State of Utah

DEPARTMENT OF ENVIRONMENTAL QUALITY
DIVISION OF RADIATION CONTROL

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November 26, 1997

Charles Hackney
State Agreements Program
Nuclear Regulatory Commission
611 Ryan Plaza Drive Suite 400
Arlington, Texas 76011

Dear Mr. Hackney:

A number of changes to the Utah Radiation Control Rules have been made and are now effective. The changes pertain to R313-12, General Provisions; R313-14, Violations and Escalated Enforcement; R313-17, Administrative Procedures (includes two non-substantive changes); R313-21, General Licenses (changes effective on January 10, 1997, with a non-substantive change, and July 18, 1997); and R313-22, Specific Licenses (changes effective on November 15, 1996, with a non-substantive change, and July 18, 1997).

Some of the changes we have made are not matters of compatibility. I believe that the changes we have made which are compatibility matters fulfill the applicable requirements, but I request that NRC review the changes and concur with this belief. A response to this request may be provided at NRC's convenience.

Please find enclosed a hard copy and a WordPerfect (version 6.1) electronic copy of the rules which have been made effective. In some cases, we are not able to submit an electronic copy of the rule and for this I apologize. New text which is shown with an underline. Deleted text is interlined and placed within brackets. If you have questions, please contact Craig Jones at (801) 536-4250.

Sincerely,

William J. Sinclair, Director
Division of Radiation Control

Enclosure: As stated

File Name: Hackney4.ltr
File Location: cwj/wp

Effective Jan. 10, 1997
Note: We do not have an electronic copy of these changes.

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 Sections 19-3-104(3) and 19-3-104(6) and 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 R313-12-55.

R313-12-3. Definitions.

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

"A_1" means the maximum activity of special form radioactive material permitted in a Type A package. "A_2" means the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are either listed in R313-19-100, Table 4, or may be derived in accordance with the procedures prescribed in R313-19-100(19).

"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 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:

(a) consistent with the purpose for which the licensed or registered activity is undertaken;

(b) taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations; and

(c) 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. "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, ·ided in or made radioactive by exposure to the radiation incident to the p·· s of producing or utilizing special nuclear material; and

(b) che 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. A licensee or registrant shall not change the method observed by him of determining calendar quarters for purposes of these rules except at the beginning of a calendar 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.

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

"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.

"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 R313-12-20 Units of exposure and dose for the SI equivalent. For purposes of these rules, this term is used as a noun.

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

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

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

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

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

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

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

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

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

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

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

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

"IND" means investigatory new drug for which an exemption has been claimed

under the United States Food, Drug and Cosmetic Act.

"Individual" means a human being.

"Individual monitoring" means the assessment of:

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

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

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

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

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

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

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

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

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

"Licensing state" means a state with rules equivalent to the Suggested State Regulations for Control of Radiation relating to, and an effective program for, the regulatory control of NARM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.

"Limits". See "Dose limits".

"Lost or missing licensed or registered material" means licensed or registered material whose location is unknown. This definition includes licensed or registered 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 in a controlled or unrestricted area. However, an individual is not a member of the public during a period in which the individual receives 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.

"NDA" means a New Drug Application which has been submitted to the United States Food and Drug Administration.

"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 a restricted area or in the course of employment in which the individual's assigned

duties involve exposure to sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received from background radiation, as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the public.

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

"Particle accelerator" means a machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one MeV.

"Person" means an individual, corporation partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, or another state or political subdivision or agency thereof, and a legal successor, representative, agent or agency of the foregoing, but does not include federal government agencies.

"Personnel monitoring equipment," see individual monitoring devices.

"Pharmacist" means an individual licensed by this state to practice pharmacy. See Sections 58-17-1 through 58-17-27.

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

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

"Public dose" means the dose received by a member of the public from exposure to sources of radiation either within a licensee's or registrant's controlled area or in unrestricted areas. It does not include occupational dose, dose received from background radiation, dose received as a patient from medical practices, or dose from voluntary participation in medical research programs.

"Pyrophoric liquid or solid or gas" means a substance that ignites spontaneously in dry or moist air at or below 130 degrees Fahrenheit (54.4 degrees Celsius).

"Qualified expert" means an individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs, for example, individuals certified in the appropriate field by the American Board of Radiology or the American Board of Health Physics, or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy, for example, individuals certified in Therapeutic Radiological Physics or X-Ray and Radium Physics by the American Board of Radiology, or those having equivalent qualifications.

"Quality factor" (Q) means the modifying factor, listed in Tables 1 and 2 of 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.

"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".

[~~"Registrable item" means a radiation machine requiring registration under R313-16-230.~~]

"Registrant" means [~~a person who owns or possesses and administratively controls an X-ray system and is required by the provisions in R313-16-230 to register with the Department~~]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.

"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.

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

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

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

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

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

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

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

"Source 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. 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 either designed or constructed after June 30, 1985, shall meet requirements of this definition applicable at the time of its design or construction.

"Special nuclear material" means:

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

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

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

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

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

"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.

"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 x 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 change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

~~[R313-12-7. Public Notice and Public Comment Period.~~

~~(1) The Executive Secretary shall give public notice of, and an opportunity to comment on the following actions:~~

~~(a) Proposed licensing action for license categories 4a, b, c, d and 6 identified in R313-70-7 or a proposed approval or denial of a significant radioactive materials license, license amendment, or license renewal;~~

~~(b) The initial proposed registration of an ionizing radiation producing machine which operates at a kilovoltage potential (kVp) greater than 200 in an open beam configuration. R313-12-7(1)(b) does not apply to use in the healing arts;~~

~~(c) Board activities that may have significant public interest and the Board requests the Executive Secretary to take public comment on those proposed activities.~~

~~(2) Public notice shall allow at least 30 days for public comment.~~

~~(3) Public notice may describe more than one action listed in R313-12-7(1) and may combine notice of a public hearing with notice of the proposed action.~~

~~(4) Public notice shall be given by publication in a newspaper of general circulation in the area affected by the proposed action; to persons on a mailing list developed by the Executive Secretary, including those who request in writing to be on the list; and any other means if necessary to assure adequate notice to the affected public.~~

~~R313-12-8. Public Comments, Response to Comments and Requests for Public Hearings.~~

~~(1) During the public comment period provided under R313-12-7, any interested person may submit written comments on the proposed action and may request a public hearing, if no hearing has already been scheduled.~~

~~(2) A request for a public hearing shall be in writing and shall state the nature of the issues proposed to be raised in the hearing.~~

~~(3) Comments received during the public comment period and during any hearing shall be considered in making the final decision.~~

~~(4) At the time of the final decision, the Executive Secretary shall issue a response to comments, which shall include:~~

~~(a) Specific provisions, if any, that have been changed in the final action and the reasons for the change; and~~

~~(b) A brief description and response to all significant comments raised during the public comment period or during any hearing.~~

~~(5) The Executive Secretary's response to public comments shall be available to the public.~~

~~R313-12-9. Public Hearings.~~

~~(1) This section applies to public hearings of proposed actions specified~~

~~in R313-12-7.~~

~~(2) The Executive Secretary shall hold a public hearing whenever he finds, on the basis of requests, a significant degree of public interest in the proposed action.~~

~~(3) The Executive Secretary may also hold a public hearing at his discretion, whenever, for instance, a hearing might clarify one or more issues involved in the proposed action.~~

~~(4) The Executive Secretary shall hold a public hearing whenever he receives written notice of opposition to a proposed action and a request for a hearing within 30 days of public notice under R313-12-7.~~

~~(5)(a) Public notice of the hearing shall be given as specified in R313-12-7.~~

~~(b) The public comment period under R313-12-7 shall automatically be extended to the close of any public hearing under this section. The hearing officer may also extend the comment period by so stating at the hearing.~~

~~(c) Whenever possible the Executive Secretary shall schedule a hearing under this section at a time and location convenient to the parties involved.~~

~~(d) Any person at the hearing may submit oral or written statements and data concerning the proposed action. Reasonable limits may be set upon the time allowed for oral statements and the submission of statements in writing may be required.~~

~~(e) A tape recording or written transcript of the hearing shall be made available to the public.~~

R313-12-20. 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 x 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 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	2.5×10^{-8}	2	980×10^6	980×10^8
	1×10^{-7}	2	980×10^6	980×10^8
	1×10^{-6}	2	810×10^6	810×10^8
	1×10^{-5}	2	810×10^6	810×10^8
	1×10^{-4}	2	840×10^6	840×10^8
	1×10^{-3}	2	980×10^6	980×10^8
	1×10^{-2}	2.5	1010×10^6	1010×10^8
	1×10^{-1}	7.5	170×10^6	170×10^8
	5×10^{-1}	11	39×10^6	39×10^8
	1	11	27×10^6	27×10^8
	2.5	9	29×10^6	29×10^8
	5	8	23×10^6	23×10^8
	7	7	24×10^6	24×10^8
	10	6.5	24×10^6	24×10^8
	14	7.5	17×10^6	17×10^8
	20	8	16×10^6	16×10^8
	40	7	14×10^6	14×10^8
	60	5.5	16×10^6	16×10^8
	1×10^2	4	20×10^6	20×10^8
	2×10^2	3.5	19×10^6	19×10^8
	3×10^2	3.5	16×10^6	16×10^8
	4×10^2	3.5	14×10^6	14×10^8

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. 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 property.

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 property.

(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.

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: [~~radiation, public comment, public hearings~~]definitions, units, inspections, exemptions

[~~1994~~]1996/7

19-3-104
19-3-108

Effective Jan 10, 1997

R313. Environmental Quality, Radiation Control.
R313-14. Violations and Escalated Enforcement.
R313-14-1. Introduction and Purpose.

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

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

(b) obtaining prompt correction of violations;

(c) deterring future violations; and

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

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

R313-14-2. Responsibilities.

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

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

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

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

[~~(3) In the absence of the Executive Secretary, the authority of the Executive Secretary may be delegated within the Division to his designee.~~]

R313-14-3. Definitions.

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

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

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

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

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

R313-14-10. Severity of Violations.

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

(a) electronically produced radiation operations; or

(b) radioactive materials operations.

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

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

(4) The severity of a violation shall be characterized at the level best suited to the significance of the particular violation. A severity level may be increased if the circumstances surrounding the violation involve careless

disregard of requirements, deception, or other indications of willfulness. In determining the specific severity level of a violation involving willfulness, consideration will be given to factors like the position of the person involved in the violation, the significance of an underlying violation, the intent of the violator and the economic advantage gained by the violation. The relative weight given to these factors in arriving at the appropriate severity level is dependent on the circumstances of the violation.

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

R313-14-15. Enforcement Actions.

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

(1) Notice of Violation

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

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

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

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

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

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

(i) it was identified by the licensee or registrant;

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

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

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

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

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

(2) Civil Penalty.

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

(b) The level of a civil penalty is established so that a penalty does not

exceed $5,000 per violation. Except as modified by provision of the next paragraphs, the base civil penalties are as follows:

TABLE

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

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

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

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

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

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

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

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

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

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

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

(3) Orders.

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

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

(c) Suspension Orders may be used:

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

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

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

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

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

(d) Revocation Orders may be used:

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

(ii) when a licensee or registrant refuses to correct a violation;

(iii) when a licensee or registrant does not respond to a Notice of Violation;

(iv) when a licensee or registrant does not pay a fee required by the Department; or

(v) for any other reason for which revocation is authorized.

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

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

(4) Escalation of Enforcement Sanctions.

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

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

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

(5) Related Administrative Actions.

