means a weight containing depleted uranium used to pull a logging tool toward the bottom of a well.~~

~~"Well-bore" means a drilled hole in which wireline service operations and subsurface tracer studies are performed.~~

~~"Well logging" means the lowering and raising of measuring devices or tools which contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well or adjacent geological formations.~~

~~"Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.~~

~~"Wireline service operation" means any evaluation or mechanical service which is performed in the well-bore using devices on a wireline.~~

~~R313-38-13. Specific Licenses for Well Logging.~~

~~The Executive Secretary will approve an application for a specific license for the use of licensed material in well logging if the applicant meets the following requirements:~~

~~(1) The applicant shall satisfy the general requirements specified in R313-22-34 and the special requirements contained in R313-38.~~

~~(2) The applicant shall develop a program for training logging supervisors and logging assistants and submit to the Executive Secretary a description of this program which specifies the:~~

~~(a) initial training;~~

~~(b) on-the-job training;~~

~~(c) annual safety reviews provided by the licensee;~~

~~(d) methods that the applicant will use to evaluate the logging supervisor's knowledge and understanding of and ability to comply with these rules and licensing requirements and the applicant's operating and emergency procedures; and~~

~~(e) methods that the applicant will use to evaluate the logging assistant's knowledge and understanding of and ability to comply with the applicant's operating and emergency procedures.~~

~~(3) The applicant shall submit to the Executive Secretary written operating and emergency procedures, as described in R313-38-63, or an outline or summary of the procedures that includes the important radiation safety aspects of the procedures.~~

~~(4) The applicant shall establish and submit to the Executive Secretary its program for annual inspections of the job performance of logging supervisors to ensure that these rules, license~~

requirements, and the applicant's operating and emergency procedures are followed. Inspection records must be retained for three years after annual internal inspections.

~~(5) The applicant shall submit a description of its overall organizational structure as it applies to the radiation safety responsibilities in well logging, including specified delegations of authority and responsibility.~~

~~(6) If an applicant wants to perform leak testing of sealed sources, the applicant shall identify the manufacturers and the model numbers of the leak test kits to be used. If the applicant wants to analyze its own wipe samples, the applicant shall establish procedures to be followed and submit a description of these procedures to the Executive Secretary. The description must include the:~~

~~(1) instruments to be used;~~

~~(2) methods of performing the analysis; and~~

~~(3) pertinent experience of the person who will analyze the wipe samples.~~

~~R313-38-15. Agreement With Well Owner or Operator.~~

~~(1) A licensee may perform well logging with a sealed source only after the licensee has a written agreement with the employing well owner or operator. The following requirements shall be met and the written agreement shall identify who will be responsible for meeting these requirements.~~

~~(a) If a sealed source becomes lodged in a well, a reasonable effort will be made to recover it.~~

~~(b) A person may not attempt to recover a sealed source in a manner which, in the licensee's opinion, could result in its rupture.~~

~~(c) The radiation monitoring required in R313-38-69(3) will be performed.~~

~~(d) If the environment, equipment, or personnel are contaminated with licensed material, they must be decontaminated before release from the site or release for unrestricted use.~~

~~(e) If the sealed source is classified as irretrievable after reasonable efforts at recovery have been expended, the following requirements shall be implemented within 30 days:~~

~~(i) Irretrievable well logging sources must be immobilized and sealed in place with a cement plug.~~

~~(ii) A mechanical device to prevent inadvertent intrusion on the source must be set at some point in the well above the cement plug, unless the cement plug and source are not accessible to subsequent drilling operations.~~

~~(iii) A permanent identification plaque, constructed of long lasting material such as stainless steel, brass, bronze, or monel, must be mounted at the surface of the well, unless the mounting of the plaque is not practical. The size of the plaque must be at least 17 centimeters (seven inches) square and three millimeters (one-eighth inch) thick. The plaque must contain:~~

~~(A) the word "CAUTION";~~

~~(B) the radiation symbol (the color requirement in R313-15-901(1) need not be met);~~

- ~~_____ (C) the date the source was abandoned;~~
 - ~~_____ (D) the name of the well owner or well operator, as appropriate;~~
 - ~~_____ (E) the well name and well identification number or other designation;~~
 - ~~_____ (F) an identification of the sealed source by radionuclide and quantity;~~
 - ~~_____ (G) the depth of the source and depth of the top of the plug; and~~
 - ~~_____ (H) an appropriate warning, such as, "DO NOT RE-ENTER THIS WELL."~~
- ~~_____ (2) The licensee shall retain a copy of the written agreement for three years after the completion of the well logging operation.~~
- ~~_____ (3) On a case by case basis, a licensee may apply for Executive Secretary approval pursuant to R313-38-91 of proposed procedures to abandon an irretrievable well logging source in a manner not otherwise authorized in R313-38-15(1)(e).~~
- ~~_____ (4) A written agreement between the licensee and the well owner or operator is not required if the licensee and the well owner or operator are part of the same corporate structure or otherwise similarly affiliated. However, the licensee shall still otherwise meet the requirements in R313-38-15(1)(a) through (e).~~

~~**R313-38-17. Request for Written Statements.**~~

~~_____ Licenses are issued with the condition that the licensee will, prior to expiration of the license, upon the Executive Secretary's request, submit written statements, signed under oath or affirmation, to enable the Executive Secretary to determine whether or not the license should be modified, suspended, or revoked.~~

~~**R313-38-20. Limits on Levels of Radiation.**~~

~~_____ Sources of radiation shall be used, stored, and transported in a manner that meets the transportation requirements in R313-19-100 and the dose limitation requirements of R313-15.~~

~~**R313-38-31. Labels, Security, and Transportation Precautions.**~~

- ~~_____ (1) Labels.~~
 - ~~_____ (a) The licensee may not use a source, source holder, or logging tool that contains licensed material unless the smallest component that is transported as a separate piece of equipment with the licensed material inside bears a durable, legible, and clearly visible marking or label. The marking or label must contain the radiation symbol specified in R313-15-901(1), without the color requirements, and the wording "CAUTION (or DANGER) RADIOACTIVE MATERIAL."~~
 - ~~_____ (b) The licensee may not use a container to store licensed material unless the container has securely attached to it a durable, legible, and clearly visible label. The label must contain the radiation symbol specified in R313-15-901(1), and the wording "CAUTION (or DANGER) RADIOACTIVE MATERIAL, NOTIFY CIVIL AUTHORITIES (or NAME OF COMPANY)."~~
 - ~~_____ (c) The licensee may not transport licensed material unless the material is packaged, labeled, marked, and accompanied with~~

~~appropriate shipping papers in accordance with rules set out in R313-19-100.~~

~~(2) Security Precautions During Storage and Transportation.~~

~~(a) The licensee shall store sources containing licensed material in a storage container or transportation package. The container or package must be locked and physically secured to prevent tampering or removal of licensed material from storage by unauthorized personnel. The licensee shall store licensed material in a manner which will minimize danger from explosion or fire.~~

~~(b) The licensee shall lock and physically secure the transport package containing licensed material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the licensed material from the vehicle.~~

~~R313-38-33. Radiation Detection Instruments.~~

~~(1) The licensee or registrant shall keep a calibrated and operable radiation survey instrument capable of detecting beta and gamma radiation at field stations and temporary job sites to make the radiation surveys required by R313-38-67 and by R313-15-501. To satisfy this requirement, the radiation survey instrument must be capable of detecting dose rates over the range of one microsievert (0.1 mrem) per hour to at least 0.5 millisievert (50 mrem) per hour.~~

~~(2) The licensee or registrant shall have available additional calibrated and operable radiation detection instruments sensitive enough to detect the low radiation and contamination levels that could be encountered if a sealed source ruptured. The licensee or registrant may own the instruments or may have a procedure to obtain them quickly from a second party.~~

~~(3) The licensee or registrant shall have radiation survey instruments required under R313-38-33(1) calibrated:~~

~~(a) at intervals not to exceed six months and after instrument servicing;~~

~~(b) for linear scale instruments, at two points located approximately one-third and two-thirds of full-scale; for logarithmic scale instruments, at midrange of the decades, and at two points of at least one decade; and for digital instruments, at appropriate points; and~~

~~(c) so that an accuracy within plus or minus 20 percent of the calibration standard can be demonstrated on the scales.~~

~~(4) The licensee or registrant shall retain calibration records for a period of three years after the date of calibration for inspection by a representative of the Board or the Executive Secretary.~~

~~R313-38-35. Leak Testing of Sealed Sources.~~

~~(1) Testing and recordkeeping. Licensees using sealed sources of radioactive material shall have the sources tested for leakage. Records of leak test results shall be kept in units of kilobecquerels (uCi) and maintained for inspection by a representative of the Board or the Executive Secretary for three years after the leak test is performed.~~

~~(2) Method of Testing. Tests for leakage shall be performed~~

~~only by persons specifically authorized to perform those tests by the Executive Secretary, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The test sample shall be taken from the surface of the source, source holder, or from the surface of the device in which the source is stored or mounted and on which one might expect contamination to accumulate. The test sample shall be analyzed for radioactive contamination, and the analysis shall be capable of detecting the presence of 185 becquerels (0.005 uCi) of radioactive material on the test sample.~~

~~(3) Interval of Testing. Sealed sources of radioactive material shall be tested 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. In the absence of a certificate from a transferor indicating that a test has been made prior to the transfer, the sealed source shall not be put into use until tested. If it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.~~

~~(4) Removal of Leaking or Contaminated Sources. If the test reveals the presence of 185 becquerels (0.005 uCi) or more of leakage or contamination, the licensee shall immediately withdraw the source from use and shall cause it to be decontaminated, repaired, or disposed of in accordance with R313-15. A report shall be filed with the Executive Secretary in accordance with R313-15-1208.~~

~~(5) Exemptions. The following sources are exempt from the periodic leak test requirements of R313-38-35(1) through (4):~~

~~(a) hydrogen-3 sources;~~

~~(b) sources of radioactive material with a half-life of 30 days or less;~~

~~(c) sealed sources of radioactive material in gaseous form;~~

~~(d) sources of beta or gamma emitting radioactive material with an activity of 3.7 megabecquerels (100 uCi) or less; and~~

~~(e) sources of alpha-emitting radioactive material with an activity of 370 kilobecquerels (10 uCi) or less.~~

~~R313-38-37. Physical Inventory.~~

~~At intervals not to exceed six months licensees or registrants shall conduct a physical inventory to account for all sources of radiation received and possessed under the license. The licensee or registrant shall retain records of the inventory for three years from the date of the inventory for inspection by a representative of the Board or the Executive Secretary. The inventory must indicate the quantity and kind of licensed material, the location of the licensed material, the date of the inventory, and the name of the individual conducting the inventory. Physical inventory records may be combined with leak test records.~~

~~R313-38-39. Records of Use.~~

~~(1) Licensees or registrants shall maintain records for uses of sources of radiation showing:~~

~~(a) the make, model number, and a serial number or a~~

~~description of sources of radiation used;~~

~~(b) in the case of unsealed licensed material used for subsurface tracer studies, the radionuclide and quantity of activity used in a particular well and the disposition of unused tracer materials;~~

~~(c) the identity of the logging supervisor who is responsible for the sources of radiation and the identity of logging assistants present;~~

~~(d) the location and date of use.~~

~~(2) The licensee or registrant shall make the records required by R313-38-39(1) available for inspection by a representative of the Board or the Executive Secretary. The licensee or registrant shall retain the records for three years from the date of the recorded event.~~

~~R313-38-41. Design, Performance, and Certification Criteria for Sealed Sources Used in Downhole Operations.~~

~~(1) Sealed sources, except those containing radioactive material in gaseous form, used in downhole operations, and manufactured after January 1, 1982, shall be certified by the manufacturer, or other testing organization acceptable to the Executive Secretary, to meet the following minimum criteria:~~

~~(a) be of doubly encapsulated construction;~~

~~(b) contain radioactive material whose chemical and physical forms are as insoluble and non-dispersible as practical; and~~

~~(c) the sealed source's prototype has been tested and found to maintain its integrity after the following tests:~~

~~(i) temperature: the test source must be held at -40 degrees Celsius for 20 minutes, 600 degrees Celsius for one hour, and then be subject to a thermal shock test with a temperature drop from 600 degrees Celsius to 20 degrees Celsius within 15 seconds.~~

~~(ii) impact test: a five kilogram steel hammer, 2.5 centimeter in diameter, must be dropped from a height of one meter onto the test source.~~

~~(iii) vibration test: the test source must be subject to a vibration from 25 hertz to 500 hertz at five gravitational units amplitude for 30 minutes.~~

~~(iv) puncture test: a one gram hammer and pin, 0.3 centimeter pin diameter, must be dropped from a height of one meter onto the test source.~~

~~(v) pressure test: has been individually pressure tested to at least 24,600 pounds per square inch absolute (1.695×10^8 pascals) without failure.~~

~~(2) For sealed sources, except those containing radioactive material in gaseous form, acquired after July 14, 1989, in the absence of a certificate from a transferor certifying that an individual sealed source meets the requirements of R313-38-41(1), the sealed source shall not be put into use until the determinations and testing have been performed.~~

~~(3) Sealed sources, except those containing radioactive material in gaseous form, used in downhole operations after July 14, 1989, shall be certified by the manufacturer, or other testing organization acceptable to the Executive Secretary, as meeting the~~

~~sealed source performance requirements for oil well logging as contained in the American National Standard N43.6, "Classification of Sealed Radioactive Sources" in effect on July 14, 1989.~~

~~(4) Certification documents shall be maintained for inspection by a representative of the Board or the Executive Secretary for a period of two years after source disposal. If the source is abandoned downhole, the certification documents shall be maintained until the Executive Secretary authorizes disposition.~~

~~R313-38-43. Inspection, Maintenance, and Opening of a Source or Source Holder.~~

~~(1) Licensees or registrants shall visually check source holders, logging tools, and source handling tools, for defects before use, to ensure that the equipment is in good working condition and that required labeling is present. If defects are found, the equipment must be removed from service until repaired, and a record must be retained for three years after the defect is found.~~

~~(2) Licensees or registrants shall have a program for semiannual visual inspection and routine maintenance of source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars to ensure that the required labeling is legible and that no physical damage is visible. If defects are found, the equipment must be removed from service until repaired, and a record must be made listing: date, equipment involved, inspection and maintenance operations performed, defects found, and actions taken to correct the defects. These records must be retained for three years after the defect is found.~~

~~(3) Removal of a sealed source from a source holder or logging tool, and maintenance on sealed sources or holders in which sealed sources are contained may not be performed by the licensee unless a written procedure developed pursuant to R313-38-63 has been approved by the Executive Secretary, the Nuclear Regulatory Commission, or by an Agreement State.~~

~~(4) If a sealed source is stuck in the source holder, the licensee may not perform operations, like drilling, cutting, or chiseling, on the source holder unless the licensee is specifically approved by the Executive Secretary, the Nuclear Regulatory Commission or an Agreement State to perform this operation.~~

~~(5) The opening, repair, or modification of sealed sources must be performed by persons specifically approved to do so by the Executive Secretary, the Nuclear Regulatory Commission or an Agreement State.~~

~~R313-38-44. Handling Tools.~~

~~The licensee shall provide and require the use of tools that will assure remote handling of sealed sources other than low-activity calibration sources.~~

~~R313-38-45. Subsurface Tracer Studies.~~

~~(1) Protective gloves and appropriate protective clothing and equipment shall be used by personnel handling radioactive tracer~~

material. Precautions shall be taken to avoid ingestion or inhalation of radioactive material.

(2) Licensees shall not cause the injection of radioactive material into fresh water aquifers without prior written authorization from the Executive Secretary and other appropriate State Agencies.

~~R313-38-47. Radioactive Markers.~~

The licensee may use radioactive markers in wells only if the individual markers contain quantities of licensed material not exceeding the quantities specified in R313-19-71. The use of markers is subject only to the requirements of R313-38-37.

~~R313-38-48. Particle Accelerators.~~

Licensees or registrants shall not permit above-ground testing of particle accelerators, designed for use in well logging, which results in the production of radiation, except in areas or facilities controlled or shielded so that the requirements of R313-15-201 and R313-15-301, as applicable, are met.

~~R313-38-49. Uranium Sinker Bars.~~

Licensees may use a uranium sinker bar in well logging after July 14, 1988, only if it is legibly impressed with the words "CAUTION - RADIOACTIVE-DEPLETED URANIUM" and "NOTIFY CIVIL AUTHORITIES (or COMPANY NAME) IF FOUND."

~~R313-38-51. Use of a Sealed Source in a Well Without a Surface Casing.~~

Licensees may use a sealed source in a well without a surface casing for protecting fresh water aquifers only if the licensee follows a procedure for reducing the probability of the source becoming lodged in the well. The procedures must be approved by the Executive Secretary, the Nuclear Regulatory Commission or an Agreement State.

~~R313-38-61. Training Requirements.~~

(1) Licensees or registrants shall not permit individuals to act as a logging supervisor as defined in R313-38 until the individual has complied with the following:

(a) received, in a course recognized by the Executive Secretary, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State, instruction in the subjects outlined in R313-38-61(5) and demonstrated an understanding thereof by successfully completing a written test;

(b) read and received instruction in the rules contained in R313-38 and the applicable sections of R313-12, R313-15 and R313-18 or their equivalent, conditions of appropriate license or certificate of registration, and the licensee's or registrant's operating and emergency procedures, and demonstrated an understanding thereof; and

(c) has completed on-the-job training and demonstrated competence in the use of licensed materials, remote handling tools, and radiation survey instruments by a field evaluation.

