



State of Utah

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Lieutenant Governor

Department of
Environmental Quality

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Acting Executive Director

DIVISION OF RADIATION CONTROL
Dane L. Finerfrock
Director

May 20, 2009

George Pangburn, Deputy Director
Division Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs
U.S. Nuclear Regulatory Commission
T8-E24
Washington, D.C. 20555-0001

Dear Mr. Pangburn,

Enclosed is a copy of the final revisions to the Utah Radiation Control Rules R313-15, R313-22 and R313-32. Enclosed are copies of documents with the changes to Utah Rules that are identified by underline/strike out text and correspond to the following equivalent amendments to NRC's regulations. Also enclosed is the final rule for R313-15 that shows 10 CFR Part 20, 2007 has been incorporated by reference.

<u>Rats ID</u>	<u>Title</u>	<u>State Section</u>
• 2006-01	Specific Licenses	R313-22 (10 CFR 32)
	Medical Use of Byproduct Material	R313-32 (10 CFR 35)
	Standards for Protection Against Radiation	R313-15 (10 CFR 20)
• 2007-01	Medical Use of Byproduct Material	R313-32 (10 CFR 35)
	Specific Licenses	R313-22 (10 CFR 32)

Part of RATS ID 2006-01 included a correction in Appendix B to 10 CFR Part 20, "Lists of Elements," "Thallium," Atomic Number 69, to be changed to read "Thulium." This change to R313-15 occurred when R313-15 was updated on March 17, 2008 which incorporated the 2007 edition of 10 CFR Part 20 by reference. 10 CFR Part 40 and 10 CFR Part 70 are compatibility category "D", and no changes to the Utah Radiation Control Rules were made.

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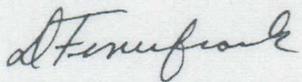
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We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200 for these amendments.

If you have any questions or comments, please contact either David Hogge or myself at (801) 536-4250.

Sincerely,

A handwritten signature in cursive script, appearing to read "Dane L. Finerfrock".

Dane L. Finerfrock, Director
Utah Division of Radiation Control

Attachments

cc: Kathleen Schneider, State Regulation Review Coordinator

R313. Environmental Quality, Radiation Control.

R313-15. Standards for Protection Against Radiation.

R313-15-2. Definitions.

"Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix B of 10 CFR 20.1001 to 20.2402, [~~2001 ed.~~](2007), which is incorporated by reference.

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

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

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

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

"Constraint (dose constraint)" in accordance with 10 CFR 20.1003, [~~2001 ed.~~](2007), means a value above which specified licensee actions are required.

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

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

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

20.1001 to 20.2402, [~~2001-ed.~~](2007), which is incorporated by reference.

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

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

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

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

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

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

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

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

"Inhalation class", refer to "Class".

"Labeled package" means a package labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations 49 CFR 172.403 and 49 CFR 172.436 through 440, [~~2000-ed.~~](2007). Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403[~~(m)~~ and ~~(w)~~] and 49 CFR 173.421 through 424, [~~2000-ed.~~](2007).

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

"Lung class", refer to "Class".

"Nationally tracked source" is a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix E of 10 CFR 20.1001

to 20.2402 (2007), which is incorporated by reference. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

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

"Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these rules, "deterministic effect" is an equivalent term.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of five Gy (500 rad) in one hour at one meter from a radiation source or one meter from any surface that the radiation penetrates.

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

TABLE

ORGAN DOSE WEIGHTING FACTORS

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

(1) 0.30 results from 0.06 for each of five "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

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

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

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

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

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

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

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

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

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

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

(3) The assigned deep dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow dose equivalent must be the dose averaged over the contiguous ten square centimeters of skin receiving the highest exposure.

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

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

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

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

(4) Derived air concentration (DAC) and annual limit on intake (ALI) values are specified in Table I of Appendix B of 10 CFR 20.1001 to 20.2402, [~~2001 ed.~~](2007), which is incorporated by reference, and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See Section R313-15-1107.

(5) Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to ten milligrams in a week in consideration of chemical toxicity. See footnote 3, of Appendix B of 10 CFR 20.1001 to 20.2402, [~~2001 ed.~~](2007), which is incorporated by reference.

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

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

(1) Licensees or registrants shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, lens dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See footnotes 1 and 2 of Appendix B of 10 CFR 20.1001 to 20.2402, [~~2001 ed.~~](2007), which is incorporated by reference.

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

R313-15-204. Determination of Internal Exposure.

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

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

(2) Unless respiratory protective equipment is used, as provided in Section R313-15-703, or the assessment of intake is based on bioassays, the licensee or registrant shall assume that

an individual inhales radioactive material at the airborne concentration in which the individual is present.

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

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

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

(c) Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See Appendix B of 10 CFR 20.1001 to 20.2402, [~~2001-ed.~~](2007), which is incorporated by reference.

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

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

(a) The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix B of 10 CFR 20.1001 to 20.2402, [~~2001-ed.~~](2007), which is incorporated by reference, for each radionuclide in the mixture; or

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

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

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

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

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

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

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

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

(b) For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.50 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix B of 10 CFR 20.1001 to 20.2402, [~~2001 ed.~~](2007), which is incorporated by reference.