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

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

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

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

~~[R313-14-20. Administrative Procedures.~~

~~(1) The following proceedings and actions are designated to be conducted either formally or informally as required by Section 63-46b-4:~~

~~(a) Issuance of Notices of Violations and Orders are exempt under Section 63-46b-1(20)(k). Appeals of Notices of Violations and Orders shall be processed using formal proceedings.~~

~~(b) Disposal of impounded radioactive materials shall be processed using formal proceedings.~~

~~(2) Before a final Order is issued, the Executive Secretary or appointed hearing officer may convert proceedings which are designated to be informal to formal, the proceedings which are designated as formal to informal if conversion is in the public interest and rights of the parties are not unfairly prejudiced.~~

~~(3) Rules for conducting formal proceedings shall be as provided in Sections 63-46b-3, and 6 through 13. The procedures in Sections 63-46b-3 and 5 apply to informal proceedings.~~

~~(4) Declaratory Orders. In accordance with the provisions of Section 63-46b-21, a person may file a request for a declaratory order. The request shall be titled a petition for declaratory order and shall specifically identify the issues requested to be the subject of the order. Requests for a declaratory order, if set for adjudicative hearing, will be processed informally unless converted to a formal proceeding under R313-14-20(2). No declaratory orders will be issued in the circumstances described in Section 63-46b-21(3)(b). Intervention rights and other procedures governing declaratory orders are outlined in Section 63-46b-21.~~]

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

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

KEY: violations, penalties, [~~licensing, radioactive materials~~]enforcement
[~~1992~~]1996
19-3-109
19-3-111

Changed by DAR

Non-substantive Changes to R313-17
Effective Jun. 2, 1997 Note: We do not have electronic copies of these changes

R313. Environmental Quality, Radiation.
R313-17. Administrative Procedures.
R313-17-5 Administrative Procedures General Provisions

(1) PURPOSE AND SCOPE

R313-17-5 through 13 set out procedures for conducting formal adjudicative proceedings in accordance with the Utah Administrative Procedures Act (UAPA), Section 63-46b-1 et seq. and govern:

(a) the contest of the validity of initial order or notice of violation as described in R313-17-5(2);

(b) the contest of proposed imposition of civil penalties under Section 19-3-109; and

(c) other formal adjudicative proceedings before the Radiation Control Board.

(2) INITIAL PROCEEDINGS EXEMPT FROM UAPA

Proceedings that culminate in the issuance of an initial order or a notice of violation under the Utah Radiation Control Act are not governed by UAPA as specified in Section 63-46b-1(2)(k). This includes, but is not limited to, initial proceedings regarding:

(a) approval, amendment, denial, termination, transfer, revocation, or renewal of licenses;

(b) requests for variances, exemptions, and other approvals;

(c) notices of violation and orders associated with notices of violation;

(d) orders to comply and orders to cease and desist;

(e) impoundment of radioactive material;

(f) orders for decommissioning;

(g) declaratory orders; and

(h) orders for surveying, monitoring, sampling, or information;

(3) DESIGNATION OF PROCEEDINGS

(a) Contest of an initial order or notice of violation or proposed imposition of civil penalties shall be conducted as a formal proceeding.

(b) The Board in accordance with Section 63-46b-4(3) may convert proceedings which are designated to be formal to informal, and proceedings which are designated as informal to formal if conversion is in the public interest and rights of all parties are not unfairly prejudiced.

(c) Unless otherwise stated in R313, informal adjudicative proceedings shall be conducted in accordance with Section 63-46b-5.

(4) APPEARANCES AND REPRESENTATION

(a) An individual who is a participant to a proceeding, or an officer designated by a partnership, corporation, association, or governmental entity which is a participant to a proceeding, may represent his, her, or its interest in the proceeding.

(b) Any participant may be represented by legal counsel.

(5) COMPUTATION OF TIME

Time shall be computed as provided in Rule 6(a) of the Utah Rules of Civil Procedure except that no additional time shall be allowed for service by mail.

KEY: administrative procedures, public comment, public hearings, orders
1997 **19-3-103.5**
19-3-104

Non-substantive Changes to R313-17
Effective Jun 2, 1997

Note: We do not have electronic copies of these changes

R313. Environmental Quality, Radiation.
R313-17. Administrative Procedures.
R313-17-7. Parties and Intervention.

(1) DETERMINATION OF A PARTY.

The following persons are Parties to a formal proceeding governed by these rules:

(a) The person to whom an initial order or notice of violation is directed, such as a person who submitted a license application that was approved or disapproved by order of the Executive Secretary;

(b) The Executive Secretary of the Radiation Control Board; and

(c) All persons whose legal rights or interests are substantially affected by the proceeding, who have standing to participate in the proceeding, and to whom the Board has granted intervention under R313-17-7(2).

(2) INTERVENTION

A petition for intervention may be filed by a petitioner to commence an adjudicative proceeding in accordance with R313-17-6(2) or to intervene after a notice of agency action or request for agency action has been filed. A petitioner for intervention shall meet the following requirements:

(a)(i) The request for agency action is timely filed in accordance with R313-17-6(2); or

(ii) The Petition to Intervene in a proceeding commenced by a party other than the Petitioner for Intervention is filed with the Board, with a copy to all parties, within 20 days from the date of the Notice of Agency Action or Request for Agency Action.

(b) The Petition to Intervene:

(i) Identifies the proceedings in which intervention is sought;

(ii) Contains a statement of facts demonstrating that the petitioner's legal rights or interests are substantially affected by the formal adjudicative proceeding and the petitioner qualifies as an Intervenor under Section 63-46b-9; and

(iii) Includes a statement of relief sought from the Board, including the basis thereof.

(c) Unless modified by the Presiding Officer, any party may respond to a Petition for Intervention during the period allowed for responsive pleadings under Section 63-46b-6. The Chair of the Radiation Control Board may act as Presiding Officer for purposes of this paragraph.

(d) Intervention may only be granted by order of the Board to a petitioner who meets the requirements of R313-17-7(2)(a) and (b).

(3) DESIGNATION OF PARTIES

Unless otherwise designed by the Hearing Officer:

(a) The person filing a Request for Agency Action shall be the Petitioner and the Executive Secretary shall be the Respondent.

(b) In a proceeding requested by a Petitioner for Intervention, the person granted Intervenor status shall be the Petitioner. The Executive Secretary and the person to whom the challenged order or notice is directed shall be the Respondents.

(4) AMICUS CURIAE (Friend of the Court)

Persons may be permitted by the Presiding Officer(s) to enter an appearance as Amicus Curiae (Friend of the Court), subject to conditions established by the Presiding Officer(s).

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1997 **19-3-103.5**
19-3-104

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R313. Environmental Quality, Radiation.
R313-17. Administrative Procedures.
R313-17-1. Application of Rule.

This rule applies to proceedings under Title 19, Chapter 3 (Radiation Control Act).

R313-17-2. Public Notice and Public Comment Period

(1) The Executive Secretary shall give public notice of, and an opportunity to comment on the following actions:

(a) Proposed licensing action for license categories 4a, b, c, d and 6 identified in R313-70-7 or a proposed approval or denial of a significant radioactive materials license, license amendment, or license renewal.

(b) The initial proposed registration of an ionizing radiation producing machine which operates at a kilovoltage potential (kVp) greater than 200 in an open beam configuration. R313-17-2(1)(b) does not apply to use in the healing arts.

(c) Board activities that may have significant public interest and the Board requests the Executive Secretary to take public comment on those proposed activities.

(2) Public notice shall allow at least 30 days for public comment.

(3) Public notice may describe more than one action listed in R313-17-2(1) and may combine notice of a public hearing with notice of the proposed action.

(4) Public notice shall be given by publication in a newspaper of general circulation in the area affected by the proposed action. Notice shall also be given to persons on a mailing list developed by the Executive Secretary and those who request in writing to be notified.

R313-17-3. Public Comments, Response to Comments and Requests for Public Hearings

(1) During the public comment period provided under R313-17-2, any interested person may submit written comments on the proposed action and may request a public hearing, if no hearing has already been scheduled.

(2) A request for a public hearing shall be in writing and shall state the nature of the issues proposed to be raised in the hearing.

(3) Comments received during the public comment period and during any hearing shall be considered in making the final decision.

(4) At the time of the final decision, the Executive Secretary shall issue a response to comments, which shall include:

(a) Specific provisions, if any, that have been changed in the final action and the reasons for the change; and

(b) A brief description and response to all significant comments raised during the public comment period or during any hearing.

(5) The Executive Secretary's response to public comments shall be available to the public.

R313-17-4. Public Hearings.

(1) This section applies to hearings for public comment on proposed actions specified in R313-12-7. This section does not govern adjudicative proceedings.

(2) The Executive Secretary shall hold a public hearing whenever he finds, on the basis of requests, a significant degree of public interest in the proposed action.

(3) The Executive Secretary may also hold a public hearing at his discretion, whenever, for instance, a hearing might clarify one or more issues involved in the proposed action.

(4) The Executive Secretary shall hold a public hearing whenever he receives written notice of opposition to a proposed action and a request for a hearing within 30 days of public notice under R313-12-7.

(5)(a) Public notice of the hearing shall be given as specified in R313-12-7.

(b) The public comment period under R313-12-7 shall automatically be extended to the close of any public hearing under this section. The hearing officer may also extend the comment period by so stating at the hearing.

(c) Whenever possible the Executive Secretary shall schedule a hearing under this section at a time and location convenient to the parties involved.

(d) Any person at the hearing may submit oral or written statements and data concerning the proposed action. Reasonable limits may be set upon the time allowed for oral statements and the submission of statements in writing may be required.

(e) A tape recording or written transcript of the hearing shall be made available to the public.

R313-17-5 Administrative Procedures General Provisions

(1) PURPOSE AND SCOPE

R313-5 through 13 set out procedures for conducting formal adjudicative proceedings in accordance with the Utah Administrative Procedures Act (UAPA), Section 63-46b-1 et seq. and govern:

(a) the contest of the validity of initial order or notice of violation as described in R313-17-5(2);

(b) the contest of proposed imposition of civil penalties under Section 19-3-109; and

(c) other formal adjudicative proceedings before the Radiation Control Board.

(2) INITIAL PROCEEDINGS EXEMPT FROM UAPA

Proceedings that culminate in the issuance of an initial order or a notice of violation under the Utah Radiation Control Act are not governed by UAPA as specified in Section 63-46b-1(2)(k). This includes, but is not limited to, initial proceedings regarding:

(a) approval, amendment, denial, termination, transfer, revocation, or renewal of licenses;

(b) requests for variances, exemptions, and other approvals;

(c) notices of violation and orders associated with notices of violation;

(d) orders to comply and orders to cease and desist;

(e) impoundment of radioactive material;

(f) orders for decommissioning;

(g) declaratory orders; and

(h) orders for surveying, monitoring, sampling, or information;

(3) DESIGNATION OF PROCEEDINGS

(a) Contest of an initial order or notice of violation or proposed imposition of civil penalties shall be conducted as a formal proceeding.

(b) The Board in accordance with Section 63-46b-4(3) may convert proceedings which are designated to be formal to informal, and proceedings which are designated as informal to formal if conversion is in the public interest and rights of all parties are not unfairly prejudiced.

(c) Unless otherwise stated in R313, informal adjudicative proceedings shall be conducted in accordance with Section 63-46b-5.

(4) APPEARANCES AND REPRESENTATION

(a) An individual who is a participant to a proceeding, or an officer designated by a partnership, corporation, association, or governmental entity which is a participant to a proceeding, may represent his, her, or its interest in the proceeding.

(b) Any participant may be represented by legal counsel.

(5) COMPUTATION OF TIME

Time shall be computed as provided in Rule 6(a) of the Utah Rules of Civil Procedure except that no additional time shall be allowed for service by mail.