~~(2) Licensees or registrants shall not permit individuals to act as a logging assistant as defined in R313-38 until the individual has complied with the following:~~

~~(a) read or received instruction in the licensee's or registrant's operating and emergency procedures and documented an understanding thereof;~~

~~(b) has received instruction in applicable sections of R313-12, R313-15 and R313-18 or their equivalent;~~

~~(c) demonstrated competence to use, under the personal supervision of the logging supervisor, the sources of radiation, related handling tools, and radiation survey instruments which will be used on the job; and~~

~~(d) has demonstrated understanding of the materials listed in R313-38-61(2)(a) and (b) by successfully completing a written or oral test.~~

~~(3) Licensees or registrants shall provide safety reviews for logging supervisors and logging assistants at least annually.~~

~~(4) The licensee or registrant shall maintain a record on logging supervisors and logging assistants training and annual safety review. The training records must include copies of written tests and dates of oral tests given after January 1, 1989. The training records must be retained until three years following the termination of employment. Records of annual safety reviews must list the topics discussed and be retained for three years.~~

~~(5) The licensee or registrant shall include the following subjects in the training required in R313-38-61(1)(a).~~

~~(a) Fundamentals of radiation safety including:~~

~~(i) characteristics of radiation;~~

~~(ii) units of radiation dose and quantity of radioactivity;~~

~~(iii) hazards of exposure to radiation;~~

~~(iv) levels of radiation from licensed material;~~

~~(v) methods of controlling radiation dose (time, distance, and shielding); and~~

~~(vi) radiation safety practices, including prevention of contamination, and methods of decontamination.~~

~~(b) Radiation detection instruments including:~~

~~(i) use, operation, calibration, and limitations of radiation survey instruments;~~

~~(ii) survey techniques; and~~

~~(iii) use of personnel monitoring equipment.~~

~~(c) Equipment to be used including:~~

~~(i) operation of equipment, including source handling equipment and remote handling tools;~~

~~(ii) storage, control, and disposal of licensed material; and~~

~~(iii) maintenance of equipment.~~

~~(d) The requirements of pertinent federal and state rules.~~

~~(e) Case histories of accidents in well logging.~~

~~**R313-38-63. Operating and Emergency Procedures.**~~

~~Licensees or registrants shall develop and follow written operating and emergency procedures that cover the following:~~

~~(1) the handling and use of sources of radiation including the use of sealed sources in wells without surface casing for~~

~~protecting fresh water aquifers, if appropriate;~~

~~(2) handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses in excess of the standards established in R313-15;~~

~~(3) methods and occasions for conducting radiation surveys;~~

~~(4) methods and occasions for locking and securing sources of radiation;~~

~~(5) personnel monitoring and the use of personnel monitoring equipment;~~

~~(6) transportation to temporary job sites and field stations, including the packaging and placing of sources of radiation in vehicles, placarding of vehicles, and securing sources of radiation during transportation;~~

~~(7) minimizing exposure of individuals in the event of an accident;~~

~~(8) procedure for notifying proper personnel in the event of an accident;~~

~~(9) maintenance of records;~~

~~(10) inspection and maintenance of sealed sources, source holders, logging tools, source handling tools, storage containers, transport containers, injection tools, and uranium sinker bars;~~

~~(11) procedure to be followed in the event a sealed source is lodged downhole;~~

~~(12) procedures to be used for picking up, receiving, and opening packages containing radioactive material;~~

~~(13) for the use of tracers, procedures to be used for decontamination of the environment, equipment, and personnel; and~~

~~(14) actions to be taken if a sealed source is ruptured including actions to prevent the spread of contamination and minimize inhalation and ingestion of licensed materials and actions to obtain suitable radiation survey instruments as required by R313-38-33.~~

~~R313-38-65. Personnel Monitoring.~~

~~(1) The licensee or registrant shall not permit an individual to act as the logging supervisor or logging assistant unless that person wears, at all times during the handling of sources of radiation, either a film badge or a thermoluminescent dosimeter (TLD). Film badges or TLD's must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and TLD's replaced at least quarterly. After replacement, the film badges or TLD's must be promptly processed.~~

~~(2) The licensee shall provide bioassay services to individuals using licensed materials in subsurface tracer studies if required by the license.~~

~~(3) The licensee or registrant shall retain records of film badge, TLD and bioassay results for inspection by a representative of the Board or the Executive Secretary.~~

~~R313-38-67. Radiation Surveys.~~

~~(1) The licensee shall make radiation surveys, including but not limited to, the surveys required under R313-38-67(2) through (6), of areas where licensed materials are used and stored.~~

~~(2) Before transporting licensed materials, the licensee shall make a radiation survey of the position occupied by individuals in the vehicle and of the exterior of a vehicle used to transport the licensed materials.~~

~~(3) If the sealed source assembly is removed from the logging tool before departure from the temporary job site, the licensee shall confirm that the logging tool is free of contamination by energizing the logging tool detector or by using a survey meter.~~

~~(4) If the licensee has reason to believe that, as a result of operations involving a sealed source, the encapsulation of the sealed source could be damaged by the operation, the licensee shall conduct a radiation survey, including a contamination survey, during and after the operation.~~

~~(5) The licensee shall make a radiation survey at the temporary job site before and after subsurface tracer studies to confirm the absence of contamination.~~

~~(6) The results of surveys required by R313-38-67(1) through (5) shall be recorded and must include the date of the survey, the name of the individual making the survey, the identification of the survey instrument used, and the location of the survey. The licensee shall retain records of surveys for three years after they are made, for inspection by a representative of the Board or the Executive Secretary.~~

~~R313-38-69. Radioactive Contamination Control.~~

~~(1) If the licensee detects evidence that a sealed source has ruptured or licensed materials have caused contamination, the licensee shall initiate immediately the emergency procedures required by R313-38-63.~~

~~(2) If contamination results from the use of licensed material in well logging, the licensee shall decontaminate all work areas, equipment, and unrestricted areas.~~

~~(3) During efforts to recover a sealed source lodged in the well, the licensee shall continuously monitor, with an appropriate radiation detection instrument or a logging tool with a radiation detector, the circulating fluids from the well, if they are present, to check for contamination resulting from damage to the sealed source.~~

~~R313-38-71. Security.~~

~~(1) A logging supervisor shall be physically present at a temporary job site whenever licensed material is being handled or is not stored and locked in a vehicle or storage place. The logging supervisor may leave the job site in order to obtain assistance if a source becomes lodged in a well.~~

~~(2) During well logging, except when radiation sources are below ground or in shipping or storage containers, the logging supervisor or individual designated by the logging supervisor shall maintain direct surveillance of the operation to prevent unauthorized entry into a restricted area, as defined in R313-12-3.~~

~~R313-38-73. Documents and Records Required at Field Stations.~~

~~Licensees or registrants shall maintain, for inspection by a~~

~~representative of the Board or the Executive Secretary, the following documents and records for the specific devices and sources used at the field station:~~

- ~~(1) appropriate license, certificate or registration, or equivalent document;~~
- ~~(2) operating and emergency procedures;~~
- ~~(3) a copy of R313-12, R313-15, R313-16, R313-18, R313-19 and R313-38 of the Utah Radiation Control rules, as applicable;~~
- ~~(4) records of the latest survey instrument calibrations pursuant to R313-38-33;~~
- ~~(5) records of the latest leak test results pursuant to R313-38-35;~~
- ~~(6) physical inventory records required pursuant to R313-38-37;~~
- ~~(7) utilization records required pursuant to R313-38-39;~~
- ~~(8) records of inspection and maintenance required pursuant to R313-38-43;~~
- ~~(9) training records required by R313-38-61; and~~
- ~~(10) survey records required pursuant to R313-38-67.~~

~~R313-38-75. Documents and Records Required at Temporary Job Sites.~~

~~Licenses or registrants conducting operations at a temporary job site shall have the following documents and records available at that site for inspection by a representative of the Board or the Executive Secretary:~~

- ~~(1) operating and emergency procedures;~~
- ~~(2) survey records required pursuant to R313-38-67 for the period of operation at the site;~~
- ~~(3) evidence of current calibration for the radiation survey instruments in use at the site; and~~
- ~~(4) when operating in the State under reciprocity, a copy of the appropriate license, certificate of registration, or equivalent document.~~

~~R313-38-77. Notification of Incidents, Abandonment, and Lost Sources.~~

~~(1) Notification of incidents and sources lost in other than downhole logging operations shall be made in accordance with appropriate provisions of R313-15.~~

~~(2) Whenever a sealed source or device containing radioactive material is lodged downhole, the licensee shall:~~

~~(a) monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations; and~~

~~(b) notify the Executive Secretary immediately by telephone if radioactive contamination is detected at the surface or if the source appears to be damaged.~~

~~(3) When it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee shall:~~

~~(a) advise the well owner or operator, as appropriate, of the Utah Radiation Control Rules regarding abandonment and an appropriate method of abandonment, which shall include:~~

~~(i) the immobilization and sealing in place of the~~

radioactive source with a cement plug;

~~(ii) the setting of a whipstock or other deflection device, and~~

~~(iii) the mounting of a permanent identification plaque, at the surface of the well, containing the appropriate information required by R313-38-15(1)(e);~~

~~(b) notify the Executive Secretary by telephone, giving the circumstances of the loss, and request approval of the proposed abandonment procedures; and~~

~~(c) file a written report with the Executive Secretary within 30 days of the abandonment, setting forth the following information:~~

~~(i) date of occurrence and a brief description of attempts to recover the source;~~

~~(ii) a description of the radioactive source involved, including radionuclide, quantity, and chemical and physical form;~~

~~(iii) surface location and identification of well;~~

~~(iv) results of efforts to immobilize and set the source in place;~~

~~(v) depth of the radioactive source;~~

~~(vi) depth of the top of the cement plug;~~

~~(vii) depth of the well; and~~

~~(viii) information contained on the permanent identification plaque.~~

~~(4) The licensee shall immediately notify the Executive Secretary by telephone and subsequently by confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable water source. Notices shall designate the well location and shall describe the magnitude and extent of loss of radioactive material, assess the consequences of the loss, and explain efforts planning or being taken to mitigate these consequences.~~

~~R313-38-91. Exemptions.~~

~~The Executive Secretary may, upon application of interested persons or upon his initiative, grant exemptions from the requirements of the rules in R313-38 as he determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.~~

~~R313-38-98. Example of Plaque for Identifying Wells Containing Sealed Sources Containing Radioactive Material Abandoned Downhole.~~

~~TABLE~~

~~" (COMPANY NAME)~~

~~(WELL IDENTIFICATION)~~

~~CAUTION~~

~~ONE - TWO CURIE CS-137 RADIOACTIVE SOURCE ABANDONED
March 3, 1975 AT 8400 FEET PLUG BACK DEPTH 8200 FEET~~

~~DO NOT RE-ENTER THIS WELL BEFORE CONTACTING~~

~~THE EXECUTIVE SECRETARY OF THE~~

UTAH RADIATION CONTROL BOARD

~~The size of the plaque should be convenient for use on active or inactive wells, for example, a seven inch square letter size of the word "CAUTION" should be approximately twice the letter size of the rest of the information, or one-half inch and one-quarter inch letter size respectively.~~

~~KEY: radioactive material, well logging, wireline studies, subsurface tracer~~

~~1994~~

~~19-3-104~~

~~Notice of Continuation January 25, 1999~~

~~19-3-113]~~

R313. Environmental Quality, Radiation Control.

R313-38. Licenses and Radiation Safety Requirements for Well Logging.

R313-38-1. Purpose and Authority.

(1) Rule R313-38 prescribes requirements for the issuance of a license authorizing the use of licensed materials including sealed sources, radioactive tracers, radioactive markers, and uranium sinker bars in well logging in a single well. This rule also prescribes radiation safety requirements for persons using licensed materials in these operations.

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

(3) The provisions and requirements of Rule R313-38 are in addition to, and not in substitution for, the other requirements of these rules. In particular, the provisions of Rules R313-15, R313-18, R313-19, and R313-22 apply to applicants and licensees subject to these rules.

R313-38-2. Scope

(1) The requirements of Rule R313-38 do not apply to the issuance of a license authorizing the use of licensed material in tracer studies involving multiple wells, such as field flooding studies, or to the use of sealed sources auxiliary to well logging but not lowered into wells.

R313-38-3. Clarifications or Exceptions.

For purposes of Rule R313-38, 10 CFR 39 (2001), is incorporated by reference with the following clarifications or exceptions:

(1) The exclusion of the following 10 CFR sections: 39.1, 39.5, 39.8, 39.11, 39.101, and 39.103;

(2) The exclusion of the following 10 CFR references within 10 CFR 39: Sec. 40.32, and Sec. 70.33;

(3) The exclusion of "licensed material" in 10 CFR 39.2 definitions;

(4) The substitution of the following wording:

(a) License for reference to NRC license;

(b) Utah Radiation Control Rules for the references to:

(i) The Commission's regulations;

(ii) The NRC regulations;

(iii) NRC regulations; and

(iv) Pertinent Federal regulations;

(c) Executive Secretary for reference to Commission, except as stated in Subsection R313-38-3(4)(d);

(d) Representatives of the Executive Secretary for the references to the Commission in:

(i) 10 CFR 39.33(d);

(ii) 10 CFR 39.35(a);

(iii) 10 CFR 39.37;
(iv) 10 CFR 39.39(b); and
(v) 10 CFR 39.67(f);
(e) Executive Secretary or the Executive Secretary for references
to:
(i) NRC in:
(A) 10 CFR 39.63(1);
(B) 10 CFR 39.77(c)(1)(i) and (ii); and
(C) 10 CFR 39.77(d)(9); and
(ii) Appropriate NRC Regional Office in:
(A) 10 CFR 39.77(a);
(B) 10 CFR 39.77(c)(1); and
(C) 10 CFR 39.77(d);
(f) Executive Secretary, the U.S. Nuclear Regulatory Commission or
an Agreement State for the references to:
(i) Commission or an Agreement State in:
(A) 10 CFR 39.35(b); and
(B) 10 CFR 39.43(d) and (e); and
(ii) Commission pursuant to Sec. 39.13(c) or by an Agreement State
in:
(A) 10 CFR 39.43(c); and
(B) 10 CFR 39.51;
(g) In 10 CFR 39.35(d)(1), persons specifically licensed by the
Executive Secretary, the U.S. Nuclear Regulatory Commission, or an
Agreement State for the reference to an NRC or Agreement State licensee
that is authorized; and
(h) In 10 CFR 39.35(d)(2), reports of test results for leaking or
contaminated sealed sources shall be made pursuant to Section R313-15-
1208, for the reference to the following statement:
(i) The licensee shall submit a report to the appropriate NRC
Regional Office listed in appendix D of part 20 of this chapter, within
5 days of receiving the test results. The report must describe the
equipment involved in the leak, the test results, any contamination which
resulted from the leaking source, and the corrective actions taken up to
the time the report is made; and
(i) In 10 CFR 39.75(e), a U.S. Nuclear Regulatory Commission or an
Agreement State for the reference to the Agreement State;
(5) The substitution of the following Title R313 references for
specific 10 CFR references:
(a) Section R313-12-3 for the reference to Sec. 20.1003 of this
chapter;
(b) Section R313-12-54 for the reference to 10 CFR 39.17;
(c) Subsection R313-12-55(1) for the reference to 10 CFR 39.91;
(d) Rule R313-15 for references to:
(i) Part 20; and
(ii) Part 20 of this chapter;
(e) Subsection R313-15-901(1) for the reference to Sec. 20.1901(a);
(f) Section R313-15-906 for the reference to Sec. 20.205 of this
chapter;
(g) Sections R313-15-1201 through R313-15-1203 for the references
to:
(i) Secs. 20.2201-20.2202; and
(ii) Sec. 20.2203;
(h) Rule R313-18 for the reference to part 19;
(i) Section R313-19-30 for the reference to Sec. 150.20 of this
chapter;
(j) Section R313-19-50 for the references to:
(i) Sec. 30.50; and

- (ii) Part 21 of this chapter;
- (k) Section R313-19-71 for the reference to Sec. 30.71;
- (l) Section R313-19-100 for the references to:
- (i) 10 CFR Part 71; and
- (ii) Sec. 71.5 of this chapter; and
- (m) Section R313-22-33 for the reference to 10 CFR 30.33;

KEY: radioactive material, well logging, surveys, subsurface tracer studies

2001

19-3-104

Notice of Continuation January 25, 1999

19-3-108

R313. Environmental Quality, Radiation Control.

R313-34. Requirements for Irradiators.

R313-34-1. Purpose and Authority.

(1) Rule R313-34 prescribes requirements for the issuance of licenses authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation.

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

(3) The requirements of Rule R313-34 are in addition to, and not in substitution for, the other requirements of these rules.

R313-34-2. Scope.

(1) Rule R313-34 shall apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources; underwater irradiators in which both the source and the product being irradiated are under water; and irradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type.

(2) The requirements of Rule R313-34 shall not apply to self-contained dry-source-storage irradiators in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel, medical radiology or teletherapy, the irradiation of materials for nondestructive testing purposes, gauging, or open-field agricultural irradiations.

R313-34-3. Clarifications or Exemptions.

For purposes of Rule R313-34, 10 CFR 36, [~~2000~~2001 ed., is incorporated by reference with the following clarifications or exceptions:

(1) The exclusion of the following 10 CFR sections: 36.1, 36.5, 36.8, 36.11, 36.17, 36.19(a), 36.91, and 36.93;

(2) The substitution of the following:

(a) Radiation Control Act for Atomic Energy Act of 1954;

(b) Utah Radiation Control Rules for the reference to NRC regulations and the Commission's regulations;

(c) The Executive Secretary or the Executive Secretary's for the Commission or the Commission's, and NRC in the following 10 CFR sections: 36.13, 36.13(f), 36.15, 36.19(b), 36.53(c), 36.69, and 36.81(a), 36.81(d) and 36.81(e); and

(d) In 10 CFR 36.51(a)(1), Rule R313-15 for NRC;

(3) Appendix B of 10 CFR Part 20 refers to the [~~2000~~2001 ed. of 10 CFR; and

(4) The substitution of Title R313 references for the following 10 CFR references:

(a) Section R313-12-51 for reference to 10 CFR 30.51;

(b) Rule R313-15 for the reference to 10 CFR 20;

(c) Subsection R313-15-501(3) for the reference to 10 CFR 20.1501(c);

(d) Section R313-15-902 for the reference to 10 CFR 20.1902;

(e) Rule R313-18 for the reference to 10 CFR 19;

(f) Section R313-19-41 for the reference to 10 CFR 30.41;

- (g) Section R313-19-50 for the reference to 10 CFR 30.50;
- (h) Section R313-22-33 for the reference to 10 CFR 30.33;
- (i) Section R313-22-210 for the reference to 10 CFR 32.210;
- (j) Section R313-22-35 for the reference to 10 CFR 30.35; and
- (k) Rule R313-70 for the reference to 10 CFR 170.31.

KEY: irradiator, survey, radiation, radiation safety

[~~March 10, 2000~~]2001

19-3-104

Notice of Continuation April 3, 2000

R313. Environmental Quality, Radiation Control.

R313-32. Medical Use of Radioactive Material.

R313-32-1. Purpose and Authority.

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

(2) The rules set forth herein are adopted pursuant to the provisions of Sections 19-3-104(3) and 19-3-104(6).

R313-32-2. Definitions.

"Authorized nuclear pharmacist" means a pharmacist who is:

(a) board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties;

(b) identified as an authorized nuclear pharmacist on a Nuclear Regulatory Commission or Agreement State license that authorizes the use of radioactive material in the practice of nuclear pharmacy; or

(c) identified as an authorized nuclear pharmacist on a permit issued by a Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of radioactive material in the practice of nuclear pharmacy.

"Authorized user" means a physician, dentist, or podiatrist who is:

(a) board certified by at least one of the boards listed in Paragraph (1) of R313-32-910, R313-32-920, R313-32-930, R313-32-940, R313-32-950, or R313-32-960;

(b) identified as an authorized user on a Nuclear Regulatory Commission or Agreement State license that authorizes the medical use of radioactive material; or

(c) identified as an authorized user on a permit issued by a Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material.

"Brachytherapy source" means an individual sealed source or a manufacturer-assembled source train that is not designed to be disassembled by the user.

"Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

"Dental use" means the intentional external administration of the radiation from radioactive material to human beings in the practice of dentistry in accordance with a license issued by this state.

"Dentist" means an individual licensed by this state to practice dentistry.

"Diagnostic clinical procedures manual" means a collection of written procedures that describes each method, other instructions, and precautions, by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been

approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

"Management" means the chief executive officer or that person's delegate.

"Medical institution" means an organization in which several medical disciplines are practiced.

"Medical use" means the intentional internal or external administration of radioactive material, or the radiation therefrom, to patients or human research subjects under the supervision of an authorized user.

"Ministerial change" means a change that is made, after ascertaining the applicable requirements, by persons in authority in conformance with the requirements and without making a discretionary judgement about whether those requirements should apply in the case at hand.

"Misadministration" means the administration of:

(a) A radiopharmaceutical dosage greater than 1.11 MBq (30 uCi) of either sodium iodide I-125 or I-131:

(i) involving the wrong individual, or wrong radiopharmaceutical; or

(ii) when both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 1.11 MBq (30 uCi).

(b) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:

(i) involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or

(ii) when the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

(c) A gamma stereotactic radiosurgery radiation dose:

(i) involving the wrong individual or wrong treatment site; or

(ii) when the calculated total administered dose differs from the total prescribed dose by more than ten percent of the total prescribed dose.