R313-17-6. Commencing a Formal Adjudicative Proceeding

(1) Except as otherwise permitted by emergency orders as described in Section 63-46b-20, all adjudicative proceedings shall be commenced by either:

(a) a Notice of Agency Action in accordance with Section 63-46b-3, if proceedings are commenced by the Board; or

(b) a Request for Agency Action in accordance with R313-17-6(2), if proceedings are commenced by a person other than the Board.

(2)(a) The validity of initial orders, notices of violation and proposed imposition of civil penalties, as described in R313-17-5(1) and (2), may be contested by filing a written Request for Agency Action with the Board and submitted to:

Executive Secretary, Utah Radiation Control Board
Division of Radiation Control
168 North 1950 West
PO Box 144850
Salt Lake City, Utah 84114-4850.

(b) Any such request is governed by and shall comply with the requirements of Section 63-46b-3(3) and shall be received for filing within 30 days of the issuance of the Executive Secretary's order or notice of violation.

(c)(i) All initial orders or notices of violation are effective upon issuance and shall become final if not contested within 30 days after the date issued.

(ii) Issuance of such orders or notices of violation means the time a signed order is mailed by certified mail to the recipient's most current address or hand delivered to the recipient.

(iii) If delivery by certified mail is refused, the issued order or notice will be sent by regular first class mail.

(d) Failure to timely contest an initial order or notice of violation waives any right of administrative contest, reconsideration, review or judicial appeal.

(3) RESPONSE TO REQUEST FOR AGENCY ACTION

In accordance with Section 63-46b-3(3)(d) and (e), notice of the time and place for a hearing shall be provided in the response to a request for agency action, or shall be provided promptly after the hearing is scheduled.

(4) PRE-HEARING RECORD

The Executive Secretary shall compile an administrative record prior to a scheduled hearing and give any party the opportunity to supplement the record. The pre-hearing record shall also consist of pleadings or other documents filed prior to the hearing.

R313-17-7. Parties and Intervention.

(1) DETERMINATION OF A PARTY.

The following persons are Parties to a formal proceeding governed by these rules:

(a) The person to whom an initial order or notice of violation is directed, such as a person who submitted a license application that was approved or disapproved by order of the Executive Secretary;

(b) The Executive Secretary of the Radiation Control Board; and

(c) All persons whose legal rights or interests are substantially affected by the proceeding, who have standing to participate in the proceeding, and to whom the Board has granted intervention under R313-17-7(2).

(2) INTERVENTION

A petition for intervention may be file by a petitioner to commence an adjudicative proceeding in accordance with R313-17-6(2) or to intervene after a notice of agency action or request for agency action has been filed. A petitioner for intervention shall meet the following requirements:

(a)(i) The request for agency action is timely filed in accordance with R313-17-6(2); or

(ii) The Petition to Intervene in a proceeding commenced by a party other than the Petitioner for Intervention is filed with the Board, with a copy to all parties, within 20 days from the date of the Notice of Agency Action or Request for Agency Action.

(b) The Petition to Intervene:

(i) Identifies the proceedings in which intervention is sought;

(ii) Contains a statement of facts demonstrating that the petitioner's legal rights or interests are substantially affected by the formal adjudicative proceeding and the petitioner qualifies as an Intervenor under Section 63-46b-9; and

(iii) Includes a statement of relief sought from the Board, including the basis thereof.

(c) Unless modified by the Presiding Officer, any party may respond to a Petition for Intervention during the period allowed for responsive pleadings under Section 63-46b-6. The Chair of the Radiation Control Board may act as Presiding Officer for purposes of this paragraph.

(d) Intervention may only be granted by order of the Board to a petitioner who meets the requirements of R313-17-7(2)(a) and (b).

(3) DESIGNATION OF PARTIES

Unless otherwise designed by the Hearing Officer:

(a) The person filing a Request for Agency Action shall be the Petitioner and the Executive Secretary shall be the Respondent.

(b) In a proceeding requested by a Petitioner for Intervention, the person granted Intervenor status shall be the Petitioner. The Executive Secretary and the person to whom the challenged order or notice is directed shall be the Respondents.

(4) AMICUS CURIAE (Friend of the Court)

Persons may be permitted by the Presiding Officer(s) to enter an appearance as Amicus Curiae (Friend of the Court), subject to conditions established by the Presiding Officer(s).

R313-17-8. Conduct of Proceedings.

(1) ROLE OF BOARD

(a) The Board is the "agency head" as that term is used in Section 63-46b. The Board is also the "presiding officer," as that term is used in Section 63-46b, except:

(i) The Chair of the Board shall be considered the Presiding Officer to the extent that these rules allow; and

(ii) The Board may by order appoint one or more Presiding Officers to preside over all or a portion of the proceedings.

(b) The Chair of the Board may delegate his or her authority as specified in this Rule to another Board member.

(2) APPOINTED PRESIDING OFFICERS

Unless otherwise explicitly provided in an order of appointment, any appointment of a Presiding Officer shall be for the purpose of conducting all aspects of an adjudicative proceeding, except grant of intervention, stays of orders and issuance of the final order. As used in these rules, the term Presiding Officer shall mean Presiding Officers if more than one Presiding Officer is appointed by the Board.

(3) PRE-HEARING CONFERENCES

The Presiding Officer may direct the Parties to appear at a specified time and place for pre-hearing conferences for the purposes of clarifying the issues, simplifying the evidence, facilitating discovery, expediting proceedings, or encouraging settlement.

(4) BRIEFS

(a) Unless otherwise directed by the Presiding Officer, parties to the proceeding may submit a pre-hearing brief at least five business days before the hearing. Post-hearing briefs will be allowed only as authorized by the Presiding Officer.

(b) Response briefs may not be filed unless permitted by the Presiding Officer.

(5) SCHEDULES

(a) The Presiding Officer shall establish schedules for discovery and other pre-hearing proceedings, for the hearing, and for any post-hearing proceedings.

(b) The parties are encouraged to prepare a joint proposed schedule. If the parties cannot agree on a joint proposed schedule, the Presiding Officer may consider proposals by any party.

(6) EXTENSIONS OF TIME

Except as otherwise provided by statute, the Presiding Officer may approve extensions of time limits established by this rule, and may extend time limits adopted in schedules established under R313-17-8(5). The Presiding Officer may also postpone hearings. The Chair of the Board may act as Presiding Officer for purposes of this paragraph.

(7) MOTIONS

All motions shall be filed a minimum of 12 days before a scheduled hearing, unless otherwise directed by the Presiding Officer. A memorandum in opposition to a motion may be filed within ten days of the filing of the motion, or at least one day before any scheduled hearing, whichever is earlier. Memoranda in support of or in opposition to motions may not exceed 15 pages unless otherwise provided by the Presiding Officer.

(8) FILING AND COPIES OF SUBMISSIONS

The original of any motion, brief, petition for intervention, or other

submission shall be filed with the Executive Secretary. In addition, the submitter shall provide a copy to each Presiding Officer and to all parties or their counsel of record.

R313-17-9. Hearings.

(1) CONDUCT OF HEARING

The Presiding Officer shall govern the conduct of a hearing, and may establish reasonable limits on the length of witness testimony, cross-examination, oral arguments or opening and closing statements.

(2) ORDER OF PRESENTATION

Unless otherwise directed by the Presiding Officer, the Executive Secretary shall present its case first, followed by the Petitioner and any other party, then the Executive Secretary, and other parties if appropriate, shall have the opportunity for tebuttal.

R313-17-10. Orders.

(1) PROPOSED ORDERS BY PARTIES

Unless otherwise directed by the Presiding Office., each party may provide proposed orders for the Presiding Officer within ten days of the conclusion of the hearing.

(2) DRAFT ORDERS OF APPOINTED PRESIDING OFFICERS

(a) The appointed Officer presiding over the adjudicative proceeding shall prepare a recommended order, provide a copy of the order to the Board and mail a copy of the order to all parties or their counsel of record.

(b) The Board shall review the recommended order and hearing record.

(c) The Board may give each party the opportunity to make a presentation to the Board specific to the recommended order.

(d) After deliberation, the Board shall determine whether to accept, reject or modify the recommended order. The Board may remand part or all of the matter to the Presiding Officer for further proceedings.

(e) The Board may modify this procedure with notice to all parties.

(3) FINAL ORDERS

The Board shall issue a final order which shall include the information required by Sections 63-46b-10 or 63-46b-5(1)(i).

R313-17-11. Stays of Orders.

(1) STAY OF ORDERS PENDING ADMINISTRATIVE ADJUDICATION

(a) A party seeking a stay of a challenged order during an adjudicative proceeding shall file a motion with the Board. If granted, a stay would suspend the challenged Order for the period as directed by the Board.

(b) The Board may order a stay of the Order that is the subject of the formal adjudicative proceeding if the party seeking the Stay demonstrates the following:

(i) The party seeking the Stay will suffer irreparable harm unless the stay issues;

(ii) The threatened injury to the party seeking the Stay outweighs whatever damage the proposed stay is likely to cause the party restrained or enjoined;

(iii) The Stay, if issued, would not be adverse to the public interest; and

(iv) There is substantial likelihood that the party seeking the Stay will prevail on the merits of the underlying claim, or the case presents serious issues on the merits which should be the subject of further adjudication.

(2) STAY OF THE ORDER PENDING JUDICIAL REVIEW

(a) A party seeking a stay of the Board's final order during judicial review shall file a motion with the Board.

(b) The Board as Presiding Officer may grant a stay of its order during the pendency of judicial review if the standards of R317-17-11(1)(b) are met.

R313-17-12. Reconsideration.

No agency review under Section 63-46b-12 is available. A party may request reconsideration of an order of the Presiding Officer as provided in Section 63-46b-13.

R313-17-13. Disqualification of Presiding Officer(s).

(1) DISQUALIFICATION OF PRESIDING OFFICER

(a) A member of the Board or other Presiding Officer shall disqualify himself or herself from performing the functions of the Presiding Officer regarding any matter in which he or she, or his or her spouse, or a person within the third degree of relationship to either of them, or the spouse of such person:

(i) Is a party to the proceeding, or an officer, director, or trustee of a party;

(ii) Has acted as an attorney in the proceeding or served as an attorney for, or otherwise represented a party concerning the matter in controversy;

(iii) Knows that he or she has an financial interest, either individually or as a fiduciary, in the subject matter in controversy or in a party to the proceeding;

(iv) Knows that he or she has any other interest that could be substantially affected by the outcome of the proceeding; or

(v) Is likely to be a material witness in the proceeding.

(b) A member of the Board or other Presiding Officer is also subject to disqualification under principles of due process and administrative law.

(2) MOTIONS FOR DISQUALIFICATION

A motion for disqualification shall be made first to the Presiding Officer. If the Presiding Officer is appointed, any determination of the Presiding Officer upon a motion for disqualification may be appealed to the Board.

R313-17-14. Other Forms of Address.

Nothing in these rules shall prevent any person from requesting an opportunity to address the Board as a member of the public, rather than as a party. An opportunity to address the Board shall be granted at the discretion of the Board. However, addressing the Board in this manner does not constitute a request for agency action under R313-17-6.

R313-17-15. Requests for Records.

Requests for records under the Utah Government Record Access and Management Act, Title 63, Chapter 2, Utah Code Ann., are not governed by R313. See R305-1.

KEY: administrative procedures, public comment, public hearings, orders
1996 19-3-103.5
19-3-104

Effective July 18, 1997

R313. Environmental Quality, Radiation Control.
R313-21. General Licenses.
R313-21-1. Purpose and Scope.

(1) R313-21 establishes general licenses for the possession and use of radioactive material contained in certain items and a general license for ownership of radioactive material.

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

R313-21-21. General Licenses--Source Material.

(1) A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local government agencies to use and transfer not more than 15 pounds (6.82 kg) of source material at any one time for research, development, educational, commercial, or operational purposes. A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of 150 pounds (68.2 kg) of source material in any one calendar year.

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

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

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

(5) Depleted uranium in industrial products and devices.

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

(b) The general license in R313-21-21(5)(a) applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to R313-22-75(12) or in accordance with a specific license issued to the manufacturer by a Licensing State, the Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the Nuclear Regulatory Commission or an Agreement State.

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

(A) name and address of the registrant;

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

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

(ii) The registrant possessing or using depleted uranium under the general license established by R313-21-21(5)(a) shall report in writing to the Executive Secretary any changes in information previously furnished on the "Registration

Form - Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of the change.

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

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

(ii) shall not abandon depleted uranium;

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

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

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

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

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

R313-21-22. General Licenses*--Radioactive Material Other Than Source Material.

NOTE: *Different general licenses are issued in this section, each of which has its own specific conditions and requirements.

(1) Certain devices and equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with the specific license issued to the manufacturer by the Nuclear Regulatory Commission for use pursuant to 10 CFR 31.3. This general license is subject to the provisions of R313-12-51 through R313-12-70, R313-15, R313-18 and R313-19 of these rules.

(a) Static Elimination Devices. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device.

(b) Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device or a total of not more than 50 millicuries (1.85 GBq) of hydrogen-3 (tritium) per device.

(2) RESERVED.

(3) RESERVED.

(4) Certain measuring, gauging or controlling devices.

(a) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, acquire, receive, possess, use or transfer, in accordance with the provisions of R313-21-22(4)(b), (c) and (d), radioactive material excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(b) The general license in R313-21-22(4)(a) applies only to radioactive material contained in devices which have been manufactured and labeled in

accordance with the specifications contained in a specific license issued by the Executive Secretary pursuant to R313-22-75 (4) or in accordance with specific license issued by the Nuclear Regulatory Commission, an Agreement State or a Licensing State, which authorizes distribution of devices to persons generally licensed by the Nuclear Regulatory Commission, an Agreement State or Licensing State.*

NOTE: *Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.

(c) Any person who owns, acquires, receives, possesses, uses or transfers radioactive material in a device pursuant to the general license in R313-21-22(4)(a):

(i) shall register all devices by submitting form DRC-13, "Registration Form - Radioactive Material in Certain Measuring, Gauging or Controlling Devices Under General License," to the Executive Secretary within 30 days after the first receipt or acquisition of a device, however:

(A) devices containing [~~less~~]no more than ten millicuries of polonium-210 and used for producing an ionized atmosphere need not be registered; and

(B) devices containing hydrogen-3 (tritium) and used for producing light need not be registered;

(ii) shall furnish on form DRC-13 the following information and other information as may be required by that form:

(A) name and address of the registrant;

(B) a statement that the registrant has developed and will maintain procedures designed to establish physical control over the device described in R313-21-22(4)(a) and designed to prevent transfer of the device other than to a specific licensee authorized to receive it or to another general licensees only as authorized by R313-21-22(4)(c)(xii); and

(C) name or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising and maintaining the procedures identified in R313-21-22(4)(c)(ii)(B);

(iii) shall report in writing to the Executive Secretary any changes in information previously furnished on form DRC-13. The information shall be submitted within 30 days after the effective date of a change;

(iv) other than those persons using less than ten millic[illegible] polonium-210 or hydrogen-3 (tritium) for producing light or an ioniz[illegible]here, shall submit the appropriate fee as required by R313-70-7(11) wi[illegible]ys after the first receipt or acquisition of the device.

(v) shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by the labels;

(vi) shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at other intervals as are specified in the label, however:

(A) devices containing only krypton need not be tested for leakage of radioactive material; and

(B) devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta or gamma emitting material or 10 microcuries (0.37 MBq) of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested;

(vii) shall assure that the tests required by R313-21-22(4)(c)(vi) and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

(A) in accordance with the instructions provided by the labels; or

(B) by a person holding a specific license from the Executive Secretary, a Licensing State, the Nuclear Regulatory Commission or an Agreement State which authorizes the activities in R313-21-22(4)(c)(vii);

(viii) shall maintain records showing compliance with the requirements of R313-21-22(4)(c)(vi) and (vii). The records shall show the results of tests. The records also shall show the dates of performance and the names of persons performing, testing, installing, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of

tests for leakage of radioactive material required by R313-21-22(4)(c)(vi) shall be maintained for [~~one~~]three years after the next required leak test is performed or the sealed source is transferred or disposed of. Records of tests of the on-off mechanism and indicator required by R313-21-22(4)(c)(vi) shall be maintained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of. Records which are required by R313-21-22(4)(c)(vii) shall be maintained for a period of two years from the date of the recorded event or until the device is transferred or disposed of;

(ix) upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding a specific license from the Executive Secretary, a Licensing State, the Nuclear Regulatory Commission, or an Agreement State to repair the devices, or disposed of by transfer to a person authorized by a specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the Executive Secretary a report containing a brief description of the event and the remedial action taken;

(x) shall not abandon any device containing radioactive material;

(xi) except as provided in R313-21-22(4)(c)(xii), shall transfer or dispose of the device containing radioactive material only by transfer to a person holding a specific license of the Executive Secretary, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State whose specific license authorizes the person to receive the device and within 30 days after transfer of a device to a specific licensee shall furnish to the Executive Secretary a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;

(xii) shall transfer the device to another general licensee only:

(A) where the device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of R313-21-22(4) and any safety documents identified in the label of the device and within 30 days of the transfer, report to the Executive Secretary the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name or position of an individual who may constitute a point of contact between the Executive Secretary and the transferee; or

(B) where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee;

(xiii) shall comply with the provisions of R313-15-1201 and R313-15-1202 for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of R313-15 and R313-18; and

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

(d) The general license in R313-21-22(4)(a) does not authorize the manufactureof devices containing radioactive material.

(e) The general license provided in R313-21-22(4)(a) is subject to the provisions of R313-12-51 through R313-12-53, R313-12-70, R313-14, R313-19-34, R313-19-41, R313-19-61, and R313-19-100.

(5) Luminous safety devices for aircraft.

(a) A general license is hereby issued to own, receive, acquire, possess and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

(i) each device contains not more than 10 curies (370.0 GBq) of tritium or 300 millicuries (11.1 GBq) of promethium-147; and

(ii) each device has been manufactured, assembled or imported in accordance with a specific license issued by the Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the Executive Secretary or an Agreement State to the manufacturer or assembler of the device pursuant to licensing requirements equivalent to those in 10 CFR 32.53.

(b) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in R313-21-22(5) are exempt from the

requirements of R313-15 and R313-18, except that they shall comply with the provisions of R313-15-1201 and R313-15-1202.

(c) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

(d) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

(e) This general license is subject to the provisions of R313-12-51 through R313-12-70, R313-14, R313-19-34, R313-19-41, R313-19-61, and R313-19-100.

(6) Ownership of radioactive material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of R313-21, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

(7) Calibration and reference sources.

(a) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use and transfer, in accordance with the provisions of R313-21-22(7)(d) and (e), americium-241 in the form of calibration or reference sources:

(i) any person who holds a specific license issued by the Executive Secretary which authorizes that person to receive, possess, use and transfer radioactive material; and

(ii) any person who holds a specific license issued by the Nuclear Regulatory Commission which authorizes that person to receive, possess, use and transfer special nuclear material.

(b) A general license is hereby issued to own, receive, possess, use and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of R313-21-22(7)(d) and (e) to a person who holds a specific license issued by the Executive Secretary which authorizes that person to receive, possess, use and transfer radioactive material.

(c) A general license is hereby issued to own, receive, possess, use and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of R313-21-22(7)(d) and (e) to a person who holds a specific license issued by the Executive Secretary which authorizes that person to receive, possess, use and transfer radioactive material.

(d) The general licenses in R313-21-22(7)(a), (b) and (c) apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the Nuclear Regulatory Commission pursuant to 10 CFR 32.57 or 10 CFR 70.39 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Executive Secretary, a Licensing State, or an Agreement State pursuant to licensing requirements equivalent to those contained in 10 CFR 32.57 or 10 CFR 70.39.

(e) The general licenses provided in R313-21-22(7)(a), (b), and (c) are subject to the provisions of R313-12-51 through R313-12-53, R313-12-70, R313-14, R313-19-34, R313-19-41, R313-19-61, R313-19-100, R313-15 and R313-18. In addition, persons who own, receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to these general licenses:

(i) shall not possess at any one time, at any one location of storage or use, more than 5 microcuries (185.0 kBq) of americium-241, 5 microcuries (185.0 kBq) of plutonium, or 5 microcuries (185.0 kBq) of radium-226 in a source;

(ii) shall not receive, possess, use or transfer a source unless the source, or the storage container, bears a label which includes one of the following statements or a substantially similar statement which contains the information called for in one of the following statements, as appropriate:

(A) The receipt, possession, use and transfer of this source, Model No. ....., Serial No. ....., are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL
THIS SOURCE CONTAINS (AMERICIUM-241)(PLUTONIUM)*
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.
.....

Typed or printed name of the manufacturer or importer

NOTE: *Show the name of the appropriate material.

(B) The receipt, possession, use and transfer of this source, Model No....., Serial No....., are subject to a general license and the regulations of a Licensing State. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL

THIS SOURCE CONTAINS RADIUM-226

DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

.....

Typed or printed name of the manufacturer or importer

(iii) shall not transfer, abandon, or dispose of a source except by transfer to a person authorized by a license from the Executive Secretary, a Licensing State, the Nuclear Regulatory Commission, or an Agreement State to receive the source;

(iv) shall store a source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

(v) shall not use a source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(f) These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

(8) RESERVED.

(9) General license for use of radioactive material for certain in vitro clinical or laboratory testing.*

NOTE: *The New Drug provisions of the Federal Food, Drug and Cosmetic Act also govern the availability and use of any specific diagnostic drug in interstate commerce.

(a) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for the following stated tests, in accordance with the provisions of R313-21-22(9) (b), (c), (d), (e), and (f) the following radioactive materials in prepackaged units for use in in-vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

(i) iodine-125, in units not exceeding 10 microcuries (370.0 kBq) each;

(ii) iodine-131, in units not exceeding 10 microcuries (370.0 kBq) each;

(iii) carbon-14, in units not exceeding 10 microcuries (370.0 kBq) each;

(iv) hydrogen-3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each;

(v) iron-59, in units not exceeding 20 microcuries (740.0 kBq) each;

(vi) cobalt-57, in units not exceeding 10 microcuries (370.0 kBq) each;

(vii) selenium-75, in units not to exceed 10 microcuries (370.0 kBq) each; or

(viii) mock iodine-125, reference or calibration sources, in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185.0 Bq) of americium-241 each.

(b) A person shall not receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by R313-21-22(9)(a) until that person has filed form DRC-07, "Registration Form-In Vitro Testing with Radioactive Material Under General License," with the Executive Secretary and received a Certificate of Registration signed by the Executive Secretary, or until that person has been authorized pursuant to R313-32 to use radioactive material under the general license in R313-21-22(9). The physician, veterinarian, clinical laboratory or hospital shall furnish on form DRC-07 the following information and other information as may be required by that form:

(i) name and address of the physician, veterinarian, clinical laboratory or hospital,

(ii) the location of use; and

(iii) a statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in R313-21-22(9)(a) and that the tests will be performed only by personnel competent in the use of radiation measuring instruments and in the handling of the radioactive material.