(d) A teletherapy radiation dose:

(i) involving the wrong individual, wrong mode of treatment, or wrong treatment site;

(ii) when the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than ten percent of the total prescribed dose;

(iii) when the calculated weekly administered dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose; or

(iv) when the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

(e) A brachytherapy radiation dose:

(i) involving the wrong individual, wrong radionuclide, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the

treatment site);

- (ii) involving a sealed source that is leaking;
- (iii) when, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or
- (iv) when the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

(f) A diagnostic radiopharmaceutical dosage, other than quantities greater than 1.11 MBq (30 uCi) of either sodium iodide I-125 or I-131, or both:

- (i) involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and
- (ii) when the dose to the individual exceeds 0.05 Sv (five rems) effective dose equivalent or 0.5 Sv (50 rems) dose equivalent to any individual organ.

"Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

"Pharmacist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

"Podiatric use" means the intentional external administration of the radiation from radioactive material to human beings in the practice of podiatry in accordance with a license issued by this State.

"Podiatrist" means an individual licensed by this State to practice podiatry.

"Prescribed dosage" means the quantity of radiopharmaceutical activity as documented:

- (a) in a written directive; or
- (b) either in the diagnostic clinical procedures manual or in an appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

"Prescribed dose" means:

- (a) for gamma stereotactic radiosurgery, the total dose as documented in the written directive;
- (b) for teletherapy, the total dose and dose per fraction as documented in the written directive; or
- (c) for brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive.

"Radiation Safety Officer" means the individual identified as the Radiation Safety Officer on a license issued by the Executive Secretary.

"Recordable event" means the administration of:

- (a) a radiopharmaceutical or radiation without a written directive where a written directive is required;
- (b) a radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;

(c) a radiopharmaceutical dosage greater than 1.11 MBq (30 uCi) of either sodium iodide I-125 or I-131 when both:

(i) the administered dosage differs from the prescribed dosage by more than ten percent of the prescribed dosage, and

(ii) the difference between the administered dosage and prescribed dosage exceed 555 kBq (15 uCi);

(d) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than ten percent of the prescribed dosage;

(e) A teletherapy radiation dose when the calculated weekly administered dose exceeds the weekly prescribed dose by 15 percent or more of the weekly prescribed dose; or

(f) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than ten percent of the prescribed dose.

"Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"Teletherapy physicist" means the individual identified as the teletherapy physicist on a license issued by the Executive Secretary.

"Visiting authorized user" means an authorized user who is not identified as an authorized user on the license of the licensee being visited.

"Written directive" means an order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in paragraph (f) of this definition, containing the following information:

(a) for any administration of quantities greater than 1.11 MBq (30 uCi) of either sodium iodide I-125 or I-131: the dosage;

(b) for a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

(c) for gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;

(d) for teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;

(e) for high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or

(f) for all other brachytherapy:

(i) prior to implantation: the radionuclide, number of sources, and source strengths; and

(ii) after implantation but prior to completion of the procedure: the radionuclide, treatment site, and total source strength and exposure time, or equivalently, the total dose.

R313-32-6. Provisions for Research Involving Human Subjects.

A licensee may conduct research involving human subjects using radioactive material provided that the research is conducted, funded, supported, or regulated by a Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive

approval of a specific amendment to its Utah license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

R313-32-7. FDA, other Federal, and State Requirements.

Nothing in R313-32 relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

R313-32-11. License Required.

(1) A person shall not manufacture, produce, acquire, receive, possess, use, or transfer radioactive material for medical use except in accordance with a specific license issued by the Executive Secretary, the Nuclear Regulatory Commission, or an Agreement State, or as allowed in R313-32-11(2) or (3).

(2) An individual shall receive, possess, use, or transfer radioactive material in accordance with the Utah Radiation Control Rules under the supervision of an authorized user as provided in R313-32-25, unless prohibited by license condition.

(3) An individual may prepare unsealed radioactive material for medical use in accordance with R313-32 under the supervision of an authorized nuclear pharmacist or authorized user as provided in R313-32-25, unless prohibited by license condition.

R313-32-12. Application for License, Amendment, or Renewal.

(1) If the application is for medical use sited in a medical institution, only the institution's management may apply. If the application is for medical use not sited in a medical institution, any person may apply.

(2) An application for a license for medical use of radioactive material as described in R313-32-100, R313-32-200, R313-32-300, R313-32-400, and R313-32-500 must be made by filing of Form DRC-02, "Application for Materials License." For guidance in completing the form, refer to the instructions in the most current versions of the appropriate Regulatory Guides. A request for a license amendment or renewal may be submitted in a letter format.

(3) An applicant that satisfies the requirements specified in R313-22-50(2) may apply for a Type A specific license of broad scope.

R313-32-13. License Amendment.

A licensee shall apply for and receive a license amendment:

(1) before it receives or uses radioactive material for a clinical procedure permitted under R313-32 but not permitted by the license issued pursuant to R313-32;

(2) before it permits anyone to work as an authorized user or authorized nuclear pharmacist under the license, except an individual who is:

(a) an authorized user certified by the organizations

specified in paragraph (1) of R313-32-910, R313-32-920, R313-32-930, R313-32-940, R313-32-950, or R313-32-960;

(b) an authorized nuclear pharmacist certified by the organization specified in paragraph (1) of R313-32-980;

(c) identified as an authorized user or an authorized nuclear pharmacist on a Nuclear Regulatory Commission or an Agreement State license that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively, or

(d) identified as an authorized user or an authorized nuclear pharmacist on a permit issued by the Executive Secretary, the Nuclear Regulatory Commission or an Agreement State specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively.

(3) before it changes Radiation Safety Officers or Teletherapy Physicists;

(4) before it orders radioactive material in excess of the amount, or radionuclide or form different than authorized on the license; and

(5) before it adds to or changes the address or addresses of use identified on the license.

R313-32-14. Notifications.

(1) A licensee shall provide to the Executive Secretary a copy of the board certification, the Nuclear Regulatory Commission or Agreement State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user or an authorized nuclear pharmacist pursuant to R313-32-13(2)(a) through (2)(d).

(2) A licensee shall notify the Executive Secretary by letter no later than 30 days after:

(a) an authorized user, an authorized nuclear pharmacist, Radiation Safety Officer, or teletherapy physicist permanently discontinues performance of duties under the license or has a name change; or

(b) the licensee's mailing address changes.

(3) The licensee shall mail the documents required in R313-32-14 to the address identified in R313-12-110.

R313-32-15. Exemptions Regarding Type A Specific Licenses of Broad Scope.

A licensee possessing a Type A specific license of broad scope for medical use is exempt from the following:

(1) The provisions of R313-32-13(2);

(2) The provisions of R313-32-13(5) regarding additions to or changes in the areas of use only at the addresses specified in the license;

(3) The provisions of R313-32-14(1); and

(4) The provisions of R313-32-14(2)(a) for an authorized user or an authorized nuclear pharmacist.

R313-32-18. License Issuance.

The Executive Secretary shall issue a license for the medical use of radioactive material for a term of five years provided the following requirements are met:

(1) The applicant has filed form DRC-02 "Application for Materials License - Medical" in accordance with the instructions in R313-22-32.

(2) The applicant has paid any applicable fee as provided in R313-70.

(3) The Executive Secretary finds the applicant equipped and committed to observe the safety standards established in R313-15 for the protection of the public health and safety.

(4) In addition to the requirements set forth in R313-22-33 a specific license for human use of radioactive material in institutions will be issued if:

(a) the applicant has appointed a radiation safety committee to coordinate the use of radioactive material throughout that institution and to maintain surveillance over the institution's radiation safety program; and

(b) if the application is for a license to use unspecified quantities or multiple types of radioactive material, the applicant's staff has training and experience in the use of a variety of radioactive materials for a variety of human uses, and meets the training and experience requirements of R313-32.

(5) A specific license for the human use of radioactive material will be issued to an individual physician if the following are complied with:

(a) The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable.

(b) The applicant has training and experience as required by R313-32, in the handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients.

(c) The application is for use in the applicant's practice in an office outside a medical institution.

(d) The Executive Secretary shall not approve an application by an individual physician or group of physicians for a specific license to receive, possess or use radioactive material on the premises of a medical institution unless:

(i) the use of radioactive material is limited to:

(A) the administration of radiopharmaceuticals for diagnostic or therapeutic purposes;

(B) the performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered;

(C) the performance of in vitro diagnostic studies;

(D) the calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation and diagnostic instrumentation;

(ii) the physician brings the radioactive material with him and removes the radioactive material when he departs. The institution cannot receive, possess or store radioactive material other than the amount of material remaining in the patient; or

(iii) the medical institution does not hold a radioactive

material license issued pursuant to the provisions of R313-32-18(4).

R313-32-19. Specific Exemptions.

The Board may, upon application of any interested person or upon its own initiative, grant exemptions from the rules in R313-32 as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. The Board will review requests for exemptions from training and experience requirements with the assistance of the Executive Secretary.

R313-32-20. ALARA Program.

(1) The licensee shall develop and implement a written radiation protection program that includes provisions for keeping doses ALARA.

(2) To satisfy the requirement of R313-32-20(1) one of the following shall be implemented:

(a) At a medical institution, management, the Radiation Safety Officer, and authorized users shall participate in the program as requested by the Radiation Safety Committee.

(b) For licensees that are not medical institutions, management and authorized users shall participate in the program as requested by the Radiation Safety Officer.

(3) The program shall include notice to workers of the program's existence and workers' responsibility to help keep dose equivalents ALARA, a review of summaries of the types and amounts of radioactive material used, occupational doses, changes in radiation safety procedures and safety measures, and continuing education and training for personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that licensees make a reasonable effort to maintain individual and collective occupational doses ALARA.

R313-32-21. Radiation Safety Officer.

(1) A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

(2) The Radiation Safety Officer shall:

(a) investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, misadministrations, and other deviations from approved radiation safety practices and implement corrective actions as necessary;

(b) establish, collect in one binder or file, and implement written policy and procedures for:

(i) authorizing the purchase of radioactive material;

(ii) receiving and opening packages of radioactive material;

(iii) storing radioactive material;

(iv) keeping an inventory record of radioactive material;

(v) using radioactive material safely;

- (vi) taking emergency action if control of radioactive material is lost;
 - (vii) performing periodic radiation surveys;
 - (viii) performing checks of survey instruments and other safety equipment;
 - (ix) disposing of radioactive material;
 - (x) training personnel who work in or frequent areas where radioactive material is used or stored;
 - (xi) keeping a copy of all records and reports required by the Utah Radiation Control Rules, a copy of these rules, a copy of each licensing request, license and amendment, and written policy and procedures required by the rules;
- (c) brief management once a year on the radioactive material program;
- (d) establish personnel exposure investigational levels that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure;
- (e) establish personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence;
- (f) for medical use not at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management; and
- (g) for medical use at a medical institution, assist the Radiation Safety Committee in the performance of its duties.

R313-32-22. Radiation Safety Committee.

The medical institution licensee shall establish a Radiation Safety Committee to oversee the use of radioactive material.

(1) The Committee shall meet the following administrative requirements:

(a) Membership shall consist of at least three individuals and shall include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.

(b) The Committee shall meet at least quarterly.

(c) To establish a quorum and to conduct business, at least one-half of the Committee's membership shall be present, including the Radiation Safety Officer and the management's representative.

(d) The minutes of each Radiation Safety Committee meeting shall include:

- (i) the date of the meeting;
 - (ii) members present;
 - (iii) members absent;
 - (iv) summary of deliberations and discussions;
 - (v) recommended actions and the numerical results of all ballots; and
 - (vi) ALARA program reviews described in R313-32-20.
- (e) The Committee shall promptly provide the members with

copies of the meeting minutes, and retain one copy for the duration of the license.

(2) To oversee the use of licensed material, the Committee shall:

(a) review recommendations on ways to maintain individual and collective doses ALARA;

(b)(i) review, on the basis of safety and with regard to the training and experience standards in R313-32-900 through R313-32-981, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the Radiation Safety Officer, or a Teletherapy Physicist before submitting a license application or request for amendment or renewal; or

(ii) review, pursuant to R313-32-13(2)(a) through (2)(d), on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist;

(c) review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove minor changes in radiation safety procedures that are not potentially important to safety and are permitted under R313-32-31;

(d) review quarterly, with the assistance of the Radiation Safety Officer, a summary of the occupational radiation dose records of personnel working with radioactive material;

(e) review quarterly, with the assistance of the Radiation Safety Officer, incidents involving radioactive material with respect to cause and subsequent actions taken; and

(f) review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

R313-32-23. Statements of Authority and Responsibilities.

(1) A licensee shall provide the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, sufficient authority, organizational freedom, and management prerogative, to:

(a) identify radiation safety problems;

(b) initiate, recommend, or provide corrective actions; and

(c) verify implementation of corrective actions.

(2) A licensee shall establish and state in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, and retain the current edition of these statements as a record until the Executive Secretary terminates the license.

R313-32-25. Supervision.

(1) A licensee that permits the receipt, possession, use or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by R313-32-11(2) shall:

(a) instruct the supervised individual in the principles of

radiation safety appropriate to that individual's use of radioactive material and in the licensee's written quality management program;

(b) require the supervised individual to follow the instructions of the supervising authorized user, follow the written radiation safety and quality management procedures established by the licensee, and comply with the Utah Radiation Control Rules and the license conditions with respect to the use of radioactive material; and

(c) periodically review the supervised individual's use of radioactive material and the records kept to reflect this use.

(2) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by R313-32-11(3), shall:

(a) instruct the supervised individual in the preparation of radioactive material for medical use and the principles of and procedures for radiation safety and in the licensee's written quality management program, as appropriate to that individual's use of radioactive material;

(b) require the supervised individual to follow the instructions given pursuant to R313-32-25(2)(a) and to comply with these rules and license conditions; and

(c) require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing radioactive material for medical use and the records kept to reflect that work.

(3) A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

R313-32-29. Administrative Requirements that Apply to the Providers of Mobile Nuclear Medicine Service.

(1) The Executive Secretary will license mobile nuclear medicine service only in accordance with R313-32-100, R313-32-200, and R313-32-500.

(2) Mobile nuclear medicine service licensees shall obtain a letter signed by the management of each client for which services are rendered that authorizes use of radioactive material at the client's address of use. The mobile nuclear medicine service licensee shall retain the letter for three years after the last provision of service.

(3) If a mobile nuclear medicine service provides services that the client is also authorized to provide, the client is responsible for assuring that services are conducted in accordance with the rules while the mobile nuclear medicine service is under the client's direction.

(4) A mobile nuclear medicine service shall not order radioactive material to be delivered directly from the manufacturer or distributor to the client's address of use.

R313-32-31. Radiation Safety Program Changes.

(1) A licensee may make minor changes in radiation safety

procedures that are not potentially important to safety, i.e., ministerial changes, that were described in the application for license, renewal, or amendment except for those changes in R313-32-13 and R313-32-606. A licensee is responsible for assuring that any change made is in compliance with the requirements of the rules and the license.

(2) A licensee shall retain a record of each change until the license has been renewed or terminated. The record shall include the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected authorized users and of management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative.

R313-32-32. Quality Management Program.

(1) The applicant or licensee shall establish and maintain a written quality management program to provide high confidence that radioactive material or radiation from radioactive material will be administered as directed by the authorized user. The quality management program shall include written policies and procedures to meet the following specific objectives:

(a) that, prior to administration, a written directive is prepared for:

- (i) teletherapy radiation doses;
- (ii) gamma stereotactic radiosurgery radiation doses;
- (iii) brachytherapy radiation doses;
- (iv) administration of quantities greater than 1.11 MBq (30 uCi) of either sodium iodide I-125 or I-131;
- (v) therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131;

(b) that the following are exceptions to the written directive:

(i) if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision;

(ii) also, a written revision to an existing written directive may be made for a diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose;

(iii) if, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral

directive;

(c) that, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

(d) that final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

(e) that each administration is in accordance with the written directive; and

(f) that each unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

(2) The licensee shall:

(a) develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of:

(i) a representative sample of patient and human research subject administrations,

(ii) all recordable events, and

(iii) all misadministrations to verify compliance with each aspect of the quality management program; these reviews shall be conducted at intervals no greater than 12 months;

(b) evaluate these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of R313-32-32(1); and

(c) retain records of the review, including the evaluations and findings of the review, in an auditable form for three years.

(3) The licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:

(a) assembling the relevant facts including the cause;

(b) identifying what, if applicable, corrective action is required to prevent recurrence; and

(c) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if applicable, was taken.

(4) The licensee shall retain:

(a) a written directive; and

(b) a record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in R313-32-32(1)(a), in an auditable form, for three years after the date of administration.

(5) The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. The licensee shall furnish the modification to the Executive Secretary within 30 days after the modification has been made.

(6)(a) Applicants for a new license, as applicable, shall submit to the Executive Secretary in accordance with R313-12-110 a quality management program as part of the application for a license and implement the program upon issuance of the license by the Executive Secretary.

(b) Existing licensees, as applicable, shall submit to the Executive Secretary in accordance with R313-12-110, prior to March

1, 1995, a written certification that the quality management program has been implemented along with a copy of the program.

R313-32-33. Notifications, Reports and Records of Misadministrations.

(1) For a misadministration:

(a) the licensee shall notify the Executive Secretary by telephone no later than the next calendar day after discovery of the misadministration.

(b) the licensee shall submit a written report to the Executive Secretary within 15 days after discovery of the misadministration. The written report shall include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the individual who received the misadministration; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not; and if there was notification, what information was provided. The report must not include the individual's name or any other information that could lead to identification of the individual. To meet the requirements of R313-32-33, the notification of the individual receiving the misadministration may be made instead to that individual's responsible relative or guardian, when appropriate.

(c) the licensee shall notify the referring physician and also notify the individual receiving the misadministration of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the individual receiving the misadministration cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

(d) if the individual was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the individual by sending either:

(i) a copy of the report that was submitted to the Executive Secretary; or

(ii) a brief description of both the event and the consequences as they may affect the individual, provided a statement is included that the report submitted to the Executive Secretary can be obtained from the licensee.

(2) The licensee shall retain a record of each misadministration for five years. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual who received the misadministration, and that individual's referring physician, if applicable), the individual's social security number or other

identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the individual, improvements needed to prevent recurrence, and the actions taken to prevent recurrence.

(3) Aside from the notification requirement, nothing in R313-32-33 affects any rights or duties of licensees and physicians in relation to each other, to individuals receiving misadministrations, or to that individual's responsible relative or guardian.

R313-32-49. Suppliers for Sealed Sources or Devices for Medical Use.

A licensee may use for medical use only:

(1) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to the rules in R313-22 and R313-22-75(10) or the equivalent requirements of the Nuclear Regulatory Commission or an Agreement State; or

(2) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to R313-22 or the equivalent requirements of the Nuclear Regulatory Commission or an Agreement State.

R313-32-50. Possession, Use, Calibration, and Check of Dose Calibrators.

(1) A licensee shall possess and use a dose calibrator to measure the activity of dosages of photon-emitting radionuclides prior to administration to each patient or human research subject.

(2) A licensee shall:

(a) check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy this requirement, the check shall be done on a frequently used setting with a sealed source of not less than 370 kBq (ten uCi) of radium-226 or 1.85 MBq (50 uCi) for a photon-emitting radionuclide;

(b) test each dose calibrator for accuracy upon installation and at least annually thereafter by assaying at least two sealed sources containing different radionuclides whose activity the manufacturer has determined within five percent of its stated activity, whose activity is at least 370 kBq (ten uCi) for radium-226 and 1.85 MBq (50 uCi) for a photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

(c) test each dose calibrator for linearity upon installation and at least quarterly thereafter over a range from the highest dosage that will be administered to a patient or human research subject to 1.1 MBq (30 uCi); and

(d) test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(3) A licensee shall also perform appropriate checks and tests required by R313-32-50 following adjustment or repair of the dose calibrator.