(c) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by R313-21-22(9)(a) shall comply with the following:

(i) The general licensee shall not possess at any one time, pursuant to the general license in R313-21-22(9)(a) at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59 and cobalt-57, or any combination, in excess of 200 microcuries (7.4 MBq).

(ii) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(iii) The general licensee shall use the radioactive material only for the uses authorized by R313-21-22(9)(a).

(iv) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Executive Secretary, the Nuclear Regulatory Commission, an Agreement State or Licensing State, nor transfer the radioactive material in a manner other than in the unopened, labeled shipping container as received from the supplier.

(v) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in R313-21-22(9)(a)(viii) as required by R313-15-1001.

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

(d) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to R313-21-22(9)(a):

(i) Except as prepackaged units which are labeled in accordance with the provision of an applicable specific license issued pursuant to R313-22-75(8) or in accordance with the provisions of a specific license issued by the Nuclear Regulatory Commission, an Agreement State or Licensing State which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3(tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under R313-21-22(9) or its equivalent, and

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

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

.....

Name of Manufacturer"

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

.....

Name of Manufacturer"

(e) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license in R313-21-22(9)(a) shall report in writing to the Executive Secretary, changes in the information previously furnished in the "Registration Form-In Vitro Testing with Radioactive Material Under General License", form DRC -07. The report shall be furnished within 30 days after the effective date of a change.

(f) Any person using radioactive material pursuant to the general license of R313-21-22(9)(a) is exempt from the requirements of R313-15 and R313-18 with respect to radioactive material covered by that general license, except that persons using the Mock Iodine-125 described in R313-21-22(9)(a)(viii) shall comply with the provisions of R313-15-1001, R313-15-1201 and R313-15-1202.

(10) Ice Detection Devices.

(a) A general license is hereby issued to own, receive, acquire, possess, use and transfer strontium-90 contained in ice detection devices, provided each device contains no more than 50 microcuries (1.85 MBq) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the Executive Secretary or an Agreement State to the manufacturer of the device pursuant to licensing requirements equivalent to those in 10 CFR 32.61.

(b) Persons who own, receive, acquire, possess, use or transfer strontium-90 contained in ice detection devices pursuant to the general license in R313-21-22(10)(a):

(i) shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from over-heating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the Nuclear Regulatory Commission or an Agreement State to manufacture or service the device; or shall dispose of the device pursuant to the provisions of these rules;

(ii) shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

(iii) are exempt from the requirements of R313-15 and R313-18 of these rules except that the persons shall comply with the provisions of R313-15-1001, R313-15-1201 and R313-15-1202.

(c) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.

(d) This general license is subject to the provision of R313-12-51 through R313-12-53, R313-12-70, R313-14, R313-19-34, R313-19-41, R313-19-61, and R313-19-100 of these rules.

KEY: radioactive material, general licenses, source material[~~licensing~~]
[~~January 10, 1997~~1997 **19-3-104**
Notice of Continuation 1994

Non-substantive change to R313-21-1(2)

R313. Environmental Quality, Radiation Control.
R313-21. General Licenses.
R313-21-1. Purpose and Scope.

(1) R313-21 establishes general licenses for the possession and use of radioactive material contained in certain items and a general license for ownership of radioactive material.

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

KEY: radioactive material, licensing
1997
Notice of Continuation 1994 **19-3-104**

Effective Jan 10, 1997

NOTE: We do not have an electronic copy of these changes.

R313. Environmental Quality, Radiation Control.
R313-21. General Licenses.
R313-21-1. Purpose and Scope.

(1) [~~This chapter~~]R313-21 establishes general licenses for the possession and use of radioactive material contained in certain items and a general license for ownership of radioactive material. [~~Chapter R313-19 also contains provisions applicable to the subject matter of this chapter.~~]

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

R313-21-21. General Licenses--Source Material.

[~~(1) A general license is hereby issued authorizing use, possession, and transfer of not more than fifteen pounds of source material at any one time by persons in the following categories: commercial and industrial firms, and research, educational, and medical institutions, federal, state and local government agencies for research, development, educational, operational, or commercial purposes; and provided, that no such person shall, pursuant to this general license, receive more than a total of one hundred fifty pounds of source material in any one calendar year.~~]

(1) A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local government agencies to use and transfer not more than 15 pounds (6.82 kg) of source material at any one time for research, development, educational, commercial, or operational purposes. A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of 150 pounds (68.2 kg) of source material in any one calendar year.

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

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

([~~3~~]4) A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize a[~~ny~~] person to receive, possess, use, or transfer source material.

([~~4~~]5) Depleted uranium in industrial products and devices.

(a) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of [~~paragraphs~~]R313-21-21(5)[~~(4)~~](b), (c), (d), and (e)[~~of this section~~], depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(b) The general license in [~~paragraph~~]R313-21-21(5)[~~(4)~~](a) [~~of this section~~]applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to R313-22-75([~~13~~]12) or in accordance with a specific license issued to the manufacturer by a Licensing State, the Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the Nuclear Regulatory Commission or an Agreement State.

(c)(i) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by [~~paragraph~~] R313-21-21(5)[~~(4)~~](a) [~~of this Section~~]shall file form [~~B~~]DRC-12 "Registration [~~Certificate~~]Form-Use of Depleted Uranium Under General License," with the [~~Bureau~~]Executive Secretary. The form shall be submitted within [~~thirty~~]30 days after the first receipt or acquisition of [~~such~~]depleted uranium. The registrant shall furnish on form [~~B~~]DRC-12 the following information and [~~such~~]other information as may be required by that form:

(A) name and address of the registrant;

(B) a statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in [~~paragraph~~]R313-21-21(5)[~~(4)~~](a) [~~of this section~~]and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(C) name or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in [~~item~~]R313-21-21(5)[~~(4)~~](c)(i)(B), [~~of this section;~~]

(ii) [~~c~~]The registrant possessing or using depleted uranium under the general license established by [~~paragraph~~]R313-21-21(5)[~~(4)~~](a) [~~of this section~~]shall report in writing to the [~~Bureau~~]Executive Secretary any changes in information previously furnished on the "Registration [~~Certificate~~]Form - Use of Depleted Uranium Under General License." The report shall be submitted within [~~thirty~~]30 days after the effective date of [~~such~~]the change[~~.~~],

(d) [~~a~~]A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by [~~paragraph~~]R313-21-21(5)(a):[~~(4)(a) of this section:~~]

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

(ii) shall not abandon [~~such~~]depleted uranium;

(iii) shall transfer or dispose of [~~such~~]depleted uranium only by transfer in accordance with the provisions of R313-19-41. In the case where the transferee receives the depleted uranium pursuant to the general license established by [~~paragraph~~]R313-21-21(5)(a), [~~(4)(a) of this section,~~] the transferor shall furnish the transferee a copy of this rule and a copy of form [~~B~~]DRC-12. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the Nuclear Regulatory Commission's or Agreement State's regulation equivalent to [~~paragraph (4)(a) of this section~~]R313-21-21(5)(a), the transferor shall furnish the transferee a copy of this rule and a copy of form [~~B~~]DRC-12 accompanied by a note explaining that use of the product or device is regulated by the Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in this rule[~~.~~];

[~~(iv) shall maintain and make available to the Bureau upon request the name and address of the person receiving the depleted uranium pursuant to such transfer;~~]

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

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

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

(e) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by [~~paragraph~~]R313-21-21(5)(a)[~~(4)(a) of this section~~] is exempt from the requirements of R313-15 and R313-18 of these rules with respect to the depleted uranium covered by that general license.

R313-21-22. General Licenses*--Radioactive Material Other Than Source Material.

NOTE: *Different general licenses are issued in this section, each of which has its own specific conditions and requirements.

(1) Certain devices and equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with the specific license issued to the manufacturer by the Nuclear Regulatory Commission for use pursuant to [~~section 31.3 of~~]10 CFR [~~Part~~]31.3. This general license is subject to the provisions of R313-12-51 through R313-12-[~~90~~]70, R313-15, R313-18 and R313-19 of these rules.

(a) Static Elimination Devices. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material

consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device.

(b) Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device or a total of not more than 50 millicuries (1.85 GBq) of hydrogen-3 (tritium) per device.

(2) RESERVED.

(3) RESERVED.

(4) Certain measuring, gauging or controlling devices.

(a) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, acquire, receive, possess, use or transfer, in accordance with the provisions of [~~paragraphs~~]R313-21-22(4)(b), (c) and (d), [~~of this section,~~]radioactive material excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(b) The general license in [~~paragraph~~]R313-21-22(4)(a) [~~of this section~~]applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the [~~Bureau~~]Executive Secretary pursuant to R313-22-75(4) or in accordance with specific license issued by the Nuclear Regulatory Commission, an Agreement State or a Licensing State, which authorizes distribution of devices to persons generally licensed by the Nuclear Regulatory Commission, an Agreement State or Licensing State.*

NOTE: *Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in [~~section 179.21 of~~]21 CFR [~~Part~~]179.21.

(c) Any person who owns, acquires, receives, possesses, uses or transfers radioactive material in a device pursuant to the general license in [~~paragraph (a)~~]R313-21-22(4)(a):[~~of this subsection:~~]

(i) shall register all devices by submitting form DRC-13, "Registration Form - Radioactive Material in Certain Measuring, Gauging or Controlling Devices Under General License," to the Executive Secretary within 30 days after the first receipt or acquisition of a device, however:

(A) devices containing less than ten millicuries of polonium-210 and used for producing an ionized atmosphere need not be registered; and

(B) devices containing hydrogen-3 (tritium) and used for producing light need not be registered;

(ii) shall furnish on form DRC-13 the following information and other information as may be required by that form:

(A) name and address of the registrant;

(B) a statement that the registrant has developed and will maintain procedures designed to establish physical control over the device described in R313-21-22(4)(a) and designed to prevent transfer of the device other than to a specific licensee authorized to receive it or to another general licensees only as authorized by R313-21-22(4)(c)(xii); and

(C) name or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising and maintaining the procedures identified in R313-21-22(4)(c)(ii)(B);

(iii) shall report in writing to the Executive Secretary any changes in information previously furnished on form DRC-13. The information shall be submitted within 30 days after the effective date of a change;

(iv) other than those persons using less than ten millicuries polonium-210 or hydrogen-3 (tritium) for producing light or an ionized atmosphere, shall submit the appropriate fee as required by R313-70-7(11) within 30 days after the first receipt or acquisition of the device.