(4) A licensee shall mathematically correct dosage readings for geometry or linearity errors that exceed ten percent if the dosage is greater than 370 kBq (ten uCi) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds ten percent.

(5) A licensee shall retain a record of each check and test required by R313-32-50 for three years unless directed otherwise. The records required in R313-32-50(2)(a) through (2)(d) shall include:

(a) for R313-32-50(2)(a), the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured, and the initials of the individual who performed the check;

(b) for R313-32-50(2)(b), the model and serial number of the dose calibrator, the model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the identity of the individual performing the test;

(c) for R313-32-50(2)(c), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the identity of the individual performing the test; and

(d) for R313-32-50(2)(d), the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the identity of the individual performing the test.

R313-32-51. Calibration and Check of Survey Instruments.

(1) A licensee shall calibrate the survey instruments used to show compliance with R313-32 before first use, annually, and following repair. The licensee shall:

(a) calibrate all scales with readings up to ten mSv (1000 mrem) per hour with a radiation source;

(b) calibrate two separated readings on each scale that shall be calibrated. The readings shall be separated by 50 percent of the scale reading; and

(c) conspicuously note on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

(2) When calibrating a survey instrument, the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and shall conspicuously attach a correction chart or graph to the instrument.

(3) A licensee shall check each survey instrument for proper operation with the dedicated check source each day of use. A licensee is not required to keep records of these checks.

(4) A licensee shall retain a record of each survey instrument calibration for three years. The record shall include:

(a) a description of the calibration procedure; and

(b) the date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the correction

factors deduced from the calibration data, and the signature of the individual who performed the calibration.

R313-32-52. Possession, Use, Calibration, and Check of Instruments to Measure Dosages or Alpha- or Beta-emitting Radionuclides.

(1) R313-32-52 does not apply to unit dosages of alpha- or beta-emitting radionuclides that are obtained from a manufacturer or preparer licensed pursuant to R313-22-75(9) or equivalent requirements of the Nuclear Regulatory Commission or an Agreement State.

(2) For other than unit dosages obtained pursuant to R313-32-52(1), a licensee shall possess and use instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. 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- or beta-emitting radionuclides prior to administration to each patient or human research subject. In addition, the licensee shall:

(a) 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

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

R313-32-53. Measurement of Dosages of Unsealed Radioactive Material for Medical Use.

A licensee shall:

(1) measure the activity of each dosage of a photon-emitting radionuclide prior to medical use;

(2) measure, by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha- or beta-emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to R313-22-75(9) or equivalent requirements of the Nuclear Regulatory Commission or an Agreement State; and

(3) retain a record of the measurements required by R313-32-53 for three years. To satisfy this requirement, the record shall contain the following:

(a) generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

(b) patient's or human research subject's name, and identification number if one has been assigned;

(c) prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than 1.1 MBq (30 uCi);

(d) date and time of the measurement; and

(e) initials of the individual who made the record.

R313-32-57. Authorization for Calibration and Reference Sources.

Persons authorized by R313-32-11 for medical use of

radioactive material may receive, possess, and use the following radioactive material for check, calibration, and reference use:

(1) sealed sources manufactured and distributed by a person licensed pursuant to R313-22-75(10) or equivalent Nuclear Regulatory Commission or Agreement State regulations and that do not exceed 555 MBq (15 mCi) each;

(2) radioactive material listed in R313-32-100 or R313-32-200 with a half-life not longer than 100 days in individual amounts not to exceed 555 MBq (15 mCi);

(3) radioactive material listed in R313-32-100 or R313-32-200 with a half-life longer than 100 days in individual amounts not to exceed 7.4 MBq (200 uCi); and

(4) technetium-99m in individual amounts not to exceed 1.85 GBq (50 mCi).

R313-32-59. Requirements for Possession of Sealed Sources and Brachytherapy Sources.

(1) A licensee in possession of sealed sources or brachytherapy sources shall follow the radiation safety and handling instructions supplied by the manufacturer, and shall maintain the instructions for the duration of source use in a legible form convenient to users.

(2) A licensee in possession of a sealed source shall:

(a) test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

(b) test the source for leakage at intervals not to exceed six months or at other intervals approved by the Executive Secretary, the Nuclear Regulatory Commission or an Agreement State and described in the label or brochure that accompanies the source.

(3) To satisfy the leak test requirements of R313-32-59, the licensee must:

(a) take a wipe sample from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which radioactive contamination might be expected to accumulate or wash the source in a small volume of detergent solution and treat the entire volume as the sample;

(b) take teletherapy and other device source test samples when the source is in the "off" position; and

(c) measure the sample so that the leakage test can detect the presence of 185 Bq (0.005 uCi) of radioactive material on the sample.

(4) A licensee shall retain leakage test records for five years. The records shall contain the model number, the serial number if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in becquerels or microcuries, a description of the method used to measure each test sample, the date of the test, and the signature of the Radiation Safety Officer.

(5) If the leakage test reveals the presence of 185 Bq (0.005 uCi) or more of removable contamination, the licensee shall:

(a) immediately withdraw the sealed source from use and store it in accordance with the requirements in R313-15; and

(b) file a report within five days of the leakage test with the Executive Secretary describing the equipment involved, the test results, and the action taken.

(6) A licensee need not perform a leakage test on the following sources:

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

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

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

(d) sources stored and not being used. The licensee shall, however, test each source for leakage before use or transfer unless it has been leakage-tested within six months before the date of use or transfer; and

(e) seeds of iridium-192 encased in nylon ribbon.

(7) A licensee in possession of a sealed source or brachytherapy source shall conduct a quarterly physical inventory of all sources in its possession. The licensee shall retain inventory records for five years. The inventory records shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the signature of the Radiation Safety Officer.

(8) A licensee in possession of a sealed source or brachytherapy source shall measure the ambient dose rates quarterly in all areas where sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

(9) A licensee shall retain a record of each survey required in R313-32-59(8) for three years. The record shall include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area expressed in microsieverts or millirem per hour, the survey instrument used, and the signature of the Radiation Safety Officer.

R313-32-60. Syringe Shields and Labels.

(1) A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield.

(2) To identify its contents, a licensee shall conspicuously label each syringe or syringe radiation shield that contains a syringe with a radiopharmaceutical. The label shall show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's or the human research subject's name.

(3) A licensee shall require each individual who prepares a radiopharmaceutical kit to use a syringe radiation shield when preparing the kit and shall require each individual to use a syringe radiation shield when administering a radiopharmaceutical by injection unless the use of the shield is contraindicated for that patient or human research subject.

R313-32-61. Vial Shields and Labels.

(1) A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

(2) To identify its contents, a licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical. The label shall show the radiopharmaceutical name or its abbreviation.

R313-32-70. Surveys for Contamination and Ambient Radiation Exposure Rate.

(1) A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

(2) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

(3) A licensee shall conduct the surveys required by R313-32-70(1) and (2) so as to be able to detect dose rates as low as one uSv (0.1 mrem) per hour.

(4) A licensee shall establish radiation dose rate trigger levels for the surveys required by R313-32-70(1) and (2). A licensee shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds a trigger level.

(5) A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

(6) A licensee shall conduct the survey required by R313-32-70(5) so as to be able to detect contamination on each wipe sample of 2200 disintegrations per minute, (0.001 uCi or 37 Bq).

(7) A licensee shall establish removable contamination trigger levels for the surveys required by R313-32-70(5). A licensee shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds the trigger level.

(8) A licensee shall retain a record of each survey for three years. The record shall include the date of the survey, a plan of each area surveyed, the trigger level established for each area, the detected dose rate at several points in each area expressed in microsieverts or millirem per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels or curies) per 100 square centimeters, the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

R313-32-75. Release of Individuals Containing Radiopharmaceuticals or Permanent Implants.

(1) The licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to

the released individual is not likely to exceed 5 mSv (0.5 rem).

NOTE: The Nuclear Regulatory Commission Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

(2) The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the dose to a breast-feeding infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include:

(a) guidance on the interruption or discontinuation of breast-feeding, and

(b) information on the consequences of failure to follow the guidance.

(3) The licensee shall maintain a record of the basis for authorizing the release of an individual, for three years after the date of release, if the total effective dose equivalent is calculated by:

(a) using the retained activity rather than the activity administered,

(b) using an occupancy factor less than 0.25 at 1 meter,

(c) using the biological or effective half-life, or

(d) considering the shielding by tissue.

(4) The licensee shall maintain a record, for three years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

R313-32-80. Technical Requirements that Apply to the Providers of Mobile Nuclear Medicine Service.

A licensee providing mobile nuclear medicine service shall:

(1) transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

(2) bring into each address of use all radioactive material to be used and, before leaving, remove all unused radioactive material and all associated waste;

(3) secure or keep under constant surveillance and immediate control all radioactive material when in transit or at an address of use;

(4) check survey instruments and dose calibrators as described in R313-32-50 and R313-32-51 and check all other transported equipment for proper function before medical use at each address of use;

(5) carry a radiation detection survey meter in each vehicle that is being used to transport radioactive material, and, before leaving a client address of use, survey all radiopharmaceutical areas of use with a radiation detection survey meter to ensure that

all radiopharmaceuticals and all associated waste have been removed; and

(6) retain a record of each survey required in R313-32-80(5) for three years. The record shall include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in microsieverts or millirems per hour, the instrument used to make the survey, and the initials of the individual who performed the survey.

R313-32-90. Storage of Volatiles and Gases.

A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container. A licensee shall store a multi-dose container in a fume hood after drawing the first dosage from it.

R313-32-92. Decay-In-Storage.

(1) A licensee may hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash and is exempt from the requirements of R313-15-1001 if it:

(a) holds radioactive material for decay a minimum of ten half-lives;

(b) monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey meter set on its most sensitive scale and with no interposed shielding;

(c) removes or obliterates all radiation labels; and

(d) separates and monitors each generator column individually with radiation shielding removed to ensure that it has decayed to background radiation level before disposal.

(2) A licensee shall retain a record of each disposal permitted under R313-32-92(1) for three years. The record shall include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

R313-32-100. Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies.

A licensee may use for uptake, dilution, or excretion studies any unsealed radioactive material prepared for medical use that is either:

(1) obtained from a manufacturer or preparer licensed pursuant to R313-22-75(9) or equivalent requirements of the Nuclear Regulatory Commission or an Agreement State; or

(2) prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in R313-32-920, or an individual under the supervision of either as specified in R313-32-25.

R313-32-120. Possession of Survey Instrument.

A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range one uSv (0.1 mrem) per hour to one mSv (100 mrem) per hour.

R313-32-200. Use of Unsealed Radioactive Material for Imaging and Localization Studies.

A licensee may use for imaging and localization studies any unsealed radioactive material prepared for medical use that is either:

(1) obtained from a manufacturer or preparer licensed pursuant to R313-22-75(9) or equivalent requirements of the Nuclear Regulatory Commission or an Agreement State; or

(2) prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in R313-32-920, or an individual under the supervision of either as specified in R313-32-25.

R313-32-204. Permissible Molybdenum-99 Concentration.

(1) A licensee shall not administer to humans a radiopharmaceutical containing more than 5.55 kBq (0.15 uCi) of molybdenum-99 per 37.0 MBq (one mCi) of technetium-99m.

(2) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each elute or extract.

(3) A licensee that is required to measure molybdenum concentration shall retain a record of each measurement for three years. The record shall include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in megabecquerels or millicuries, the measured activity of the molybdenum expressed in kilobecquerels or microcuries, the ratio of the measures expressed as kilobecquerels or microcuries of molybdenum per megabecquerels or millicuries of technetium, the time and date of the measurement, and the initials of the individual who made the measurement.

R313-32-205. Control of Aerosols and Gases.

(1) A licensee that administers radioactive aerosols or gases shall do so in a room with a system that will keep airborne concentrations within the limits prescribed in R313-15-201(4) and R313-15-301. The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(2) A licensee shall administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

(3) Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a spill to reduce the concentration in the room to the occupational limit as specified in R313-15-201. The calculation shall be based on the highest activity of gas handled in a single container, the air volume of the room, and the measured available air exhaust rate.

(4) A licensee shall make a record of the calculations required in R313-32-205(3) that includes the assumptions, measurements, and calculations made and shall retain the record for the duration of use of the area. A licensee shall also post the calculated time and safety measures to be instituted in case of a spill at the area of use.

(5) A licensee shall check the operation of reusable collection systems each month, and measure the ventilation rates available in areas of radioactive gas use each six months. Records of the measurement shall be kept for three years.

R313-32-220. Possession of Survey Instruments.

A licensee authorized to use radioactive material for imaging and localization studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range of one uSv (0.1 mrem) per hour to one mSv (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range ten uSv (one mrem) per hour to ten mSv (1000 mrem) per hour.

R313-32-300. Use of Unsealed Radioactive Material for Therapeutic Administration.

A licensee may use for therapeutic administration any unsealed radioactive material prepared for medical use that is either:

(1) obtained from a manufacturer or preparer licensed pursuant to R313-22-75(9) or equivalent requirements of the Nuclear Regulatory Commission or an Agreement State; or

(2) prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in R313-32-920, or an individual under the supervision of either as specified in R313-32-25.

R313-32-310. Safety Instruction.

(1) A licensee shall provide radiation safety instruction for all personnel caring for the patient or the human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with R313-32-75. To satisfy this requirement, the instruction shall describe the licensee's procedures for:

(a) patient or human research subject control;

(b) visitor control;

(c) contamination control;

(d) waste control; and

(e) notification of the Radiation Safety Officer in case of the patient's or the human research subjects's death or medical emergency.

(2) A licensee shall keep for three years a list of individuals receiving instruction required by R313-32-310(1), a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

R313-32-315. Safety Precautions.

(1) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with

R313-32-75, a licensee shall:

(a) provide a private room with a private sanitary facility;

(b) post the patient's or the human research subject's door with a "Radioactive Materials" sign and note on the door or in the patient's or the human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room;

(c) authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

(d) promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of R313-15, and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in microsieverts or millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

(e) either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste;

(f) survey the patient's or the human research subject's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient or human research subject to the room. The room shall not be reassigned until removable contamination is less than 200 disintegrations per minute per 100 square centimeters; and

(g) measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage, and retain for the period required by R313-15-1107 a record of each thyroid burden measurement, its date, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

(2) A licensee shall notify the Radiation Safety Officer immediately if the patient or the human research subject dies or has a medical emergency.

R313-32-320. Possession of Survey Instruments.

A licensee authorized to use radioactive material for radiopharmaceutical therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range one μSv (0.1 mrem) per hour to one mSv (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range ten μSv (one mrem) per hour to ten mSv (1000 mrem) per hour.

R313-32-400. Use of Sources for Brachytherapy.

A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:

(1) Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(2) Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(3) Gold-198 as a sealed source in seeds for interstitial treatment of cancer;

(4) Iridium-192 as seeds encased in nylon ribbon for interstitial and intracavitary treatment of cancer and as seeds for topical treatment of cancer;

(5) Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions;

(6) Iodine-125 as a sealed source in seeds for topical, interstitial and intracavitary treatment of cancer;

(7) Palladium-103 as a sealed source in seeds for interstitial treatment of cancer.

R313-32-404. Release of Patients or Human Research Subjects Treated With Temporary Implants.

(1) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a radiation survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed. The licensee shall not release from confinement for medical care a patient or a human research subject treated by temporary implant until all sources have been removed.

(2) A licensee shall retain a record of patient or human research subject surveys for three years. Each record shall include the date of the survey, the name of the patient or the human research subject, the dose rate from the patient or the human research subject expressed as microsieverts per hour or millirem per hour and measured at one meter from the patient or the human research subject, the survey instrument used, and the initials of the individual who made the survey.

R313-32-406. Brachytherapy Sources Inventory.

(1) Promptly after removing them from a patient or a human research subject, a licensee shall return brachytherapy sources to the storage area, and count the number returned to ensure that all sources taken from the storage area have been returned.

(2) A licensee shall make a record of brachytherapy source use which shall include:

(a) the names of the individuals permitted to handle the sources;

(b) the number and activity of sources removed from storage, the patient's or the human research subject's name and room number, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from storage; and

(c) the number and activity of sources returned to storage,

the patient's or the human research subject's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

(3) Immediately after implanting sources in a patient or a human research subject the licensee shall make a radiation survey of the patient or the human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

(4) A licensee shall retain the records required in R313-32-406(2) and (3) for three years.

R313-32-410. Safety Instruction.

(1) The licensee shall provide radiation safety instruction to all personnel caring for the patient or the human research subject undergoing implant therapy. To satisfy this requirement, the instruction shall describe:

- (a) size and appearance of the brachytherapy sources;
- (b) safe handling and shielding instructions in case of a dislodged source;
- (c) procedures for patient or human research subject control;
- (d) procedures for visitor control; and
- (e) procedures for notification of the Radiation Safety Officer if the patient or the human research subject dies or has a medical emergency.

(2) A licensee shall retain for three years a record of individuals receiving instruction required by R313-32-410(1), a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

R313-32-415. Safety Precautions.

(1) For each patient or human research subject receiving implant therapy and not released from licensee control pursuant to R313-32-75, a licensee shall:

(a) not quarter the patient or the human research subject in the same room with an individual who is not receiving radiation therapy;

(b) post the patient's or human research subject's door with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(c) authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

(d) promptly after implanting the material, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of R313-15, and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in microsieverts or millirem per hour, the instrument used to make the survey, and the initials

of the individual who made the survey; and

(e) provide the patient or the human research subject with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before releasing the individual if the individual was administered a permanent implant.

(2) A licensee shall notify the Radiation Safety Officer immediately if the patient or the human research subject dies or has a medical emergency.

R313-32-420. Possession of Survey Instrument.

A licensee authorized to use radioactive material for implant therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range one uSv (0.1 mrem) per hour to one mSv (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range ten uSv (one mrem) per hour to ten mSv (1000 mrem) per hour.

R313-32-500. Use of Sealed Sources for Diagnosis.

A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:

(1) iodine-125, americium-241, or gadolinium-153 as a sealed source in a device for bone mineral analysis; and

(2) iodine-125 as a sealed source in a portable imaging device.

R313-32-520. Availability of Survey Instrument.

A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range one uSv (0.1 mrem) per hour to one mSv per hour to (100 mrem) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range ten uSv (one mrem) per hour to ten mSv (1000 mrem) per hour. The instrument shall be calibrated in accordance with R313-32-51.

R313-32-600. Use of a Sealed Source in a Teletherapy Unit.

The rules and provisions of R313-32-600 through R313-32-647 govern the use of teletherapy units for medical use that contain a sealed source of cobalt-60 or cesium-137.

R313-32-605. Maintenance and Repair Restrictions.

Only a person specifically licensed by the Executive Secretary, the Nuclear Regulatory Commission, or an Agreement State to perform teletherapy unit maintenance and repair shall:

(1) install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source; or

(2) maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

R313-32-606. License Amendments.

In addition to the changes specified in R313-32-13, a licensee shall apply for and shall receive a license amendment before:

- (1) making any change in the treatment room shielding;
- (2) making any change in the location of the teletherapy unit within the treatment room;
- (3) using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;
- (4) relocating the teletherapy unit; or
- (5) allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

R313-32-610. Safety Instruction.

(1) A licensee shall post instructions at the teletherapy unit console. To satisfy this requirement, these instructions shall inform the operator of:

(a) the procedure to be followed to ensure that only the patient or the human research subject is in the treatment room before turning the primary beam of radiation on to begin a treatment or after a door interlock interruption; and

(b) the procedure to be followed if:

(i) the operator is unable to turn the primary beam of radiation off with controls outside the treatment room or any other abnormal operation occurs; and

(ii) the names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately contacted if the teletherapy unit or console operates abnormally.

(2) A licensee shall provide instruction in the topics identified in R313-32-610(1) to individuals who operate a teletherapy unit.

(3) A licensee shall retain for three years a record of individuals receiving instruction required by R313-32-610(2), a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

R313-32-615. Safety Precautions.

(1) A licensee shall control access to the teletherapy room by a door at each entrance.

(2) A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that will:

(a) prevent the operator from turning the primary beam of radiation on unless each treatment room entrance door is closed;

(b) turn the primary beam of radiation off immediately when an entrance door is opened; and

(c) prevent the primary beam of radiation from being turned on following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

(3) A licensee shall equip each entrance to the teletherapy room with a beam condition indicator light.

(4) A licensee shall install in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam

status.

(a) A radiation monitor shall provide visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source, and shall be observable by an individual entering the teletherapy room.

(b) A radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

(c) A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects.

(d) A licensee shall maintain a record of the check required by R313-32-615(4)(c) for three years. The record shall include the date of the check, notation that the monitor indicates when its detector is and is not exposed, and the initials of the individual who performed the check.

(e) If a radiation monitor is inoperable, the licensee shall require individuals entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in R313-32-615(4)(d).

(f) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

(5) A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient or the human research subject from the teletherapy unit console during irradiation.

R313-32-620. Possession of Survey Instrument.

A licensee authorized to use radioactive material in a teletherapy unit shall have in its possession either a portable radiation detection survey instrument capable of detecting dose rates over the range one μSv (0.1 mrem) per hour to one mSv (100 mrem) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range ten μSv (one mrem) per hour to ten mSv (1000 mrem) per hour.

R313-32-630. Dosimetry Equipment.

(1) A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:

(a) The system shall be calibrated by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration shall have been performed within the previous two years and after any servicing that may have affected system calibration.

(b) The system shall have been calibrated within the previous four years; eighteen to thirty months after that calibration, the system shall have been intercompared at an intercomparison meeting

with another dosimetry system that was calibrated within the past twenty-four months by the National Bureau of Standards or by a calibration laboratory accredited by the AAPM. The intercomparison meeting shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM. The results of the intercomparison meeting shall have indicated that the calibration factor of the licensee's system had not changed by more than two percent. The licensee shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.

(2) The licensee shall have available for use a dosimetry system for spot-check measurements. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with R313-32-630(1). This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in R313-32-630(1).

(3) The licensee shall retain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by R313-32-630(1) and (2), the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by AAPM.

R313-32-632. Full Calibration Measurements.

(1) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

- (a) before the first medical use of the unit; and
- (b) before medical use under the following conditions:
 - (i) whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
 - (ii) following replacement of the source or following reinstallation of the teletherapy unit in a new location; or
 - (iii) following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
- (c) at intervals not exceeding one year.

(2) To satisfy the requirement of R313-32-632(1), full calibration measurements shall include determination of:

- (a) the output within plus or minus three percent for the

range of field sizes and for the distance or range of distances used for medical use;

(b) the coincidence of the radiation field and the field indicated by the light beam localizing device;

(c) the uniformity of the radiation field and its dependence on the orientation of the useful beam;

(d) timer constancy and linearity over the range of use;

(e) on-off error; and

(f) the accuracy of all distance measuring and localization devices in medical use.

(3) A licensee shall use the dosimetry system described in R313-32-630(1) to measure the output for one set of exposure conditions. The remaining radiation measurements required in R313-32-632(2)(a) may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by R313-32-632(1) in accordance with either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in Physics in Medicine and Biology Vol. 16, No. 3, 1971, pp. 379-396, or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics Vol. 10, No. 6, 1983, pp. 741-711, and Vol. 11, No. 2, 1984, p. 213.

(5) A licensee shall correct mathematically the outputs determined in R313-32-632(2)(a) for physical decay for intervals not exceeding one month for cobalt-60 or six months for cesium-137.

(6) Full calibration measurement required in R313-32-632(1) and physical decay corrections required by R313-32-632(5) shall be performed by the licensee teletherapy physicist.

(7) A licensee shall retain a record of each calibration for the duration of the teletherapy unit source. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, an assessment of timer linearity and constancy, the calculated on-off error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.

R313-32-634. Periodic Spot-Checks.

(1) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

(a) timer constancy, and timer linearity over the range of use;

(b) on-off error;

(c) the coincidence of the radiation field and the field indicated by the light beam localizing device;

(d) the accuracy of all distance measuring and localization devices used for medical use;

(e) the output for one typical set of operating conditions measured with the dosimetry system described in R313-32-630(2); and

(f) the difference between the measurement made in R313-32-634(2)(e) and the anticipated output, expressed as a percentage of the anticipated output (the value obtained at last full calibration corrected mathematically for physical decay).

(2) A licensee shall perform measurements required by R313-32-634(1) in accordance with procedures established by the teletherapy physicist. That individual need not actually perform the spot-check measurements.

(3) A licensee shall have the teletherapy physicist review the results of each spot-check within 15 days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each spot-check. The licensee shall keep a copy of each written notification for three years.

(4) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks for each teletherapy facility once in each calendar month that assure proper operation of:

(a) electrical interlocks at each teletherapy room entrance;

(b) electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(c) beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

(d) viewing systems;

(e) treatment room doors from inside and outside the treatment room; and

(f) electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(5) A licensee shall arrange for prompt repair of any system identified in R313-32-634(4) that is not operating properly, and shall not use the teletherapy unit following door interlock malfunction until the interlock system has been repaired.

(6) A licensee shall retain a record of each spot-check required by R313-32-634(1) and (4) for three years. The record shall include the date of the spot-check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, an assessment of linearity and constancy, the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the calculated on-off error, the determined accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot-check.

R313-32-636. Safety Checks for Teletherapy Facilities.

(1) A licensee shall promptly check all systems listed in R313-32-634(4) for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by R313-32-606(1) through (4).

(2) If the results of the checks required in R313-32-636(1) indicate the malfunction of a system specified in R313-32-634(4), the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(3) A licensee shall retain for three years a record of the facility checks following installation of a source. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, and doors, and the signature of the Radiation Safety Officer.

R313-32-641. Radiation Surveys for Teletherapy Facilities.

(1) Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by R313-32-606(1) through (4), the licensee shall perform radiation surveys with a portable radiation measurement survey instrument calibrated in accordance with R313-32-51 to verify that:

(a) the maximum and average dose rates at one meter from the teletherapy source with the source in the off position and the collimators set for a normal treatment field do not exceed 100 uSv (ten mrem) per hour and 20 uSv (two mrem) per hour, respectively;

(b) with the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of the radiation, that:

(i) radiation dose [~~quantities per unit time~~] rates in restricted areas are not likely to cause [~~personnel exposures~~] any occupationally exposed individual to receive a dose in excess of the limits specified in R313-15-201; and

(ii) radiation dose [~~quantities per unit time~~] rates in controlled or unrestricted areas [do not exceed] are not likely to cause any individual member of the public to receive a dose in excess of the limits specified in R313-15-301.

(2) If the results of the surveys required in R313-32-641(1) indicate any radiation dose quantity per unit time in excess of the respective limit specified in R313-32-641(1), the licensee shall lock the control in the off position and not use the unit:

(a) except as may be necessary to repair, replace, or test the teletherapy unit shielding or the treatment room shielding; or

(b) until the licensee has received a specific exemption pursuant to R313-12-54.

(3) A licensee shall retain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, the instrument used to measure radiation levels, each dose

rate measured around the teletherapy source while in the off position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microseverts or millirem per hour, the calculated maximum quantity of radiation over a period of one week for each restricted and unrestricted area, and the signature of the Radiation Safety Officer.

R313-32-643. Modification of Teletherapy Unit or Room Before Beginning a Treatment Program.

(1) If the survey required by R313-32-641 indicates that an individual ~~[in an unrestricted area may be exposed to levels of radiation greater than those permitted by]~~ member of the public is likely to receive a dose in excess of the limits specified in R313-15-301, [before beginning the treatment program] the licensee shall, before beginning the treatment program:

(a) either equip the unit with stops or add additional radiation shielding to ensure compliance with R313-15-301(3);
(b) perform the survey required by R313-32-641 again; and
(c) include in the report required by R313-32-645 the results of the initial survey, a description of the modification made to comply with R313-32-643(1)(a), and the results of the second survey.

(2) As an alternative to the requirements set out in R313-32-643(1), a licensee may request a license amendment under R313-15-301(3) that authorizes radiation levels in unrestricted areas greater than those permitted by R313-15-301(1). A licensee shall not begin the treatment program until the license amendment has been issued.

R313-32-645. Reports of Teletherapy Surveys, Checks, Tests and Measurements.

A licensee shall mail a copy of the records required in R313-32-636, R313-32-641, R313-32-643, and the output from the teletherapy source expressed as coulombs/kilogram (roentgens) or gray (rad) per hour at one meter from the source and determined during the full calibration required in R313-32-632 to the Executive Secretary within thirty days following completion of the action that initiated the record requirement.

R313-32-647. Five-Year Inspection.

(1) A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(2) This inspection and servicing shall only be performed by persons specifically licensed to do so by the Executive Secretary, the Nuclear Regulatory Commission, or an Agreement State.

(3) A licensee shall keep a record of the inspection and servicing for the duration of the license. The record shall contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of

components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

R313-32-900. Radiation Safety Officer.

Except as provided in R313-32-901, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in R313-32-21 to be an individual who:

- (1) is certified by:
 - (a) American Board of Health Physics in comprehensive health physics;
 - (b) American Board of Radiology;
 - (c) American Board of Nuclear Medicine;
 - (d) American Board of Science in nuclear medicine;
 - (e) Board of Pharmaceutical Specialties in nuclear pharmacy;
 - (f) American Board of Medical Physics in radiation oncology physics;
 - (g) Royal College of Physicians and Surgeons of Canada in nuclear medicine;
 - (h) American Osteopathic Board of Radiology; or
 - (i) American Osteopathic Board of Nuclear Medicine; or
- (2) has had classroom and laboratory training and experience as follows:
 - (a) 200 hours of classroom and laboratory training that includes:
 - (i) radiation physics and instrumentation;
 - (ii) radiation protection;
 - (iii) mathematics pertaining to the use and measurement of radioactivity;
 - (iv) radiation biology; and
 - (v) radiopharmaceutical chemistry; and
 - (b) one year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a license issued by the Executive Secretary, Nuclear Regulatory Commission or Agreement State license that authorizes the medical use of radioactive material; or
- (3) be an authorized user identified on the licensee's license.

R313-32-901. Training for Experienced Radiation Safety Officer.

An individual identified as a Radiation Safety Officer on a license issued by the Executive Secretary, Nuclear Regulatory Commission or Agreement State before January 1, 1989, need not comply with the training requirements of R313-32-900.

R313-32-910. Training for Uptake, Dilution, and Excretion Studies.

Except as provided in R313-32-970 and R313-32-971, the licensee shall require the authorized user of a radiopharmaceutical in R313-32-100(1) to be a physician who:

- (1) is certified in:
 - (a) nuclear medicine by the American Board of Nuclear Medicine;

(b) diagnostic radiology by the American Board of Radiology;
(c) diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

(d) nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(e) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

(2) has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows:

(a) 40 hours of classroom and laboratory training that includes:

(i) radiation physics and instrumentation;
(ii) radiation protection;
(iii) mathematics pertaining to the use and measurement of radioactivity;

(iv) radiation biology; and
(v) radiopharmaceutical chemistry; and

(b) 20 hours of supervised clinical experience under the supervision of an authorized user and that includes:

(i) examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(ii) selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(iii) administering dosages to patients or human research subjects and using syringe radiation shields;

(iv) collaborating with the authorized user in the interpretation of radionuclide test results; and

(v) patient or human research subject follow-up; or

(3) has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in the topics identified in R313-32-910(2).

R313-32-920. Training for Imaging and Localization Studies.

Except as provided in R313-32-970 or R313-32-971, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in R313-32-200(1) to be a physician who:

(1) is certified in:

(a) nuclear medicine by the American Board of Nuclear Medicine;

(b) diagnostic radiology by the American Board of Radiology;

(c) diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

(d) nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(e) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

(2) has had classroom and laboratory training in basic

radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows:

(a) 200 hours of classroom and laboratory training that includes:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity;

(iv) radiopharmaceutical chemistry; and

(v) radiation biology; and

(b) 500 hours of supervised work experience under the supervision of an authorized user that includes:

(i) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

(iii) calculating and safely preparing patient or human research subject dosages;

(iv) using administrative controls to prevent the misadministration of radioactive material;

(v) using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) eluting technetium-99m from generator systems, measuring and testing the elute for molybdenum-99 and alumina contamination, and processing the elute with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

(c) 500 hours of supervised clinical experience under the supervision of the authorized user that includes:

(i) examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(ii) selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(iii) administering dosages to patients or human research subjects and using syringe radiation shields;

(iv) collaborating with the authorized user in the interpretation of radioisotope test results; and

(v) patient or human research subject follow-up; or

(3) has successfully completed a six-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in the topics identified in R313-32-920(2).

R313-32-930. Training for Therapeutic Use of Unsealed Radioactive Material.

Except as provided in R313-32-970, the licensee shall require the authorized user of radiopharmaceuticals in R313-32-300 to be a physician who:

(1) is certified by:

(a) the American Board of Nuclear Medicine;

(b) the American Board of Radiology in radiology, therapeutic

radiology, or radiation oncology;

(c) nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(d) the American Osteopathic Board of Radiology after 1984;
or

(2) has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows:

(a) 80 hours of classroom and laboratory training that includes:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity; and

(iv) radiation biology; and

(b) supervised clinical experience under the supervision of an authorized user at a medical institution that includes:

(i) use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in ten individuals; and

(ii) use of iodine-131 for treatment of thyroid carcinoma in three individuals.

R313-32-932. Training for Treatment of Hyperthyroidism.

Except as provided in R313-32-970, the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows:

(1) 80 hours of classroom and laboratory training that includes:

(a) radiation physics and instrumentation;

(b) radiation protection;

(c) mathematics pertaining to the use and measurement of radioactivity; and

(d) radiation biology; and

(2) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in ten individuals.

R313-32-934. Training for Treatment of Thyroid Carcinoma.

Except as provided in R313-32-970, the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma, and supervised clinical experience as follows:

(1) 80 hours of classroom and laboratory training that

includes:

- (a) radiation physics and instrumentation;
 - (b) radiation protection;
 - (c) mathematics pertaining to the use and measurement of radioactivity; and
 - (d) radiation biology; and
- (2) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in three individuals.

R313-32-940. Training for Use of Brachytherapy Sources.

Except as provided in R313-32-970 the licensee shall require the authorized user of a brachytherapy source listed in R313-32-400 for therapy to be a physician who:

- (1) is certified in:
 - (a) radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;
 - (b) radiation oncology by the American Osteopathic Board of Radiology;
 - (c) radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
 - (d) therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or
- (2) is in the active practice of therapeutic radiology, has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows:
 - (a) 200 hours of classroom and laboratory training that includes:
 - (i) radiation physics and instrumentation;
 - (ii) radiation protection;
 - (iii) mathematics pertaining to the use and measurement of radioactivity; and
 - (iv) radiation biology;
 - (b) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:
 - (i) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (ii) checking survey meters for proper operation;
 - (iii) preparing, implanting, and removing sealed sources;
 - (iv) maintaining running inventories of material on hand;
 - (v) using administrative controls to prevent the misadministration of radioactive material; and
 - (vi) using emergency procedures to control radioactive material; and
 - (c) three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and

an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

- (i) examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;
- (ii) selecting the proper brachytherapy sources and dose and method of administration;
- (iii) calculating the dose; and
- (iv) post-administration follow-up and review of case histories in collaboration with the authorized user.

R313-32-941. Training for Ophthalmic Use of Strontium-90.

Except as provided in R313-32-970, the licensee shall require the authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows:

- (1) 24 hours of classroom and laboratory training that includes:
 - (a) radiation physics and instrumentation;
 - (b) radiation protection;
 - (c) mathematics pertaining to the use and measurement of radioactivity; and
 - (d) radiation biology.
- (2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals that includes:
 - (a) examination of each individual to be treated;
 - (b) calculation of the dose to be administered;
 - (c) administration of the dose; and
 - (d) follow-up and review of each individual's case history.

R313-32-950. Training for Use of Sealed Sources for Diagnosis.

Except as provided in R313-32-970, the licensee shall require the authorized user of a sealed source in a device listed in R313-32-500 to be a physician, dentist, or podiatrist who:

- (1) is certified in
 - (a) radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;
 - (b) nuclear medicine by the American Board of Nuclear Medicine;
 - (c) diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
 - (d) nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or
- (2) has had eight hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes:

- (a) radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;
- (b) radiation biology;
- (c) radiation protection; and
- (d) training in the use of the device for the uses requested.

R313-32-960. Training for Teletherapy.

Except as provided in R313-32-970, the licensee shall require the authorized user of a sealed source listed in R313-32-600 in a teletherapy unit to be a physician who:

- (1) is certified in:
 - (a) radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;
 - (b) radiation oncology by the American Osteopathic Board of Radiology;
 - (c) radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
 - (d) therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or
- (2) is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, supervised work experience, and supervised clinical experience as follows:
 - (a) 200 hours of classroom and laboratory training that includes:
 - (i) radiation physics and instrumentation;
 - (ii) radiation protection;
 - (iii) mathematics pertaining to the use and measurement of radioactivity; and
 - (iv) radiation biology;
 - (b) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:
 - (i) review of the full calibration measurements and periodic spot checks;
 - (ii) preparing treatment plans and calculating treatment times;
 - (iii) using administrative controls to prevent misadministrations;
 - (iv) implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and
 - (v) checking and using survey meters; and
 - (c) three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

(i) examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;

(ii) selecting the proper dose and how it is to be administered;

(iii) calculating the teletherapy doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and

(iv) post-administration follow-up and review of case histories.

R313-32-961. Training for Teletherapy Physicist.

The licensee shall require the teletherapy physicist to be an individual who:

(1) is certified by the American Board of Radiology in:

(a) therapeutic radiological physics;

(b) roentgen ray and gamma ray physics;

(c) x-ray and radium physics; or

(d) radiological physics; or

(2) is certified by the American Board of Medical Physics in radiation oncology physics; or

(3) holds a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and has completed one year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of a teletherapy physicist at a medical institution that includes the tasks listed in R313-32-59, R313-32-632, R313-32-634 and R313-32-641.

R313-32-970. Training for Experienced Authorized Users.

Physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of radioactive material on a license issued by the Executive Secretary, Nuclear Regulatory Commission, or Agreement State license issued before January 1, 1989, who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of R313-32-900 to R313-32-961.

R313-32-971. Physician Training in a Three Month Program.

A physician who, before October 1, 1988, began a three month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program need not comply with the requirements of R313-32-910 or R313-32-920.

R313-32-972. Recentness of Training.

The training and experience specified in R313-32-900 through R313-32-981 shall have been obtained within the seven years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

R313-32-980. Training for an Authorized Nuclear Pharmacist.