([~~i~~]v) shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions

provided by [~~such~~]the labels;

([~~ii~~]vi) shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month[~~s~~] intervals or at [~~such~~] other intervals as are specified in the label, however:

(A) devices containing only krypton need not be tested for leakage of radioactive material; and

(B) devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta or gamma emitting material or ten microcuries (0.37 MBq) of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested[~~;~~];

([~~iii~~]vii) shall assure that the tests required by [~~item (4)(c)(ii) of this section~~]R313-21-22(4)(c)(vi) and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

(A) in accordance with the instructions provided by the labels; or

(B) by a person holding a specific license from the [~~Bureau~~]Executive Secretary, [~~or from~~]a Licensing State, the Nuclear Regulatory Commission or [~~from~~] an[~~y~~] Agreement State which authorizes the activities in R313-21-22(4)(c)(vii);[~~ to perform such activities~~]

([~~iv~~]viii) shall maintain records showing compliance with the requirements of [~~items~~]R313-21-22(4)(c)([~~ii~~]vi) and ([~~iii~~]vii)[~~ of this section~~]. The records shall show the results of tests. The records also shall show the dates of performance and the names of persons performing, testing, installing, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by [~~item~~]R313-21-22(4)(c)([~~ii~~]vi) [~~of this section~~]shall be maintained for one year after the next required leak test is performed or the sealed source is transferred or disposed of. Records of tests of the on[~~/~~]-off mechanism and indicator required by [~~item~~]R313-21-22(4)(c)([~~ii~~]vi) [~~of this section~~]shall be maintained for [~~one~~]three years after the next required test of the on[~~/~~]-off mechanism and indicator is performed or until the sealed source is transferred or disposed of. Records [~~of other testing, installation, servicing, and removal from installation~~]which are required by [~~item~~]R313-21-22(4)(c)([~~iii~~]vii) [~~of this section~~]shall be maintained for a period of two years from the date of the recorded event or until the device is transferred or disposed of;

([~~v~~]ix) upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on[~~/~~]-off mechanism or indicator, or upon the detection of 0.005 microcurie[~~s~~] (185 Bq) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding a specific license from the [~~Bureau~~]Executive Secretary, a Licensing State, the Nuclear Regulatory Commission, or [~~from~~]an Agreement State to repair [~~such~~]the devices, or disposed of by transfer to a person authorized by a specific license to receive the radioactive material contained in the device and, within [~~thirty~~]30 days, furnish to the [~~Bureau~~]Executive Secretary a report containing a brief description of the event and the remedial action taken;

([~~vi~~]x) shall not abandon any device containing radioactive material;

([~~vii~~]xi) except as provided in [~~item~~]R313-21-22(4)(c)([~~viii~~]xii)[~~ of this section~~], shall transfer or dispose of the device containing radioactive material only by transfer to a person holding a specific license of the [~~Bureau~~]Executive Secretary, the Nuclear Regulatory Commission, [~~or~~]an Agreement State, or a Licensing State whose specific license authorizes the person to receive the device and within [~~thirty~~]30 days after transfer of a device to a specific licensee shall furnish to the [~~Bureau~~]Executive Secretary a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device[~~;~~];

([~~viii~~]xii) [~~e~~]shall transfer the device to another general licensee only:

where the device remains in use at a particular location. In [~~such~~]this case, the transferor shall give the transferee a copy of [~~this subsection~~]R313-21-22(4) and any safety documents identified in the label of the

device and within [~~thirty~~]30 days of the transfer, report to the [~~Bureau~~]Executive Secretary the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name or position of an individual who may constitute a point of contact between the [~~Bureau~~]Executive Secretary and the transferee; or

(B) where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee[~~.~~];

([~~ix~~]xiii) shall comply with the provisions of R313-15-1201 and R313-15-1202 for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of R313-15 and R313-18[~~.~~]; and

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

(d) The general license in [~~paragraph~~]R313-21-22(4)(a)[~~of this section~~] does not authorize the manufacture[~~, import or export~~]of devices containing radioactive material.

(e) The general license provided in [~~subsection (4) of this section~~]R313-21-22(4)(a) is subject to the provisions of R313-12-51 through R313-12-53, R313-12-70, R313-14, [~~R313-12-90,~~]R313-19-34, R313-19-41, R313-19-61, and R313-19-100.

(5) Luminous safety devices for aircraft.

(a) A general license is hereby issued to own, receive, acquire, possess and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

(i) each device contains not more than ten curies (370.0 GBq) of tritium or 300 millicuries (11.1 GBq) of promethium-147; and

(ii) each device has been manufactured, assembled or imported in accordance with a specific license issued by the Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the [~~Bureau~~]Executive Secretary or an[~~y~~] Agreement State to the manufacturer or assembler of [~~such~~]the device pursuant to licensing requirements equivalent to those in [~~Section 32.53 of~~] 10 CFR [~~Part~~]32.53[~~of the Nuclear Regulatory Commission regulations~~].

(b) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in [~~subsection~~]R313-21-22(5) [~~of this section~~]are exempt from the requirements of R313-15 and R313-18, except that they shall comply with the provisions of R313-15-1201 and R313-15-1202.

(c) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

(d) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

(e) This general license is subject to the provisions of R313-12-51 through R313-12-[~~9~~]70, R313-14, R313-19-34, R313-19-41, R313-19-61, [~~R313-19-41,~~]and R313-19-100.

(6) Ownership of radioactive material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of [~~this chapter~~]R313-21, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

(7) Calibration and reference sources.

(a) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use and transfer, in accordance with the provisions of [~~paragraphs~~]R313-21-22(7)(d) and (e)[~~of this section~~], americium-241 in the form of calibration or reference sources:

(i) any person who holds a specific license issued by the [~~Bureau~~]Executive Secretary which authorizes that person to receive, possess, use and transfer radioactive material; and

(ii) any person who holds a specific license issued by the Nuclear Regulatory Commission which authorizes that person to receive, possess, use and transfer special nuclear material.

(b) A general license is hereby issued to own, receive, possess, use and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of [~~paragraphs~~]R313-21-22(7)(d) and (e) [~~of this section~~]to a[~~ny~~] person who holds a specific license issued by the [~~Bureau~~]Executive Secretary which authorizes that person to receive, possess, use and transfer radioactive material.

(c) A general license is hereby issued to own, receive, possess, use and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of [~~paragraphs~~]R313-21-22(7)(d) and (e) [~~of this section~~]to a[~~ny~~] person who holds a specific license issued by the [~~Bureau~~]Executive Secretary which authorizes that person to receive, possess, use and transfer radioactive material.

(d) The general licenses in [~~paragraphs~~]R313-21-22(7)(a), (b) and (c) [~~of this section~~]apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the Nuclear Regulatory Commission pursuant to [~~Section 32.57 of~~]10 CFR [~~Part~~]32.57 or [~~Section 70.39 of~~]10 CFR [~~Part~~]70.39 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the [~~Bureau~~]Executive Secretary, a Licensing State, or an[~~y~~] Agreement State pursuant to licensing requirements equivalent to those contained in [~~Section 32.57 of~~]10 CFR [~~Part~~]32.57 or [~~Section 70.39 of~~]10 CFR [~~Part~~]70.39[~~of the regulations of the Nuclear Regulatory Commission~~].

(e) The general licenses provided in [~~paragraphs~~]R313-21-22(7)(a), (b), and (c) are subject to the provisions of R313-12-51 through R313-12-53, [~~R313-14,~~]R313-12-[~~9~~]70, R313-14, R313-19-34, R313-19-41, R313-19-61, R313-19-100, R313-15 and R313-18. In addition, persons who own, receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to these general licenses:

(i) shall not possess at any one time, at any one location of storage or use, more than 5 microcuries (185.0 kBq) of americium-241, 5 microcuries (185.0 kBq) of plutonium, or 5 microcuries (185.0 kBq) of radium-226 in [~~such~~]a source[~~s~~];

(ii) shall not receive, possess, use or transfer [~~such~~]a source unless the source, or the storage container, bears a label which includes one of the following statements or a substantially similar statement which contains the information called for in one of the following statements, as appropriate:

(A) The receipt, possession, use and transfer of this source, Model No. ....., Serial No. ....., are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL[~~—~~]
THIS SOURCE CONTAINS (AMERICIUM-241)[~~—~~
~~———~~](PLUTONIUM)*
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

.....
Typed or printed name of the manufacturer or importer

NOTE: *Show[~~ing only~~] the name of the appropriate material.

(B) The receipt, possession, use and transfer of this source, Model No. ....., Serial No. ....., are subject to a general license and the regulations of a[~~ny~~] Licensing State. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL[~~——~~]
THIS SOURCE CONTAINS RADIUM-226[~~—~~]
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

.....
Typed or printed name of the manufacturer or importer

(iii) shall not transfer, abandon, or dispose of [~~such~~]a source except by transfer to a person authorized by a license from the [~~Bureau~~]Executive Secretary, a Licensing State, the Nuclear Regulatory Commission, or an Agreement State to receive the source;

(iv) shall store [~~such~~]a source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

(v) shall not use [~~such~~]a source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(f) These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

(8) [~~Medical Diagnostic Uses.*~~] RESERVED.

[~~NOTE: *The New Drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.~~

~~(a) A general license is hereby issued to any physician to receive, possess, transfer, or use radioactive material set forth below for the stated diagnostic uses, provided, however, that the use is in accordance with the provision of R313-21-22(8)(b),(c), and (d); the radioactive material is in the form of capsules, disposable syringes, or other prepackaged individual doses; and the radioactive material has been manufactured in accordance with a specific license issued by the Bureau pursuant to R313-22-75(7)**, or by the U.S. Nuclear Regulatory Commission, any Agreement State or a Licensing State pursuant to equivalent regulations authorizing distribution to persons generally licensed.~~

~~NOTE: **R313-22-75(7) requires manufacturers of radiopharmaceuticals which are under the general license in this paragraph to affix a certain identifying label to the container or in the leaflet or brochure which accompanies the radiopharmaceutical.~~

~~(i) Iodine 131 as sodium iodide for thyroid uptake pursuant to R313-21-22(8) or its equivalent;~~

~~(ii) Iodine 131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;~~

~~(iii) Iodine 125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;~~

~~(iv) Cobalt 57 for the measurement of intestinal absorption of cyanocobalamin;~~

~~(v) Cobalt 58 for the measurement of intestinal absorption of cyanocobalamin;~~

~~(vi) Cobalt 60 for the measurement of intestinal absorption of cyanocobalamin; and~~

~~(vii) Chromium 51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time.~~

~~(b) No physician shall receive, possess, use, or transfer radioactive material pursuant to the general license established by R313-21-22(8)(a) until he has filed form BRC-08, "Certificate - Medical Use of Radioactive Material Under General License" with the Bureau and received from the Bureau a validated copy of the Bureau form BRC-08 with certification number assigned. The generally licensed physician shall furnish on form BRC-08 the following information and such other information as may be required by that form:~~

~~(i) name and address of the generally licensed physician;~~

~~(ii) a statement that the generally licensed physician is a duly licensed physician (authorized to dispense drugs) in the practice of medicine in this state;~~

~~(iii) a statement that the generally licensed physician has appropriate radiation measuring instruments to carry out the diagnostic procedures for which he proposes to use radioactive material under the general license of R313-21-22(8) and that he is competent in the use of such instruments;~~

~~(c) A physician who receives, possesses, or uses a pharmaceutical containing radioactive material pursuant to the general license established by R313-21-22(8)(a) shall comply with the following:~~

~~(i) He shall not possess at any one time, pursuant to the general license in R313-21-22(8)(a) more than:~~

~~(A) 200 microcuries (7.4 MBq) of iodine 131;~~

~~(B) 200 microcuries (7.4 MBq) of iodine 125;~~

~~(C) 5 microcuries (185.0 kBq) of cobalt 57;~~

~~(D) 5 microcuries (185.0 kBq) of cobalt 58;~~

~~(E) 5 microcuries (185.0 kBq) of cobalt 60; and~~

~~(F) 200 microcuries (7.4 MBq) of chromium 51;~~

~~(ii) He shall store the pharmaceutical until administered in the original shipping container, or a container providing equivalent radiation protection;~~

~~(iii) He shall use the pharmaceutical only for the uses authorized by R313-21-22(8)(a);~~

~~(iv) He shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under 18 years of age;~~

~~(v) He shall not transfer the radioactive material to a person who is not~~

~~authorized to receive it pursuant to a license issued by the Bureau, the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.~~

~~(d) The generally licensed physician possessing or using radioactive material under the general license of R313-21-22(8)(a) shall report in duplicate to the Bureau, any changes in the information furnished by him in the "Certificate - Medical Use of Radioactive Material Under General License," form DRC-08. The report shall be submitted within 30 days after the effective date of such change.~~

~~(e) Any person using radioactive material pursuant to the general license of R313-21-22(8)(a) is exempt from the requirements of R313-15 and R313-18 of these rules with respect to the radioactive material covered by the general license.~~]

(9) General license for use of radioactive material for certain in vitro clinical or laboratory testing.*

NOTE: *The New Drug provisions of the Federal Food, Drug and Cosmetic Act also govern the availability and use of any specific diagnostic drug in interstate commerce.