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(1) has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties, or

(2)(a) has completed 700 hours in a structured educational program consisting of both:

(i) didactic training in the following areas:

(A) radiation physics and instrumentation;

(B) radiation protection;

(C) mathematics pertaining to the use and measurement of radioactivity;

(D) chemistry of radioactive material for medical use; and

(E) radiation biology; and

(ii) supervised experience in a nuclear pharmacy involving the following:

(A) shipping, receiving, and performing related radiation surveys;

(B) using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) using administrative controls to avoid mistakes in the administration of radioactive material;

(E) using procedures to prevent or minimize contamination and using proper decontamination procedures; and

(b) has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

R313-32-981. Training for Experienced Nuclear Pharmacists.

A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in R313-32-980(2)(a) before January 1, 1998 and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement (See R313-32-980(2)(b)) and recentness of training (See R313-32-972) to qualify as an authorized nuclear pharmacist.

R313-32-999. Resolution of Conflicting Requirements During Transition Period.

If the rules in R313-32 conflict with the licensee's radiation safety program as identified in its license, and if that license was approved by the Bureau of Radiation Control, Department of Health, before January 1, 1989, and has not been renewed since January 1, 1989, then the requirements in the license will apply.

However, if the licensee exercises its privilege to make minor changes in its radiation safety procedures that are not potentially important to safety under R313-32-31, the portion changed shall comply with the requirements of R313-32. At the time of license renewal and thereafter, these amendments to R313-32 shall apply.

KEY: radioactive material, radiopharmaceutical, brachytherapy, nuclear medicine

[~~August 11, 1998~~]2001

19-3-104

Notice of Continuation May 1, 1997

19-3-108

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.

"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, [~~2000~~]2001 ed. or the equivalent regulations of an Agreement State.

(7) As provided by Section R313-22-35, certain applications for specific licenses filed under these rules shall contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning. In the case of renewal applications submitted before January 1, 1995, this submittal may follow the renewal application but shall be submitted on or before January 1, 1995.

(8)(a) Applications to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in Section R313-22-90, "Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release", shall contain either:

(i) An evaluation showing that the maximum dose to a individual off-site due to a release of radioactive materials would not exceed one rem effective dose equivalent or five rems to the thyroid; or

(ii) An emergency plan for responding to a release of radioactive material.

(b) One or more of the following factors may be used to support an evaluation submitted under Subsection R313-22-32(8)(a)(i):

(i) The radioactive material is physically separated so that only a portion could be involved in an accident;

(ii) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(iii) The release fraction in the respirable size range would be lower than the release fraction shown in Section R313-22-90 due to the chemical or physical form of the material;

(iv) The solubility of the radioactive material would reduce the dose received;

(v) Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Section R313-22-90;

(vi) Operating restrictions or procedures would prevent a release fraction as large as that shown in Section R313-22-90; or

(vii) Other factors appropriate for the specific facility.

(c) An emergency plan for responding to a release of

radioactive material submitted under Subsection R313-22-32(8)(a)(ii) shall include the following information:

(i) Facility description. A brief description of the licensee's facility and area near the site.

(ii) Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.

(iii) Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

(iv) Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

(v) Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers on-site, and a description of the program for maintaining equipment.

(vi) Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

(vii) Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying off-site response organizations and the Executive Secretary; also responsibilities for developing, maintaining, and updating the plan.

(viii) Notification and coordination. A commitment to and a brief description of the means to promptly notify off-site response organizations and request off-site assistance, including medical assistance for the treatment of contaminated injured on-site workers when appropriate. A control point shall be established. The notification and coordination shall be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the Executive Secretary immediately after notification of the appropriate off-site response organizations and not later than one hour after the licensee declares an emergency.

NOTE: These reporting requirements do not supersede or release licensees of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499 or other state or federal reporting requirements, including 40 CFR 302, [~~1992~~2000 ed.

(ix) Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to off-site response organizations and to the Executive Secretary.

(x) Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site

including the use of team training for the scenarios.

(xi) Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

(xii) Exercises. Provisions for conducting quarterly communications checks with off-site response organizations and biennial on-site exercises to test response to simulated emergencies. Quarterly communications checks with off-site response organizations shall include the check and update of all necessary telephone numbers. The licensee shall invite off-site response organizations to participate in the biennial exercises. Participation of off-site response organizations in biennial exercises although recommended is not required. Exercises shall use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises shall evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques shall be corrected.

(xiii) Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

(d) The licensee shall allow the off-site response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the Executive Secretary. The licensee shall provide any comments received within the 60 days to the Executive Secretary with the emergency plan.

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

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

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

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

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

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

(e) the applicant satisfies applicable special requirements in Sections R313-22-50 and R313-22-75, and Rules R313-25, 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, [~~2000~~2001 ed., which is incorporated by reference, shall submit a decommissioning funding plan as described in Subsection R313-22-35(5). The decommissioning funding plan shall also be submitted when a combination of radionuclides is involved if R divided by 10^5 is greater than one, where R is defined here as the sum of the ratios of the quantity of each radionuclide to the

applicable value in Appendix B of 10 CFR 30.1 through 30.72, [~~2000~~2001 ed., which is incorporated by reference.

(2) Applicants for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in Subsection R313-22-35(4) shall either:

(a) submit a decommissioning funding plan as described in Subsection R313-22-35(5); or

(b) submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by Subsection R313-22-35(4) using one of the methods described in Subsection R313-22-35(6). For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but before the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of Subsection R313-22-35(6) shall be submitted to the Executive Secretary before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the Executive Secretary, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements in Subsection R313-22-35(6).

(3)(a) Holders of a specific license issued on or after January 1, 1995, which is of a type described in Subsections R313-22-35(1) or (2) shall provide financial assurance for decommissioning in accordance with the criteria set forth in Section R313-22-35.

(b) Holders of a specific license issued before January 1, 1995, and of a type described in Subsection R313-22-35(1) shall submit, on or before January 1, 1995, a decommissioning funding plan as described in Subsection R313-22-35(5) or a certification of financial assurance for decommissioning in an amount at least equal to \$750,000 in accordance with the criteria set forth in Section R313-22-35. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan, the licensee shall include a decommissioning funding plan in any application for license renewal.

(c) Holders of a specific license issued before January 1, 1995, and of a type described in Subsection R313-22-35(2) shall submit, on or before January 1, 1995, a decommissioning funding plan as described in Subsection R313-22-35(5) or a certification of financial assurance for decommissioning in accordance with the criteria set forth in Section R313-22-35.

(d) A licensee who has submitted an application before January 1, 1995, for renewal of license in accordance with Section R313-22-37 shall provide financial assurance for decommissioning in accordance with Subsections R313-22-35(1) and (2). This assurance shall be submitted before January 1, 1997.

(4) Table of required amounts of financial assurance for decommissioning by quantity of material:

TABLE

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, [~~2000~~2001 ed., which is incorporated by reference, in unsealed form. For a combination of radionuclides, if R, as defined in Subsection R313-22-35(1) divided by 10^4 is greater than one but R divided by 10^5 is less than or equal to one:

\$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, [~~2000~~2001 ed., which is incorporated by reference, in unsealed form. For a combination of radionuclides, if R, as defined in Subsection R313-22-35(1) divided by 10^3 is greater than one but R divided by 10^4 is less than or equal to one:

\$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, [~~2000~~2001 ed., which is incorporated by reference, in sealed sources or plated foils. For combination of radionuclides, if R, as defined in R313-22-35(1), divided by 10^{10} is greater than one:

\$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);

(d) In the case of Federal, State or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in Subsection R313-22-35(4) and indicating that funds for decommissioning will be obtained when necessary; or

(e) When a governmental entity is assuming custody and

ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(7) Persons licensed under Rule R313-22 shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with Subsection R313-19-34(2), licensees shall transfer all records described in Subsections R313-22-35(7)(a) through (d) to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the Executive Secretary considers important to decommissioning consists of the following:

(a) records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records shall include any known information on identification of involved nuclides, quantities, forms, and concentrations;

(b) as-built drawings and modification of structures and equipment in restricted areas where radioactive materials are used or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations;

(c) except for areas containing only sealed sources, provided the sources have not leaked or no contamination remains after a leak, or radioactive materials having only half-lives of less than 65 days, a list contained in a single document and updated every two years, including all of the following:

(i) all areas designated and formerly designated as restricted areas as defined under Section R313-12-3;

(ii) all areas outside of restricted areas that require documentation under Subsection R313-22-35(7)(a);

(iii) all areas outside of restricted areas where current and previous wastes have been buried as documented under Section R313-15-1109; and

(iv) all areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in Sections R313-15-401 through R313-15-406, or apply for approval for disposal under Section R313-15-1002; and

(d) records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

(8) Criteria relating to use of financial tests and parent company guarantees for providing reasonable assurance of funds for decommissioning.

(a) To pass the financial test referred to in Subsection R313-22-35(6)(b), the parent company shall meet one of the following criteria:

(i) The parent company shall have all of the following:

(A) Two of the following three ratios: a ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5;

(B) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates, or prescribed amount if a certification is used;

(C) Tangible net worth of at least \$10 million; and

(D) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates, or prescribed amount if a certification is used; or

(ii) The parent company shall have all of the following:

(A) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or Aaa, Aa, A or Baa as issued by Moody's;

(B) Tangible net worth at least six times the current decommissioning cost estimate, or prescribed amount if a certification is used;

(C) Tangible net worth of at least \$10 million; and

(D) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates, or prescribed amount if certification is used.

(b) The parent company's independent certified public accountant shall have compared the data used by the parent company in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform the Executive Secretary within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(c)(i) After the initial financial test, the parent company shall repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

(ii) If the parent company no longer meets the requirements of Subsection R313-22-35(8)(a) the licensee shall send notice to the Executive Secretary of intent to establish alternative financial assurance as specified in Section R313-22-35. The notice shall be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee shall provide alternate financial assurance within 120

days after the end of such fiscal year.

(d) The terms of a parent company guarantee which an applicant or licensee obtains shall provide that:

(i) The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the Executive Secretary. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Executive Secretary, as evidenced by the return receipts.

(ii) If the licensee fails to provide alternate financial assurance as specified in Section R313-22-35 within 90 days after receipt by the licensee and Executive Secretary of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

(iii) The parent company guarantee and financial test provisions shall remain in effect until the Executive Secretary has terminated the license.

(iv) If a trust is established for decommissioning costs, the trustee and trust shall be acceptable to the Executive Secretary. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(9) Criteria relating to use of financial tests and self guarantees for providing reasonable assurance of funds for decommissioning.

(a) To pass the financial test referred to in Subsection R313-22-35(6)(b), a company shall meet all of the following criteria:

(i) Tangible net worth at least ten times the total current decommissioning cost estimate, or the current amount required if certification is used, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor;

(ii) Assets located in the United States amounting to at least 90 percent of total assets or at least ten times the total current decommissioning cost estimate, or the current amount required if certification is used, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor; and

(iii) A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poor's, or Aaa, Aa, or A as issued by Moody's.

(b) To pass the financial test, a company shall meet all of the following additional requirements:

(i) The company shall have at least one class of equity securities registered under the Securities Exchange Act of 1934;

(ii) The company's independent certified public accountant shall have compared the data used by the company in the financial test which is derived from the independently audited, yearend financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure,

the licensee shall inform the Executive Secretary within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test; and

(iii) After the initial financial test, the company shall repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(c) If the licensee no longer meets the requirements of Subsection R313-22-35(9)(a), the licensee shall send immediate notice to the Executive Secretary of its intent to establish alternate financial assurance as specified in Section R313-22-35 within 120 days of such notice.

(d) The terms of a self-guarantee which an applicant or licensee furnishes shall provide that:

(i) The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Executive Secretary. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Executive Secretary, as evidenced by the return receipt.

(ii) The licensee shall provide alternative financial assurance as specified in Section R313-22-35 within 90 days following receipt by the Executive Secretary of a notice of a cancellation of the guarantee.

(iii) The guarantee and financial test provisions shall remain in effect until the Executive Secretary has terminated the license or until another financial assurance method acceptable to the Executive Secretary has been put in effect by the licensee.

(iv) The licensee shall promptly forward to the Executive Secretary and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

(v) If, at any time, the licensee's most recent bond issuance ceases to be rated in a category of "A" or above by either Standard and Poor's or Moody's, the licensee shall provide notice in writing of such fact to the Executive Secretary within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poor's and Moody's, the licensee no longer meets the requirements of Subsection R313-22-35(9)(a).

(vi) The applicant or licensee shall provide to the Executive Secretary a written guarantee, a written commitment by a corporate officer, which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Board, the licensee shall set up and fund a trust in the amount of the current cost estimates for decommissioning.

R313-22-36. Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas.

(1) A specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under Section R313-22-37 no less than 30

days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days prior to the expiration date stated in the existing license, the existing license expires at the end of the day on which the Executive Secretary makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(2) A specific license revoked by the Executive Secretary expires at the end of the day on the date of the Executive Secretary's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by an Order issued by the Executive Secretary.

(3) A specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the Executive Secretary notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

(a) limit actions involving radioactive material to those related to decommissioning; and

(b) continue to control entry to restricted areas until they are suitable for release so that there is not an undue hazard to public health and safety or the environment.

(4) Within 60 days of the occurrence of any of the following, a licensee shall provide notification to the Executive Secretary in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release so that there is not an undue hazard to public health and safety or the environment, or submit within 12 months of notification a decommissioning plan, if required by Subsection R313-22-36(7), and begin decommissioning upon approval of that plan if:

(a) the license has expired pursuant to Subsections R313-22-36(1) or (2); or

(b) the licensee has decided to permanently cease principal activities at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release because of an undue hazard to public health and safety or the environment; or

(c) no principal activities under the license have been conducted for a period of 24 months; or

(d) no principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release because of an undue hazard to public health and safety or the environment.

(5) Coincident with the notification required by Subsection R313-22-36(4), the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to Section R313-22-35 in conjunction with a license issuance or renewal or as required by Section R313-22-36. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for

decommissioning established pursuant to Subsection R313-22-36(7)(d)(v).

(a) A licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so on or before August 15, 1997.

(b) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Executive Secretary.

(6) The Executive Secretary may grant a request to extend the time periods established in Subsection R313-22-36(4) if the Executive Secretary determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to Subsection R313-22-36(4). The schedule for decommissioning set forth in Subsection R313-22-36(4) may not commence until the Executive Secretary has made a determination on the request.

(7)(a) A decommissioning plan shall be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Executive Secretary and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(i) procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(ii) workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(iii) procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(iv) procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(b) The Executive Secretary may approve an alternate schedule for submittal of a decommissioning plan required pursuant to Subsection R313-22-36(4) if the Executive Secretary determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(c) Procedures such as those listed in Subsection R313-22-36(7)(a) with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(d) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(i) a description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(ii) a description of planned decommissioning activities;

(iii) a description of methods used to ensure protection of

workers and the environment against radiation hazards during decommissioning;

(iv) a description of the planned final radiation survey; and

(v) an updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(vi) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in Subsection R313-22-36(8).

(e) The proposed decommissioning plan will be approved by the Executive Secretary if the information therein demonstrates that the decommissioning will be completed as soon as practical and that the health and safety of workers and the public will be adequately protected.

(8)(a) Except as provided in Subsection R313-22-36(9), licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practical but no later than 24 months following the initiation of decommissioning.

(b) Except as provided in Subsection R313-22-36(9), when decommissioning involves the entire site, the licensee shall request license termination as soon as practical but no later than 24 months following the initiation of decommissioning.

(9) The Executive Secretary may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Executive Secretary determines that the alternative is warranted by consideration of the following:

(a) whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(b) whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(c) whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(d) whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(e) other site-specific factors which the Executive Secretary may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(10) As the final step in decommissioning, the licensee shall:

(a) certify the disposition of all licensed material, including accumulated wastes, by submitting a completed Form DRC-14 or equivalent information; and

(b) conduct a radiation survey of the premises where the

licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in Sections R313-15-401 through R313-15-406. The licensee shall, as appropriate:

(i) report levels of gamma radiation in units of millisieverts (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 in accordance with the criteria for decommissioning in Sections R313-15-401 through R313-15-406; or

(ii) other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in Sections R313-15-401 through R313-15-406.

R313-22-37. Renewal of Licenses.

Application for renewal of a specific license shall be filed on a form prescribed by the Executive Secretary and in accordance with Section R313-22-32.

R313-22-38. Amendment of Licenses at Request of Licensee.

Applications for amendment of a license shall be filed in accordance with Section R313-22-32 and shall specify the respects in which the licensee desires the license to be amended and the grounds for the amendment.

R313-22-39. Executive Secretary Action on Applications to Renew or Amend.

In considering an application by a licensee to renew or amend the license, the Executive Secretary will use the criteria set forth in Sections R313-22-33, R313-22-50, and R313-22-75 and in Rules R313-25, R313-32, R313-34, R313-36, or R313-38, as applicable.

R313-22-50. Special Requirements for Specific Licenses of Broad Scope.

Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity or other product containing byproduct material whose subsequent possession, use, transfer and disposal by all other persons who are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(1) The different types of broad licenses are set forth below:

(a) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

(b) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Section R313-22-100 for any authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Section R313-22-100, Column I. If two or more radionuclides are possessed thereunder, the possession limits are determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Section R313-22-100, Column I, for that radionuclide. The sum of the ratios for the radionuclides possessed under the license shall not exceed unity.

(c) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Section R313-22-100, for any authorized purpose. The possession limit for a Type C broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Section R313-22-100, Column II. If two or more radionuclides are possessed thereunder, the possession limits are determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Section R313-22-100, Column II, for that radionuclide. The sum of the ratios for the radionuclides possessed under the license shall not exceed unity.

(2) An application for a Type A specific license of broad scope shall be approved if all of the following are complied with:

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

(b) the applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

(c) the applicant has established administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(i) the establishment of a radiation safety committee composed of such persons as a radiation safety officer, a

representative of management, and persons trained and experienced in the safe use of radioactive material;

(ii) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(iii) the establishment of appropriate administrative procedures to assure:

(A) control of procurement and use of radioactive material,

(B) completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures, and

(C) review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with Subsection R313-22-50(2)(c)(iii)(B) prior to use of the radioactive material.

(3) An application for a Type B specific license of broad scope shall be approved if all of the following are complied with:

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

(b) the applicant has established administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(i) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(ii) the establishment of appropriate administrative procedures to assure:

(A) control of procurement and use of radioactive material,

(B) completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures, and

(C) review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with Subsection R313-22-50(3)(b)(iii)(B) prior to use of the radioactive material.

(4) An application for a Type C specific license of broad scope shall be approved, if:

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

(b) the applicant submits a statement that radioactive material will be used only by, or under the direct supervision of individuals, who have received:

(i) a college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

(ii) at least forty hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities,

radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

(c) the applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, recordkeeping, material control and accounting, and management review necessary to assure safe operations.

(5) Specific licenses of broad scope are subject to the following conditions:

(a) unless specifically authorized by the Executive Secretary, persons licensed pursuant to this section shall not:

(i) conduct tracer studies in the environment involving direct release of radioactive material;

(ii) receive, acquire, own, possess, use, or transfer devices containing 100,000 curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;

(iii) conduct activities for which a specific license issued by the Executive Secretary under Section R313-22-75, and Rules R313-25, R313-32 or R313-36 is required; or

(iv) add or cause the addition of radioactive material to a food, beverage, cosmetic, drug or other product designed for ingestion or inhalation by, or application to, a human being.

(b) Type A specific licenses of broad scope issued under Rule R313-22 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(c) Type B specific license of broad scope issued under Rule R313-22 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

(d) Type C specific license of broad scope issued under Rule R313-22 shall be subject to the condition that radioactive material possessed under the license may only be used, by or under the direct supervision of, individuals who satisfy the requirements of Subsection R313-22-50(4).