(a) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for [~~any of~~]the following stated tests, in accordance with the provisions of [~~paragraphs (2)~~]R313-21-22(9) (b), (c), (d), (e), and (f) [~~of this section~~]the following radioactive materials in prepackaged units for use in in-vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

(i) iodine-125, in units not exceeding 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 to exceed ten microcuries (370.0 kBq) each; or

(viii) mock iodine-125, reference or calibration sources, in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185.0 Bq) of americium-241 each.

(b) [~~No~~]A person shall not receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by [~~paragraph (8)~~]R313-21-22(9)(a) [~~of this section~~]until that person has filed form [~~B~~]DRC-07, "[~~Certificate~~]Registration Form-In Vitro Testing with Radioactive Material Under General License," with the [~~Bureau~~]Executive Secretary and received a Certificate of Registration signed by the [~~from the Bureau~~]Executive Secretary[~~a validated copy form DRC-07 with certification number assigned~~], or until that person has been authorized pursuant to R313-32[~~-(3)~~] to use radioactive material under the general license in [~~subsection (8)~~]R313-21-22(9) [~~of this section~~]. The physician, veterinarian, clinical laboratory or hospital shall furnish on form [~~B~~]DRC-07 the following information and [~~such~~] other information as may be required by that form:

(i) name and address of the physician, veterinarian, clinical laboratory or hospital;

(ii) the location of use; and

(iii) a statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in [~~paragraph (8)~~]R313-21-22(9)(a) [~~of this section~~]and that [~~such~~]the tests will be performed only by personnel competent in the use of [~~such~~]radiation measuring instruments and in the handling of the radioactive material.

(c) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by [~~paragraph (8)~~]R313-21-22(9)(a) [~~of this section~~]shall comply with the following:

(i) The general licensee shall not possess at any one time, pursuant to

the general license in [~~paragraph (8)~~]R313-21-22(9)(a) [~~of this section~~]at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59[~~, or~~] and cobalt-57, or any combination, in excess of 200 microcuries (7.4 MBq).

(ii) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(iii) The general licensee shall use the radioactive material only for the uses authorized by [~~paragraph (8)~~]R313-21-22(9)(a)[~~of this section~~].

(iv) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the [~~Bureau~~]Executive Secretary, the Nuclear Regulatory Commission, an[~~y~~] Agreement State or Licensing State, nor transfer the radioactive material in a manner other than in the unopened, labeled shipping container as received from the supplier.

(v) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in [~~item~~]R313-21-22(9)(a)(viii) [~~of this section~~]as required by R313-15-1001.

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

(d) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to [~~paragraph (8)~~]R313-21-22(9)(a)[~~of this section~~]:

(i) Except as prepackaged units which are labeled in accordance with the provision of an applicable specific license issued pursuant to R313-22-75(8) or in accordance with the provisions of a specific license issued by the Nuclear Regulatory Commission, [~~or~~] an[~~y~~] Agreement State or Licensing State which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3(tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under [~~subsection (8) of this section~~]R313-21-22(9) or its equivalent[~~,~~], and

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

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

.....

Name of Manufacturer"

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

.....

Name of Manufacturer"

(e) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license [~~of paragraph~~]in R313-21-22(9)(a) [~~of this section~~]shall report in writing to the Executive Secretary, changes in the information previously furnished in the "[~~Certificate~~]Registration Form-In Vitro Testing with Radioactive Material Under General License", form DRC [~~form~~]-07. The report shall be furnished within [~~thirty~~]30 days after the effective date of [~~such~~]a change.

(f) Any [~~P~~]person[~~s~~] using radioactive material pursuant to the general license of [~~paragraph (8)~~]R313-21-22(9)(a) [~~of this section~~]is exempt from the requirements of R313-15 and R313-18 [~~of these rules~~]with respect to radioactive

material covered by that general license, except that [~~such~~]persons using the Mock Iodine-125 described in [~~item~~]R313-21-22(9)(a)(viii) [~~of this section~~]shall comply with the provisions of R313-15-1001, R313-15-1201 and R313-15-1202.

(10) Ice Detection Devices.

(a) A general license is hereby issued to own, receive, acquire, possess, use and transfer strontium-90 contained in ice detection devices, provided each device contains no[~~t~~] more than 50 microcuries (1.85 MBq) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the [~~Bureau~~]Executive Secretary or an[~~y~~] Agreement State to the manufacturer of [~~such~~]the device pursuant to licensing requirements equivalent to those in [~~Section 32.61 of~~]10 CFR [~~Part 32 of the regulations of the Nuclear Regulatory Commission~~]32.61.

(b) Persons who own, receive, acquire, possess, use or transfer strontium-90 contained in ice detection devices pursuant to the general license in [~~paragraph (10)(a) of this section~~]R313-21-22(10)(a):

(i) shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from over-heating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the Nuclear Regulatory Commission or an Agreement State to manufacture or service [~~such~~]the device[~~s~~]; or shall dispose of the device pursuant to the provisions of these rules;

(ii) shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

(iii) are exempt from the requirements of R313-15 and R313-18 of these rules except that [~~such~~]the persons shall comply with the provisions of R313-15-1001, R313-15-1201 and R313-15-1202.

(c) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.

(d) This general license is subject to the provision of R313-12-51 through R313-12-53, R313-12-70, R313-14, [~~R313-12-90,~~]R313-19-34, R313-19-41, R313-19-61, and R313-19-100 of these rules.

KEY: radioactive material, licensing
[~~1989~~]1996
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[~~26-1-29~~]19-3-104

Effective July 18, 1997

R313. Environmental Quality, Radiation Control.
R313-22. Specific Licenses.
R313-22-1. Purpose and Authority.

(1) The purpose of this rule is to prescribe the requirements for the issuance of specific licenses.

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

R313-22-2. General.

The provisions and requirements of R313-22 are in addition to, and not in substitution for, other requirements of these rules. In particular the provisions of R313-19 apply to applications and licenses subject to R313-22.

R313-22-4. Definitions.

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

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

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

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

R313-22-30. Specific License by Rule.

A license by rule is issued in the following circumstances, without the necessity of filing an application for a specific license as required by R313-22-32(1), and the licensee shall be subject to the applicable provisions of 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 [~~either:~~ ~~(a)~~] identify the source or device by manufacturer and model number as registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210, [~~1992~~]1996 ed.[~~,~~]or the equivalent regulations of[~~Executive Secretary, or~~] an Agreement State[~~, or~~].[

~~(b) contain the information identified in R313-22-210.~~]

(7) As provided by 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 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 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 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 R313-22-90;

(vi) Operating restrictions or procedures would prevent a release fraction as large as that shown in 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 R313-22-32(8)(a)(ii) shall include the following information:

(i) Facility description. A brief description of the licensee's facility and area near the site.

(ii) Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.

(iii) Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

(iv) Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

(v) Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers on-site, and a description of the program for maintaining equipment.

(vi) Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

(vii) Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying off-site response organizations and the Executive Secretary; also responsibilities for developing, maintaining, and updating the plan.

(viii) Notification and coordination. A commitment to and a brief description of the means to promptly notify off-site response organizations and request off-site assistance, including medical assistance for the treatment of contaminated injured on-site workers when appropriate. A control point shall be established. The notification and coordination shall be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the Executive Secretary immediately after notification of the appropriate off-site response organizations and not later than one hour after the licensee declares an emergency.

NOTE: These reporting requirements do not supersede or release licensees of complying with the requirements under the Emergency Planning and Community

Right-to-Know Act of 1986, Title III, Public Law 99-499 or other state or federal reporting requirements, including 40 CFR 302, 1992 ed.

(ix) Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to off-site response organizations and to the Executive Secretary.

(x) Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site including the use of team training for the scenarios.

(xi) Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

(xii) Exercises. Provisions for conducting quarterly communications checks with off-site response organizations and biennial on-site exercises to test response to simulated emergencies. Quarterly communications checks with off-site response organizations shall include the check and update of all necessary telephone numbers. The licensee shall invite off-site response organizations to participate in the biennial exercises. Participation of off-site response organizations in biennial exercises although recommended is not required. Exercises shall use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises shall evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques shall be corrected.

(xiii) Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

(d) The licensee shall allow the off-site response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the Executive Secretary. The licensee shall provide any comments received within the 60 days to the Executive Secretary with the emergency plan.

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

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

(a) the applicant and all personnel who will be handling the radioactive material are[~~is~~] 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 [~~property~~]the environment;

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

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

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

([~~d~~]e) the applicant satisfies applicable special requirements in R313-22-50, R313-22-75, R313-25, R313-32, R313-34, R313-36, or R313-38; and

([e]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 R313-22 as he deems appropriate or necessary in order to:

(a) minimize danger to public health and safety or [~~property~~]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 R313-22.

R313-22-35. Financial Assurance and Recordkeeping for Decommissioning.

(1) Applicants for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in Appendix B of 10 CFR 30.1 through 30.72, 1996 ed., which is incorporated by reference, shall submit a decommissioning funding plan as described in R313-22-35(5). The decommissioning funding plan shall also be submitted when a combination of radionuclides is involved if R divided by 10^5 is greater than one, where R is defined here as the sum of the ratios of the quantity of each radionuclide to the applicable value in Appendix B of 10 CFR 30.1 through 30.72, 1996 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 R313-22-35(4) shall either:

(a) submit a decommissioning funding plan as described in R313-22-35(5); or

(b) submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by R313-22-35(4) using one of the methods described in 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 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 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 R313-22-35(1) or (2) shall provide financial assurance for decommissioning in accordance with the criteria set forth in R313-22-35.

(b) Holders of a specific license issued before January 1, 1995, and of a type described in R313-22-35(1) shall submit, on or before January 1, 1995, a decommissioning funding plan as described in 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 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 R313-22-35(2) shall submit, on or before January 1, 1995, a decommissioning funding plan as described in R313-22-35(5) or a certification of financial assurance for decommissioning in accordance with the criteria set forth in R313-22-35.

(d) A licensee who has submitted an application before January 1, 1995, for renewal of license in accordance with R313-22-37 shall provide financial assurance for decommissioning in accordance with 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, 1996 ed., which is incorporated by reference, in unsealed form. For a combination of radionuclides, if R, as defined in 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, 1996 ed., which is incorporated by reference, in unsealed form. For a combination of radionuclides, if R, as defined in 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, 1996 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 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 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 R313-22-35(8). A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of 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 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 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 R313-22-35(6)(b); or

(d) In the case of Federal, State or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in R313-22-35(4) and indicating that funds for decommissioning will be obtained when necessary.