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

(1) Licensing the introduction of radioactive material into products in exempt concentrations.

(a) In addition to the requirements set forth in Section R313-22-33, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under Subsection R313-19-13(2)(a) will be issued if:

(i) the applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or

material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and

(ii) the applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Section R313-19-70, that reconcentration of the radioactive material in concentrations exceeding those in Section R313-19-70 is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to a human being.

(b) Persons licensed under Subsection R313-22-75(1) shall file an annual report with the Executive Secretary which shall identify the type and quantity of products or materials into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product and material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into the product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to Subsection R313-22-75(1) during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within thirty days thereafter.

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

(a) An application for a specific license to distribute naturally occurring and accelerator-produced radioactive material (NARM) to persons exempted from these rules pursuant to Subsection R313-19-13(2)(b) will be approved if:

(i) the radioactive material is not contained in a food, beverage, cosmetic, drug or other commodity designed for ingestion or inhalation by, or application to, a human being;

(ii) the radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into a manufactured or assembled commodity, product, or device intended for commercial distribution; and

(iii) the applicant submits copies of prototype labels and brochures and the Executive Secretary approves the labels and brochures;

(b) The license issued under Subsection R313-22-75(2) (a) is subject to the following conditions:

(i) No more than ten exempt quantities shall be sold or transferred in a single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantities provided the sum of the fractions shall not exceed unity.

(ii) Exempt quantities shall be separated and individually packaged. No more than ten packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to Subsection R313-19-13(2) (b). The outer package shall not allow the dose rate at the external surface of the package to exceed 0.5 millirem (5.0 uSv) per hour.

(iii) The immediate container of a quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

(A) identifies the radionuclide and the quantity of radioactivity; and

(B) bears the words "Radioactive Material."

(iv) In addition to the labeling information required by Subsection R313-22-75(2) (b) (iii), the label affixed to the immediate container, or an accompanying brochure, shall:

(A) state that the contents are exempt from Licensing State requirements;

(B) bear the words "Radioactive Material - Not for Human Use - Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited - Exempt Quantities Should Not Be Combined;" and

(C) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage and disposal of the radioactive material.

(c) Persons licensed under Subsection R313-22-75(2) shall maintain records identifying, by name and address, persons to whom radioactive material is transferred for use under Subsection R313-19-13(2) (b) or the equivalent regulations of a Licensing State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of radionuclides transferred under the specific license shall be filed with the Executive Secretary. Reports shall cover the year ending June 30, and shall be filed within thirty days thereafter. If no transfers of radioactive material have been made pursuant to Subsection R313-22-75(2) during the reporting period, the report shall so indicate.

(3) Licensing the incorporation of naturally occurring and accelerator-produced radioactive material (NARM) into gas and aerosol detectors. An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under Subsection R313-19-13(2) (c) (iii) will be approved if the application satisfies requirements equivalent to those contained in 10 CFR 32.26, 2001 ed. The maximum quantity of radium-226 in each device shall not exceed 0.1 microcurie (3.7 kBq).

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

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

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

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

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

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

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

TABLE

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

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

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

(B) the requirement, or lack of requirement, for leak testing, or for testing an "on-off" mechanism and indicator, including the maximum time interval for testing, and the

identification of radioactive material by radionuclide, quantity of radioactivity, and date of determination of the quantity, and

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

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

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

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

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

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

(d) Persons licensed under Subsection R313-22-75(4) to distribute devices to generally licensed persons shall:

(i) furnish a copy of the general license contained in Subsection R313-21-22(4) to each person to whom the person directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in Subsection R313-21-22(4);

(ii) furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's, Agreement State's, or Licensing State's regulation equivalent to Subsection R313-21-22(4), or alternatively, furnish a copy of the general license contained in Subsection R313-21-22(4) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission, the Agreement State or the Licensing State. If a copy of the general license in Subsection R313-21-22(4) is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the U.S. Nuclear Regulatory Commission, Agreement State or Licensing State under requirements substantially the same as those in Subsection R313-21-22(4);

(iii) report to the Executive Secretary all transfers of such devices to persons for use under the general license in Subsection R313-21-22(4). The reports shall identify the general licensee by name and address, an individual by name or position who may constitute a point of contact between the Executive Secretary and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under Subsection R313-21-22(4) during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed

within thirty days thereafter;

(iv) furnish reports to other agencies.

(A) Report to the U.S. Nuclear Regulatory Commission all transfers of those devices to persons for use under the U.S. Nuclear Regulatory Commission general license in 10 CFR 31.5, 2001 ed.

(B) Report to the responsible State agency all transfers of devices manufactured and distributed pursuant to Subsection R313-22-75(4) for use under a general license in that State's regulations equivalent to Subsection R313-21-22(4).

(C) The reports shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the responsible agency and general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within thirty days after the end of each calendar quarter in which a device is transferred to the generally licensed person.

(D) If transfers have not been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.

(E) If transfers have not been made to general licensees within a particular state during the reporting period, this information shall be reported to the responsible state agency upon request of that agency; and

(v) keep records showing the name, address and the point of contact for each general licensee to whom the person directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in Subsection R313-21-22(4), or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. The records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of intermediate persons, and compliance with the report requirements of Subsection R313-22-75(4).

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

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

(b) the applicant satisfies the requirements of 10 CFR 32.53 through 32.56 and 32.101, 2001 ed., or their equivalent.

(6) Special requirements for license to manufacture calibration sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under Subsection

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

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

(b) the applicant satisfies the requirements of 10 CFR 32.57 through 32.59, 32.102 and 10 CFR 70.39, 2001 ed., or their equivalent.

(7) Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license. An application for a specific license to manufacture or distribute radioactive material for use under the general license of Subsection R313-21-22(9) will be approved if:

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

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

(i) iodine-125 in units not exceeding ten microcuries (370.0 kBq) each;

(ii) iodine-131 in units not exceeding ten microcuries (370.0 kBq) each;

(iii) carbon-14 in units not exceeding ten microcuries (370.0 kBq) each;

(iv) hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each;

(v) iron-59 in units not exceeding 20 microcuries (740.0 kBq) each;

(vi) cobalt-57 in units not exceeding ten microcuries (370.0 kBq) each;

(vii) selenium-75 in units not exceeding ten microcuries (370.0 kBq) each; or

(viii) mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185.0 Bq) of americium-241 each;

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

(i) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed ten microcuries (370.0 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740.0 kBq) of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcuries (1.85 kBq) of iodine-129 and 0.005 microcurie (185.0 Bq) of americium-241 each; and

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

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

(i) "This radioactive material shall be received, acquired,

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

.....
Name of Manufacturer"

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

.....
Name of Manufacturer"

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

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

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

(b) the criteria of 10 CFR 32.61, 32.62, 32.103, 2001 ed. are met.

(9) Manufacture and distribution of radiopharmaceuticals containing radioactive material for medical use under group licenses.

(a) An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to Rule R313-32 will be approved if:

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

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

(A) registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;

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

manufacturer;

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

(D) operating as a nuclear pharmacy within a medical institution.

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

(iv) the applicant satisfies the following labeling requirements:

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

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

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

(i) May prepare radioactive drugs for medical use, as defined in Section R313-32-2, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in Subsections R313-22-75(9)(b)(ii) and (iii), or an individual under the supervision of an authorized nuclear pharmacist as specified in Section R313-32-25.

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

(A) this individual qualifies as an authorized nuclear pharmacist as defined in Section R313-32-2;

(B) this individual meets the requirements specified in Subsection R313-32-980(2) and Section R313-32-972 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

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

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

(iv) May designate a pharmacist, as defined in Section R313-32-2, as an authorized nuclear pharmacist if the individual is identified as of January 1, 1997 as an "authorized user" on a nuclear pharmacy license issued by the Executive Secretary under

Subsection R313-22-75(9).

(v) Shall provide to the Executive Secretary a copy of each individual's certification by the Board of Pharmaceutical Specialties, the U.S. Nuclear Regulatory Commission or Agreement State license, or the permit issued by a licensee of broad scope, and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to Subsections R313-22-75(9)(b)(ii)(A) and (B), the individual to work as an authorized nuclear pharmacist.

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

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

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

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

(10) Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Section R313-32-18 for use as a calibration or reference source or for the uses listed in Sections R313-32-400 and R313-32-500 will be approved if:

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

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

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

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

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

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

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

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

(vii) legend and methods for labeling sources and devices as

to their radioactive content, and

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

(c) the label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the source or device is licensed by the Executive Secretary for distribution to persons licensed pursuant to Sections R313-32-18, R313-32-400, and R313-32-500 or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State; provided that labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source;

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

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

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

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

(a) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to Subsection R313-21-21(5) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

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

(ii) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses and potential

hazards of the industrial product or device to provide reasonable assurance that possession, use or transfer of the depleted uranium in the product or device is not likely to cause an individual to receive a radiation dose in excess of ten percent of the annual limits specified in Subsection R313-15-201(1); and

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

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

(c) The Executive Secretary may deny an application for a specific license under Subsection R313-22-75(11) if the end use of the industrial product or device cannot be reasonably foreseen.

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

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

(ii) label or mark each unit to:

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

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

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

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

(A) a copy of the general license contained in Subsection R313-21-21(5) and a copy of form DRC-12; or

(B) a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to Subsection R313-21-21(5) and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in Subsection R313-21-21(5) and a copy of form DRC-12 with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under

requirements substantially the same as those in Subsection R313-21-21(5);

(v) report to the Executive Secretary all transfers of industrial products or devices to persons for use under the general license in Subsection R313-21-21(5). The report shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the Executive Secretary and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within thirty days after the end of the calendar quarter in which the product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under Subsection R313-21-21(5) during the reporting period, the report shall so indicate;

(vi) provide certain other reports as follows:

(A) report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in 10 CFR 40.25, 2001 ed.;

(B) report to the responsible state agency all transfers of devices manufactured and distributed pursuant to Subsection R313-22-75(11) for use under a general license in that state's regulations equivalent to Subsection R313-21-21(5),

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

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

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

(vii) records shall be kept showing the name, address and point of contact for each general licensee to whom the person transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in Subsection R313-21-21(5) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in the product or device transferred, and compliance with the report requirements of Subsection R313-22-75(11).

R313-22-90. Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release. Refer to Subsection R313-22-32(8).

TABLE

Radioactive Material(1)	Release Fraction	Quantity (curies)
Actinium-228	0.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252 (20 mg)	.001	9
Carbon-14	.01	50,000
	Non CO	
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Germanium-68	.01	2,000
Gadolinium-153	.01	5,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holmium-166m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10
Indium-114m	.01	1,000
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000

Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment, beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma(2)	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha(2)	.0001	20
Combinations of radioactive materials listed above(1)	-----	-----

(1) For combinations of radioactive materials, consideration of the need for 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	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, [~~2000~~2001 ed. or equivalent regulations of an Agreement State.

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

[~~March 10, 2000~~2001

19-3-104

Notice of Continuation May 1, 1997

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]2001 ed., which is incorporated by reference.

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

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

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

"Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the

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

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

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

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

"Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these rules, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of Appendix B of 10 CFR 20.1001 to 20.2402, [~~1997~~] 2001 ed., which is incorporated by reference.

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

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

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

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

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

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

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

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

"Inhalation class", refer to "Class".

"Labeled package" means a package labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations 49 CFR 172.403 and 49 CFR 172.436 through 440, [~~1997~~2000 ed. Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403(m) and (w) and 49 CFR 173.421 through 424, [~~1997~~2000 ed.

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

"Lung class", refer to "Class".

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

"Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these rules, "deterministic effect" is an equivalent term.

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

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

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

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

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

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

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

"Reference Man" means a hypothetical aggregation of human physical and physiological characteristics determined by

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

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

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

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

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

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

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

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

"Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of five Gy (500 rad) in one hour at one meter from a [source of] radiation source or one meter from any surface that the radiation penetrates. [~~At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.~~]

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

TABLE

ORGAN DOSE WEIGHTING FACTORS

Organ or Tissue	w_T
Gonads	0.25
Breast	0.15

Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30(1)
Whole Body	1.00(2)

(1) 0.30 results from 0.06 for each of five "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

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

R313-15-3. Implementation.

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

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

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

R313-15-101. Radiation Protection Programs.

(1) Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of Rule R313-15. See Section R313-15-1102 for recordkeeping requirements relating to these programs.

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

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

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

constraint, the licensee or registrant shall report the exceedance as provided in Section R313-15-1203 and promptly take appropriate corrective action to ensure against recurrence.

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

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

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

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

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

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

(i) ~~A [An eye] lens~~ dose equivalent of 0.15 Sv (15 rem), and

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

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

(3) The assigned deep dose equivalent and shallow dose equivalent shall be for the ~~[portion]~~part of the body receiving the highest exposure ~~[determined as follows].~~

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

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

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

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

(4) Derived air concentration (DAC) and annual limit on

intake (ALI) values are specified in Table I of Appendix B of 10 CFR 20.1001 to 20.2402, [~~1997~~]2001 ed., which is incorporated by reference, and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See Section R313-15-1107.

(5) Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to ten milligrams in a week in consideration of chemical toxicity. See footnote 3, of Appendix B of 10 CFR 20.1001 to 20[~~=~~]2402, [~~1997~~]2001 ed., which is incorporated by reference.

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

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

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

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

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

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

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

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

demonstrating compliance with the limits.

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

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

(1) Licensees or registrants shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, ~~[eye]~~lens dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See footnotes 1 and 2 of Appendix B of 10 CFR 20.1001 to 20.2402, [~~1997~~]2001 ed., which is incorporated by reference.

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

R313-15-204. Determination of Internal Exposure.

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

(a) Concentrations of radioactive materials in air in work areas; or

(b) Quantities of radionuclides in the body; or

(c) Quantities of radionuclides excreted from the body; or

(d) Combinations of these measurements.

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

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

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

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

(c) Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See Appendix B of 10 CFR

20.1001 to 20.2402, [~~1997~~2001 ed., which is incorporated by reference.

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

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

(a) The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix B of 10 CFR 20.1001 to 20.2402, [~~1997~~2001 ed., which is incorporated by reference, for each radionuclide in the mixture; or

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

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

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

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

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

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

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

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

(b) For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.50 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix B of 10 CFR 20.1001 to 20.2402, [~~1997~~2001 ed., which is incorporated by reference. The licensee or registrant may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALI, the licensee or registrant shall also demonstrate that the limit in

Subsection R313-15-201(1)(a)(ii) is met.

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

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

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

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

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

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

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

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

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

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

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

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

(b) For the purpose of complying with this requirement,

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

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

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

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

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

R313-15-206. Planned Special Exposures.

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

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

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

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

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

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

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

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

(5) Subject to Subsection R313-15-201(2), the licensee or registrant shall not authorize a planned special exposure that

would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

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

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

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

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

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

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

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

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

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

(3) The dose equivalent to an embryo/fetus [~~shall be taken as~~]is the sum of:

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

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

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

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

dose equivalent for the region of the embryo/fetus.

(4) If [~~by the time the woman declares pregnancy to the licensee or registrant,~~] the dose equivalent to the embryo/fetus [has]is found to have exceeded [4.5]five mSv (0.[4]5 rem) or is within 0.5 mSv (0.05 rem) of this dose by the time the woman declares the pregnancy to the licensee or registrant, the licensee or registrant shall be deemed to be in compliance with Subsection R313-15-208(1) if the additional dose equivalent to the embryo/fetus does not exceed 0.50 mSv (0.05 rem) during the remainder of the pregnancy.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) Demonstrating that:

(i) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B of 10 CFR 20.1001 to 20.2402, [~~1997~~2001 ed., which is incorporated by reference; and

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

(3) Upon approval from the Executive Secretary, the licensee or registrant may adjust the effluent concentration values in Appendix B, Table II of 10 CFR 20.1001 to 20.2402, [~~1997~~2001 ed., which is incorporated by reference, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as, aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

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

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

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

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

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

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

(3) After a site has been decommissioned and the license terminated in accordance with the criteria in Sections R313-15-401 through R313-15-406, the Executive Secretary will require additional cleanup only if, based on new information, the Executive Secretary determines that the criteria in Sections R313-15-401

through R313-15-406 was not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(B) Will be enforceable; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(c) Reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal; and

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

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

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

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

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

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

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

(1) Notify and solicit comments from:

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

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

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

R313-15-406. Minimization of Contamination.

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

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

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

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

(b) Are necessary under the circumstances to evaluate:

(i) The magnitude and the extent of r[R]adiation levels; and

(ii) Concentrations or quantities of radioactive material;

and

(iii) The potential radiological hazards[~~that could be present~~].

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

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

(a) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of

the National Institute of Standards and Technology; and

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

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

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

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

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

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

(b) Minors [~~and declared pregnant women~~] likely to receive, in one year, from radiation sources external to the body, a deep dose equivalent in excess of [ten percent of any of the applicable limits in Sections R313-15-207 or R313-15-208] one mSv (0.1 rem), a lens dose equivalent in excess of 1.5 mSv (0.15 rem), or a shallow dose equivalent to the skin or to the extremities in excess of five mSv (0.5 rem); and

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

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

(~~d~~)e) Individuals working with medical fluoroscopic equipment.

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

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

(ii) An individual monitoring device used for [~~eye~~] lens dose

equivalent shall be located at the neck, or an unshielded location closer to the eye, outside the protective apron.

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

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

(a) Adults likely to receive, in one year, an intake in excess of ten percent of the applicable ALI(s) in Table I, Columns 1 and 2, of Appendix B of 10 CFR 20.1001 to 20.2402, [1997]2001 ed., which is incorporated by reference; and

(b) Minors [~~and declared pregnant women~~] likely to receive, in one year, a committed effective dose equivalent in excess of [~~0.50 mSv (0.05 rem).~~] one mSv (0.1 rem); and

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

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

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

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

(1) An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar).

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

(3) An individual monitoring device used for monitoring the [eye] lens dose equivalent, to demonstrate compliance with Subsection R313-15-201(1)(b)(i), shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye.

(4) An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with Subsection R313-15-201(1)(b)(ii), shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

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

(1) The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

(a) A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of one mSv (0.1 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates; or

(b) A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

(c) Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

(2) In place of the controls required by Subsection R313-15-601(1) for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(3) The licensee or registrant may apply to the Executive Secretary for approval of alternative methods for controlling access to high radiation areas.

(4) The licensee or registrant shall establish the controls required by Subsections R313-15-601(1) and R313-15-601(3) in a way that does not prevent individuals from leaving a high radiation area.

(5) The licensee or registrant is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the rules of the U.S. Department of Transportation provided that:

(a) The packages do not remain in the area longer than three days; and

(b) The dose rate at one meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.

(6) The licensee or registrant is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in Rule R313-15 and to operate within the ALARA provisions of the licensee's or registrant's radiation protection program.

(7) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in Section R313-15-601 if the registrant has met all the specific requirements for access and control specified in other applicable sections of these rules, such as, Rule R313-36 for industrial radiography, Rule R313-28 for x rays in the healing arts, Rule R313-30 for

therapeutic radiation machines, and Rule R313-35 for industrial use of x-ray systems.

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

(1) In addition to the requirements in Section R313-15-601, the licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at five Gy (500 rad) or more in one hour at one meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation, or to non-self-shielded irradiators.

(2) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in Subsection R313-15-602(1) if the registrant has met all the specific requirements for access and control specified in other applicable sections of these rules, such as, Rule R313-36 for industrial radiography, Rule R313-28 for x rays in the healing arts, Rule R313-30 for therapeutic radiation machines, and Rule R313-35 for industrial use of x-ray systems.

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

(1) Section R313-15-603 applies to licensees or registrants with sources of radiation in non-self-shielded irradiators. Section R313-15-603 does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create a high levels of radiation in an area that is accessible to any individual.

(2) Each area in which there may exist radiation levels in excess of five Gy (500 rad) in one hour at one meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

(a) Each entrance or access point shall be equipped with entry control devices which:

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

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

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

(b) Additional control devices shall be provided so that,

upon failure of the entry control devices to function as required by Subsection R313-15-603(2)(a):

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

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

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

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

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

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

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

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

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

(h) Each area shall be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of one mSv (0.1 rem) in one hour.

(i) The entry control devices required in Subsection R313-15-603(2)(a) shall be tested for proper functioning. See Section R313-

15-1110 for recordkeeping requirements.

(i) Testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day; and

(ii) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and

(iii) The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

(j) The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.

(k) Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and automatically to prevent loose radioactive material from being carried out of the area.

(3) Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of Subsection R313-15-603(2) which will be used in a variety of positions or in locations, such as open fields or forests, that make it impractical to comply with certain requirements of Subsection R313-15-603(2), such as those for the automatic control of radiation levels, may apply to the Executive Secretary for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in Subsection R313-15-603(2). At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

(4) The entry control devices required by Subsections R313-15-603(2) and R313-15-603(3) shall be established in such a way that no individual will be prevented from leaving the area.

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

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

R313-15-702. Use of Other Controls.

(1) When it is not practical to apply process or other engineering controls to control the concentration[s] of radioactive material in the air to values below those that define an airborne radioactivity area, the licensee or registrant shall, consistent

with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

- [+1)](a) Control of access; or
- [+2)](b) Limitation of exposure times; or
- [+3)](c) Use of respiratory protection equipment; or
- [+4)](d) Other controls.

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

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

[+1)] If the licensee or registrant uses respiratory protection equipment to limit the intake~~[s pursuant to Section R313-15-702] of radioactive material~~:

[+a)](1) Except as provided in Subsection R313-15-703 ~~[+1)(b)](2)~~, the licensee or registrant shall use only respiratory protection equipment that is tested and certified ~~[or had certification extended]~~ by the National Institute for Occupational Safety and Health ~~[and the Mine Safety and Health Administration]~~.

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

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

[+i)](a) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate ~~[exposures]~~ doses; and

[+ii)](b) Surveys and bioassays, as ~~[appropriate]~~ necessary, to evaluate actual intakes; and

[+iii)](c) Testing of respirators for operability, user seal check for face sealing devices and functional check for others, immediately prior to each use; and

[+iv)](d) Written procedures regarding ~~[selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use, supervision and training of personnel, monitoring, including air sampling and bioassays, and recordkeeping]~~

(i) Monitoring, including air sampling and bioassays;

- (ii) Supervision and training of respirator users;
- (iii) Fit testing;
- (iv) Respirator selection;
- (v) Breathing air quality;
- (vi) Inventory and control;
- (vii) Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;
- (viii) Recordkeeping; and
- (ix) Limitations on periods of respirator use and relief from respirator use; and

~~[-v]~~ (e) Determination by a physician prior to initial fitting of respirators, before the first field use of non-face sealing respirators, and either every 12 months thereafter or periodically at a frequency determined by a physician, that the individual user is medically fit to use the respiratory protection equipment[-]; and

(f) Fit testing, with fit factor greater than or equal to ten times the APF for negative pressure devices, and a fit factor greater than or equal to 500 for positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed one year. Fit testing must be performed with the facepiece operating in the negative pressure mode. [

~~(d) The licensee or registrant shall issue a written policy statement on respirator usage covering:~~

~~(i) The use of process or other engineering controls, instead of respirators; and~~

~~(ii) The routine, nonroutine, and emergency use of respirators; and~~

~~(iii) The length of periods of respirator use and relief from respirator use.~~

~~]~~ [+e)] (4) The licensee or registrant shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

(5) The licensee or registrant shall also consider limitations appropriate to the type and mode of use. When selecting respiratory devices the licensee shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The licensee or registrant shall use equipment in such a way as not to interfere with the proper operation of the respirator.

(6) Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons

shall observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

(7) Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997 ed. and included in 29 CFR 1910.134(i)(1)(ii)(A) through (E), 2000 ed. Grade D quality air criteria include:

(a) Oxygen content (v/v) of 19.5 to 23.5%;

(b) Hydrocarbon (condensed) content of five milligrams per cubic meter of air or less;

(c) Carbon monoxide (CO) content of ten ppm or less;

(d) Carbon dioxide content of 1,000 ppm or less; and

(e) Lack of noticeable odor.

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

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

~~(f) The licensee or registrant shall use respiratory protection equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities, such as adequate skin protection, when needed.~~

~~(2) When estimating exposure of individuals to airborne radioactive materials, the licensee or registrant may make allowance for respiratory protection equipment used to limit intakes pursuant to Section R313-15-702, provided that the following conditions, in addition to those in Subsection R313-15-703(1), are satisfied:~~

~~(a) The licensee or registrant selects respiratory protection equipment that provides a protection factor, specified in Appendix A of 10 CFR 20.1001 to 20.2402, 1997 ed., which is incorporated by reference, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B, Table I, Column 3 of 10 CFR 20.1001 to 20.2402, 1997 ed., which is incorporated by reference. However, if the selection of respiratory protection~~

~~equipment with a protection factor greater than the multiple defined in the preceding sentence is inconsistent with the goal specified in Section R313-15-702 of keeping the total effective dose equivalent ALARA, the licensee or registrant may select respiratory protection equipment with a lower protection factor provided that such a selection would result in a total effective dose equivalent that is ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used.~~

~~(b) The licensee or registrant shall obtain authorization from the Executive Secretary before assigning respiratory protection factors in excess of those specified in Appendix A of 10 CFR 20.1001 to 20.2402, 1997 ed., which is incorporated by reference. The Executive Secretary may authorize a licensee or registrant to use higher protection factors on receipt of an application that:~~

~~(i) Describes the situation for which a need exists for higher protection factors, and~~

~~(ii) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.~~

~~(3) In an emergency, the licensee or registrant shall use as emergency equipment only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.~~

~~(4) The licensee or registrant shall notify the Executive Secretary in writing at least 30 days before the date that respiratory protection equipment is first used pursuant to either Subsections R313-15-703(1) or R313-15-703(2).]~~

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

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

(1) Ensure that the respiratory protection program of the licensee or registrant is adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and

(2) Limit the extent to which a licensee or registrant may use respiratory protection equipment instead of process or other engineering controls.

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

Factors.

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

(1) Describes the situation for which a need exists for higher protection factors; and

(2) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

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

(1) The licensee or registrant shall secure licensed or registered radioactive material from unauthorized removal or access.

(2) The licensee or registrant shall maintain constant surveillance, and use devices or administrative procedures to prevent unauthorized use of licensed or registered radioactive material that is in an unrestricted area and that is not in storage.

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

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

R313-15-901. Caution Signs.

(1) Standard Radiation Symbol. Unless otherwise authorized by the Executive Secretary, the symbol prescribed by 10 CFR 20.1901, [~~1997~~2001 ed., which is incorporated by reference, shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

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

(b) The background is to be yellow.

(2) Exception to Color Requirements for Standard Radiation Symbol. Notwithstanding the requirements of 10 CFR 20.1901(a), [~~1997~~2001 ed., which is incorporated by reference, licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

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

R313-15-902. Posting Requirements.

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

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

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

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

(5) Posting of Areas or Rooms in which Licensed or Registered Material is Used or Stored. The licensee or registrant shall post each area or room in which there is used or stored an amount of licensed or registered material exceeding ten times the quantity of such material specified in Appendix C of 10 CFR 20.1001 to 20.2402, [~~1997~~2001 ed., which is incorporated by reference, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL."

R313-15-903. Exceptions to Posting Requirements.

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

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

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

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

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

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

(5) Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs

under Section R313-15-902 if:

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

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

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

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

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

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

R313-15-905. Exemptions to Labeling Requirements.

A licensee or registrant is not required to label:

(1) Containers holding licensed or registered material in quantities less than the quantities listed in Appendix C of 10 CFR 20.1001 to 20.2402, [~~1997~~]2001 ed., which is incorporated by reference; or

(2) Containers holding licensed or registered material in concentrations less than those specified in Table III of Appendix B of 10 CFR 20.1001 to 20.2402, [~~1997~~]2001 ed., which is incorporated by reference; or

(3) Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by Rule R313-15; or

(4) Containers when they are in transport and packaged and labeled in accordance with the rules of the U.S. Department of Transportation; or

(5) Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

(6) Installed manufacturing or process equipment, such as

piping and tanks.

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

(1) Each licensee or registrant who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as used in Section R313-19-100, which incorporates 10 CFR 71.4 by reference, shall make arrangements to receive:

- (a) The package when the carrier offers it for delivery; or
- (b) The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

(2) Each licensee or registrant shall:

(a) Monitor the external surfaces of a labeled package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in Section R313-12-3; and

(b) Monitor the external surfaces of a labeled package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as used in Section R313-19-100, which incorporates 10 CFR 71.4 by reference; and

(c) Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

(3) The licensee or registrant shall perform the monitoring required by Subsection R313-15-906(2) as soon as practical after receipt of the package, but not later than three hours after the package is received at the licensee's or registrant's facility if it is received during the licensee's or registrant's normal working hours or if there is evidence of degradation of package integrity, such as a package that is crushed, wet, or damaged. If a package is received after working hours, and has no evidence of degradation of package integrity, the package shall be monitored no later than three hours from the beginning of the next working day.

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

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

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

(5) Each licensee or registrant shall:

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

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

(6) Licensees or registrants transferring special form sources in vehicles owned or operated by the licensee or registrant

to and from a work site are exempt from the contamination monitoring requirements of Subsection R313-15-906(2), but are not exempt from the monitoring requirement in Subsection R313-15-906(2) for measuring radiation levels that ensures that the source is still properly lodged in its shield.

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

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

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

(b) By decay in storage; or

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

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

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

(a) Treatment prior to disposal; or

(b) Treatment or disposal by incineration; or

(c) Decay in storage; or

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

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

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

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

(1) A description of the waste containing licensed or registered material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal; and

(2) An analysis and evaluation of pertinent information on the nature of the environment; and

(3) The nature and location of other potentially affected facilities; and

(4) Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in Rule R313-15.

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

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

(a) The material is readily soluble, or is readily dispersible biological material, in water; and

(b) The quantity of licensed or registered radioactive material that the licensee or registrant releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee or registrant does not exceed the concentration listed in Table III of Appendix B of 10 CFR 20.1001 to 20.2402, [1997]2001 ed., which is incorporated by reference; and

(c) If more than one radionuclide is released, the following conditions shall also be satisfied:

(i) The licensee or registrant shall determine the fraction of the limit in Table III of Appendix B of 10 CFR 20.1001 to 20.2402, [1997]2001 ed., which is incorporated by reference, represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee or registrant into the sewer by the concentration of that radionuclide listed in Table III of Appendix B of 10 CFR 20.1001 to 20.2402, [1997]2001 ed., which is incorporated by reference; and

(ii) The sum of the fractions for each radionuclide required by Subsection R313-15-1003(1)(c)(i) does not exceed unity; and

(d) The total quantity of licensed or registered radioactive material that the licensee or registrant releases into the sanitary sewerage system in a year does not exceed 185 GBq (five Ci) of hydrogen-3, 37 GBq (one Ci) of carbon-14, and 37 GBq (one Ci) of all other radioactive materials combined.

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

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

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

R313-15-1005. Disposal of Specific Wastes.

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

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

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

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

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

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

~~[(1) Requirements of Section R313-15-1006 and Appendix F and G of 10 CFR 20.1001 to 20.2402, 1997 ed.]~~

[(a)](1) The requirements of Section R313-15-1006 and

Appendix [~~F and~~]G of 10 CFR 20.1001 to 20.2402, [1997]2001 ed., which are incorporated into these rules by reference, are designed to:

~~[(i)](a)~~ control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in Appendix [~~F or~~]G in 10 CFR 20.1001 to 20.2402, [1997]2001 ed., who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility as defined in Section R313-25-2;

~~[(ii)](b)~~ establish a manifest tracking system; and

~~[(iii)](c)~~ supplement existing requirements concerning transfers and recordkeeping for those wastes.

~~[(b) Beginning March 1, 1998, all affected licensees must use Appendix G of 10 CFR 20.1001 to 20.2402, 1997 ed., which is incorporated into these rules by reference. Prior to March 1, 1998, a low-level waste disposal facility operator or its regulatory authority may require the shipper to use Appendix F or Appendix G of 10 CFR 20.1001 to 20.2402, 1997 ed. Licensees using Appendix F shall comply with Subsection R313-15-1006(2)(a). Licensees using Appendix G shall comply with Subsection R313-15-1006(2)(b).]~~

~~(2) Shipment of Radioactive Waste.~~

~~(a) Each shipment of radioactive waste designated for disposal at a licensed low-level radioactive waste disposal facility shall be accompanied by a shipment manifest as specified in Section I of Appendix F of 10 CFR 20.1001 to 20.2402, 1997 ed., which is incorporated by reference.~~

~~[(b)](2)~~ Any licensee or shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G to 10 CFR 20.1001 to 20.2402, [1997]2001 ed., which is incorporated into these rules by reference.

(3) Each shipment manifest shall include a certification by the waste generator as specified in Section II of Appendix [~~F or~~]G[, ~~as appropriate, of~~] to 10 CFR 20.1001 to 20.2402, [1997]2001 ed., which is incorporated by reference. [~~See Subsection R313-15-1006(1)(b) to determine the appropriate Appendix.~~]

(4) Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix [~~F or~~]G[, ~~as appropriate, of~~] to 10 CFR 20.1001 to 20.2402, [1997]2001 ed., which is incorporated by reference. [~~See Subsection R313-15-1006(1)(b) to determine the appropriate Appendix.~~]

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

Nothing in Sections R313-15-1001, R313-15-1002, R313-15-1003,

R313-15-1004, R313-15-1005, or R313-15-1006 relieves the licensee or registrant from complying with other applicable Federal, State and local rules governing any other toxic or hazardous properties of materials that may be disposed of pursuant to Sections R313-15-1001, R313-15-1002, R313-15-1003, R313-15-1004, R313-15-1005, or R313-15-1006.

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

(1) Classification of Radioactive Waste for Land Disposal

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

(b) Classes of waste.

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

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

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

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

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

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

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

(iv) For wastes containing mixtures of radionuclides listed

in Table I, the total concentration shall be determined by the sum of fractions rule described in Subsection R313-15-1008(1)(g).

TABLE I

Concentration

Radionuclide	curie/cubic meter(1)	nanocurie/gram(2)
C-14	8	
C-14 in activated metal	80	
Ni-59 in activated metal	220	
Nb-94 in activated metal	0.2	
Tc-99	3	
I-129	0.08	
Alpha emitting transuranic radionuclides with half-life greater than five years		100
Pu-241		3,500
Cm-242		20,000
Ra-226		100

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

(2) To convert the nCi/g values to becquerel (Bq)/gram, multiply the nCi/g value by 37.

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

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

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

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

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

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

TABLE II

Radionuclide meter(1)	Concentration, [————]curie/cubic		
	Column 1	Column 2	Column 3
Total of all radio-			

nuclides with less than 5-year half-life	700	(2)	(2)
H-3	40	(2)	(2)
Co-60	700	(2)	(2)
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7000
Sr-90	0.04	150	7000
Cs-137	1	44	4600

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

(2) There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other radionuclides in Table II determine the waste to be Class C independent of these radionuclides.

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

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

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

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

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

Class B.

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

(2) Radioactive Waste Characteristics

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

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

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

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

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

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

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

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

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

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

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

(i) Waste shall have structural stability. A structurally

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

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

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

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

R313-15-1101. Records - General Provisions.

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

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

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

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

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

(a) The provisions of the program; and

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

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

R313-15-1103. Records of Surveys.

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

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

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

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

(c) Records showing the results of air sampling, surveys, and bioassays required pursuant to Subsections R313-15-703[(1)(c)(i)](3)(a) and R313-15-703[(1)(c)(ii)](3)(b); and

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

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

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

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

For each individual who is likely to receive in a year an occupational dose requiring monitoring pursuant to Section R313-15-502, the licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in Section R313-15-205 on form DRC-05 or equivalent until the Executive Secretary terminates each pertinent license requiring this record. The licensee or registrant shall retain records used in preparing form DRC-05 or equivalent for three years after the record is made.

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

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

(a) The exceptional circumstances requiring the use of a planned special exposure; and

(b) The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and

(c) What actions were necessary; and

(d) Why the actions were necessary; and

(e) What precautions were taken to assure that doses were maintained ALARA; and

(f) What individual and collective doses were expected to

result; and

(g) The doses actually received in the planned special exposure.

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

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

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

(a) The deep dose equivalent to the whole body, [eye]lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and

(b) The estimated intake of radionuclides, see Section R313-15-202; and

(c) The committed effective dose equivalent assigned to the intake of radionuclides; and

(d) The specific information used to calculate the committed effective dose equivalent pursuant to Subsections R313-15-204(1) and R313-15-204(3) and when required by Section R313-15-502; and

(e) The total effective dose equivalent when required by Section R313-15-202; and

(f) The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

(2) Recordkeeping Frequency. The licensee or registrant shall make entries of the records specified in Subsection R313-15-1107(1) at intervals not to exceed one year.

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

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

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

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

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

(2) The licensee or registrant shall retain the records required by Subsection R313-15-1108(1) until the Executive

Secretary terminates each pertinent license or registration requiring the record. Requirements for disposition of these records, prior to license termination, are located in Section R313-12-51 for activities licensed under these rules.

R313-15-1109. Records of Waste Disposal.

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

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

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

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

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

R313-15-1111. Form of Records.

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

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

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

(a) Immediately after its occurrence becomes known to the licensee or registrant, stolen, lost, or missing licensed or registered radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C of 10 CFR 20.1001 to 20.2402, [~~1997~~2001 ed., which is incorporated by reference, under such circumstances that it appears to the licensee or registrant that an exposure could result to individuals in unrestricted areas;

(b) Within 30 days after its occurrence becomes known to the

licensee or registrant, lost, stolen, or missing licensed or registered radioactive material in an aggregate quantity greater than ten times the quantity specified in Appendix C of 10 CFR 20.1001 to 20.2402, [1997]2001 ed., which is incorporated by reference, that is still missing.

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

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

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

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

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

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

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

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

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

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

R313-15-1202. Notification of Incidents.

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

(a) An individual to receive:

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

(ii) A ~~n-eye~~ lens dose equivalent of 0.75 Sv (75 rem) or more; or

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

(b) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24

hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

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

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

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

(ii) A ~~non-eye~~ lens dose equivalent exceeding 0.15 Sv (15 rem); or

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

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

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

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

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

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

(1) Reportable Events. In addition to the notification required by Section R313-15-1202, each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:

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

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

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

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

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

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

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

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

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

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

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

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

(2) Contents of Reports.

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

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

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

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

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

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

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

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

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

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

When a licensee or registrant is required, pursuant to the

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

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

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

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

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

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

R313-15-1301. Vacating Premises.

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

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

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

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

(b) Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not

to exceed six months or at alternative intervals approved by the Executive Secretary, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission.

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

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

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

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

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

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

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

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

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

(d) Sealed sources containing only hydrogen-3;

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

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

(3) Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the

Executive Secretary, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such services.

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

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

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

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

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

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

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

KEY: radioactive material, contamination, waste disposal, safety
[~~March 10, 2000~~]2001 **19-3-104**
Notice of Continuation April 30, 1998 **19-3-108**