(7) Persons licensed under R313-22 shall keep records of information important to the [~~safe and effective~~]decommissioning of [~~the~~]a facility in an identified location until the [~~license is terminated by the Executive Secretary.~~]site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with R313-19-34(2), licensees shall transfer all records described in 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 [~~of relevant information~~]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 R313-12-3;

(ii) all areas outside of restricted areas that require documentation under R313-22-35(7)(a);

(iii) all areas outside of restricted areas where current and previous wastes have been buried as documented under R313-15-11 and

(iv) all areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal under 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 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 R313-22-35(8)(a) the licensee shall send notice to the Executive Secretary of intent to establish alternative financial assurance as specified in 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 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 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 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 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 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 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) Except as provided in R313-22-37(2), specific licenses shall expire at the end of the day, in the month and year stated therein.~~

~~(2) Each licensee shall notify the Executive Secretary, in writing, and request termination of the license when the licensee decides to terminate all activities involving radioactive material authorized under the license. This notification and request for termination of the license shall include the reports and information specified in R313-22-36(4)(a)(iv) and (v).~~

~~(3) No less than 30 days before the expiration date specified in the license, the licensee shall either:~~

~~(a) submit an application for license renewal under R313-22-37; or~~

~~(b) notify the Executive Secretary, in writing, if the licensee decided not to renew the license.~~

~~(4)(a) If a licensee does not submit an application for license renewal under R313-22-37, the licensee shall, on or before the expiration date specified in the license:~~

~~(i) terminate use of radioactive material;~~

~~(ii) remove radioactive contamination to the extent practicable;~~

~~(iii) properly dispose of radioactive material;~~

~~(iv) submit a completed Form DRC-14; and~~

~~(v) submit a radiation survey report to confirm the absence of radioactive material or to establish the levels of residual radioactive contamination, unless the licensee demonstrates the absence of residual radioactive contamination in some other acceptable manner. The licensee shall, as appropriate:~~

~~(A) report levels of radiation in units of microrads per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces; and report levels of radioactivity, including alpha, in units of disintegrations per minute, or microcuries, per 100 square centimeters removable and fixed on surfaces; microcuries per milliliter in water; and picocuries per gram in contaminated solids such as soils or concrete; and~~

~~(B) specify the instrumentation used and certify that each instrument was properly calibrated and tested.~~

~~(b) If no residual radioactive contamination attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive contamination was found. The Executive Secretary will notify the licensee, in writing, of the termination of the license.~~

~~(c)(i) If detectable levels of residual radioactive contamination attributable to activities conducted under the license are found, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual radioactive material present as contamination until the Executive Secretary notifies the licensee in writing that the license is terminated. During this time the licensee is subject to the provisions of R313-22-36(5).~~

~~(ii) In addition to the information submitted under R313-22-36(4)(a)(iv)~~

~~and (v), the licensee shall submit a plan for decontamination, if required, as regards residual radioactive contamination remaining at the time the license expires.~~

~~(5) Each licensee who possesses residual radioactive material under R313-22-36(4)(c), following the expiration date specified in the license shall:~~

~~(a) limit actions involving radioactive material to those related to decontamination and other activities related to preparation for release for unrestricted use; and~~

~~(b) continue to control entry to restricted areas until they are suitable for release for unrestricted use and the Executive Secretary notifies the licensee in writing that the license is terminated.~~)(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 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 R313-22-36(6), and begin decommissioning upon approval of that plan if:

(a) the license has expired pursuant to 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 R313-22-36(4), the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to R313-22-35 in conjunction with a license issuance or renewal or as required by 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 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 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 R313-22-36(4). The schedule for decommissioning set forth in 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 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 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 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 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 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 that the premises are suitable for release in some other manner. 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)(i) a radiation survey has been performed which demonstrates that the premises are suitable for release so that there is not an undue hazard to public health and safety or the environment; or

(ii) other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release so that there is not an undue hazard to public health and safety or the environment.

R313-22-37. Renewal of Licenses.

(1) Application[s] for renewal of a specific license[s] shall be filed on a form prescribed by the Executive Secretary and in accordance with R313-22-32.[~~(2) In cases in which a licensee, has filed an application in proper form for renewal or for a new license authorizing the same activities, not less than 30 days prior to expiration of the existing license, the existing license shall not expire until the application has been finally determined by the Executive Secretary.~~]

R313-22-38. Amendment of Licenses at Request of Licensee.

Applications for amendment of a license shall be filed in accordance with 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 R313-22-33, R313-22-50, and R313-22-75 and in 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 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 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 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 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 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 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 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 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 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 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 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 R313-22-75, 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 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 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 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 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 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 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 R313-19-70, that reconcentration of the radioactive material in concentrations exceeding those in 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 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 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 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 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 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 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 R313-22-75(2) shall maintain records identifying, by name and address, persons to whom radioactive material is transferred for use under 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 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 R313-19-13(2)(c)(iii) will be approved if the application satisfies requirements equivalent to those contained in 10 CFR 32.26. The maximum quantity of radium-226 in each device shall not exceed 0.1 microcurie (3.7 kBq).

(4) Licensing the manufacture and distribution of devices to persons generally licensed under 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 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 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 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; lens of eye	15 rems (150.0 mSv)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no	

larger than one square centimeter	200 rems (2.0 Sv)
Other organs	50 rems (500.0 msv); and

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

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

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

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

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

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

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

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

(c) In the event the applicant desires that the general licensee under 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 R313-15-201(1).

(d) Persons licensed under R313-22-75(4) to distribute devices to generally licensed persons shall:

(i) furnish a copy of the general license contained in 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 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 R313-21-22(4), or alternatively, furnish a copy of the general license contained in 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 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 R313-21-22(4);

(iii) report to the Executive Secretary all transfers of such devices to persons for use under the general license in 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 R313-21-22(4) during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within thirty days thereafter;

(iv) furnish reports to other agencies.

(A) Report to the U.S. Nuclear Regulatory Commission all transfers of those devices to persons for use under the U.S. Nuclear Regulatory Commission general license in 10 CFR 31.5.

(B) Report to the responsible State agency all transfers of devices manufactured and distributed pursuant to R313-22-75(4) for use under a general license in that State's regulations equivalent to 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 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 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 R313-21-22(5) will be approved if:

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

(b) the applicant satisfies the requirements of 10 CFR 32.53 through 32.56 and 32.101, or their equivalent.

(6) Special requirements for license to manufacture calibration sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under 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 R313-21-22(7) will be approved if:

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

(b) the applicant satisfies the requirements of 10 CFR 32.57 through 32.59, 32.102 and 10 CFR 70.39, or their equivalent.

(7) Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license. An application for a specific license to manufacture or distribute radioactive material for use under the general license of R313-21-22([~~6~~]9) will be approved if:

(a) the applicant satisfies the general requirements specified in 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 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 [~~may~~]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.[~~"The name of manufacturer shall be printed on the label."~~]

Name of Manufacturer"

(ii) "This radioactive material [~~may~~]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.[~~"The name of manufacturer shall be printed on the label; and~~]

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 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 R313-21-22([~~9~~]10) will be approved if:

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

(b) the criteria of 10 CFR 32.61, 32.62, 32.103 are met.

(9) Manufacture and distribution of radiopharmaceuticals containing radioactive material for medical use under group licenses.

(a) An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to R313-32[~~-10 for the uses listed in R313-32-100, R313-32-200 and R313-32-300~~] will be approved if:

([~~a~~]i) the applicant satisfies the general requirements specified in R313-22-33;

([~~b~~]ii) the applicant submits evidence that the applicant is at least one of the following:

[~~(i) the radiopharmaceutical containing radioactive material will be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the U.S. Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA; or~~

~~(ii) The manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;~~

~~(c) the applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage of radiopharmaceuticals by group licensees; and~~

~~(d) the label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity and date of assay, and the label affixed to the package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the Executive Secretary for distribution to persons licensed pursuant to R313-32-10 for the uses listed in R313-32-100, R313-32-200 and R313-32-300, or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. The labels, leaflets or brochures required by R313-22-75(9) are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA;~~]

(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 R313-22-75(9)(a)(ii)(C) or (D):

(i) May prepare radioactive drugs for medical use, as defined in R313-32-2, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in R313-22-75(9)(b)(ii) and (iii), or an individual under the supervision of an authorized nuclear pharmacist as specified in 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 R313-32-2;

(B) this individual meets the requirements specified in R313-32-980(2) and 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 R313-22-75(9)(b)(iii).

(iii) The actions authorized in 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 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 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 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 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 generators or reagent kits for preparation of radiopharmaceuticals~~.

~~(a) An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to R313-32-18 for the uses listed in R313-32-200 will be approved if:~~

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

~~(ii) the applicant submits evidence that:~~

~~(A) the generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA) or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA, or~~

~~(B) the manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;~~

~~(iii) the applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;~~

~~(iv) the label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and~~

~~(v) the label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:~~

~~(A) adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding used in eluting the generator or processing radioactive material with kit, and~~

~~(B) a statement that this generator or reagent kit is appropriate, is approved for use by persons licensed by the Executive Secretary pursuant to R313-32-18 and R313-32-200, or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. The labels, leaflets or brochures required by R313-22-75(10) are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.~~

~~(b) Manufacturers of reagent kits that do not contain radioactive material who desire to have their reagent kits approved by the Executive Secretary for use by persons licensed pursuant to R313-32-18 and R313-32-200 shall submit the pertinent information specified in R313-22-75(10). The Department does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, but it does regulate the use of reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material.]~~

([~~11~~]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 R313-32-18 for use as a calibration or reference source or for the uses listed in R313-32-400 and R313-32-500 will be approved if:

(a) the applicant satisfies the general requirements in 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 contents, 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 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.

([~~12~~]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 R313-21-21(4) 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 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 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 R313-22-75([12]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 R313-22-75([~~12~~]11) if the end use of the industrial product or device cannot be reasonably foreseen.

(2) Persons licensed pursuant to R313-22-75([~~12~~]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 R313-21-21(4) or its equivalent:

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

(v) report to the Executive Secretary all transfers of industrial products or devices to persons for use under the general license in R313-21-21(4). 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 R313-21-21(4) during the reporting period, the report shall so indicate;

(vi) provide certain other reports as follows:

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

(B) report to the responsible state agency all transfers of devices manufactured and distributed pursuant to R313-22-75([~~12~~]11) for use under a general license in that state's regulations equivalent to R313-21-21(4),

(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 R313-21-21(4) 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 R313-22-75([~~12~~]11).

R313-22-90. Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release. Refer to 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 Non CO	50,000
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 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 R313-22-50.

TABLE

RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II
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.

[~~(1)~~]Licensees who [~~M~~]manufacture[~~rs~~] or initially distribute[~~ors of~~] a sealed source or device containing a sealed source whose product is intended for use under a specific license or general license are deemed to have provided reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and the environment if the sealed source or device has been evaluated in accordance with 10 CFR 32.210, 1996 ed. or equivalent regulations of an Agreement State.[~~may submit a request to the Executive Secretary for evaluation of radiation safety information about its product for its registration.~~

~~(2) The request for review shall be sent to the Executive Secretary of the Radiation Control Board, P.O. Box 144850, Salt Lake City, Utah 84114-4850.~~

~~(3) The request for review of a sealed source or a device shall include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request shall also include sufficient information about installation, service and~~

~~maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.~~

~~(4) The Executive Secretary normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the Executive Secretary formulates reasonable standards and criteria with the help of the manufacturer or distributor. The Executive Secretary shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.~~

~~(5) After completion of the evaluation, the Executive Secretary issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product.~~

~~(6) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:~~

~~(a) the statements and representations, including quality control program, contained in the request; and~~

~~(b) the provisions of the registration certificate.]~~

KEY: ~~[radioactive, radioactive material]~~specific licenses, decommissioning, broad scope, radioactive material

~~[November 15, 1996]~~1997

19-3-104
19-3-108

Non-substantive change to R313-22-30
Effective May 19, 1997

Note: We do not have an electronic copy of these changes.

R313. Environmental Quality, Radiation Control.
R313-22. Specific Licenses.
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 R313-22-32(1), and the licensee shall be subject to the applicable provisions of 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.

KEY: radioactive, radioactive material
1996

19-3-104
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(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.

KEY: radioactive, radioactive material
~~June 16, 1995~~1996

19-3-104
19-3-108