The licensee or registrant may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALI, the licensee or registrant shall also demonstrate that the limit in Subsection R313-15-201(1)(a)(ii) is met.

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

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

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

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

(b) Demonstrating that:

(i) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B of 10 CFR 20.1001 to 20.2402, [~~2001 ed.~~](2007), which is incorporated by reference; and

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

(3) Upon approval from the Executive Secretary, the licensee or registrant may adjust the effluent concentration values in Appendix B, Table II of 10 CFR 20.1001 to 20.2402, [~~2001 ed.~~](2007), which is incorporated by reference, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as, aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

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

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

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

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

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

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

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

(e) Individuals working with medical fluoroscopic equipment.

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

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

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

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

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

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

(a) Adults likely to receive, in one year, an intake in excess of ten percent of the applicable ALI(s) in Table I, Columns 1 and 2, of Appendix B of 10 CFR 20.1001 to 20.2402, [~~2001 ed.~~](2007), which is incorporated by reference; and

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

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

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

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

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

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

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

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

(a) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses; and

(b) Surveys and bioassays, as necessary, to evaluate actual intakes; and

(c) Testing of respirators for operability, user seal check for face sealing devices and functional check for others, immediately prior to each use; and

(d) Written procedures regarding

(i) Monitoring, including air sampling and bioassays;

- (ii) Supervision and training of respirator users;
- (iii) Fit testing;
- (iv) Respirator selection;
- (v) Breathing air quality;
- (vi) Inventory and control;
- (vii) Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;
- (viii) Recordkeeping; and
- (ix) Limitations on periods of respirator use and relief from respirator use; and

(e) Determination by a physician prior to initial fitting of respirators, before the first field use of non-face sealing respirators, and either every 12 months thereafter or periodically at a frequency determined by a physician, that the individual user is medically fit to use the respiratory protection equipment; and

(f) Fit testing, with fit factor greater than or equal to ten times the APF for negative pressure devices, and a fit factor greater than or equal to 500 for positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed one year. Fit testing must be performed with the facepiece operating in the negative pressure mode.

(4) The licensee or registrant shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

(5) The licensee or registrant shall also consider limitations appropriate to the type and mode of use. When selecting respiratory devices the licensee shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The licensee or registrant shall use equipment in such a way as not to interfere with the proper operation of the respirator.

(6) Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

(7) Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997 ed. and included in 29 CFR 1910.134(i)(1)(ii)(A) through (E), [~~2000-ed~~](2007). Grade D quality air criteria include:

- (a) Oxygen content (v/v) of 19.5 to 23.5%;
 - (b) Hydrocarbon (condensed) content of five milligrams per cubic meter of air or less;
 - (c) Carbon monoxide (CO) content of ten ppm or less;
 - (d) Carbon dioxide content of 1,000 ppm or less; and
 - (e) Lack of noticeable odor.
- (8) The licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face and facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

(9) In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor.

If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

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

The Executive Secretary may impose restrictions in addition to the provisions of Section R313-15-702, Section R313-15-703, and Appendix A of 10 CFR 20.1001 to 20.2402, [~~2001-ed~~](2007), which is incorporated by reference to:

(1) Ensure that the respiratory protection program of the licensee or registrant is adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and

(2) Limit the extent to which a licensee or registrant may use respiratory protection equipment instead of process or other engineering controls.

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

The licensee or registrant shall obtain authorization from the Executive Secretary before using assigned protection factors in excess of those specified in Appendix A of 10 CFR 20.1001 to 20.2402, [~~2001-ed~~](2007), which is incorporated by reference. The Executive Secretary may authorize a licensee or registrant to use higher assigned protection factors on receipt of an application that:

(1) Describes the situation for which a need exists for higher protection factors; and

(2) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

R313-15-901. Caution Signs.

(1) Standard Radiation Symbol. Unless otherwise authorized by the Executive Secretary, the symbol prescribed by 10 CFR 20.1901, [~~2001-ed.~~](2007), which is incorporated by reference, shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

- (a) Cross-hatched area is to be magenta, or purple, or black, and
- (b) The background is to be yellow.

(2) Exception to Color Requirements for Standard Radiation Symbol. Notwithstanding the requirements of 10 CFR 20.1901(a), [~~2001-ed.~~](2007), which is incorporated by reference, licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

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

R313-15-902. Posting Requirements.

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

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

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

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

(5) Posting of Areas or Rooms in which Licensed or Registered Material is Used or Stored. The licensee or registrant shall post each area or room in which there is used or stored an amount of licensed or registered material exceeding ten times the quantity of such material specified in Appendix C of 10 CFR 20.1001 to 20.2402, [~~2001-ed.~~](2007), which is incorporated by reference, with a conspicuous sign or signs bearing the radiation

symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL."

R313-15-903. Exceptions to Posting Requirements.

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

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

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

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

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

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

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

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

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

R313-15-905. Exemptions to Labeling Requirements.

A licensee or registrant is not required to label:

(1) Containers holding licensed or registered material in quantities less than the quantities listed in Appendix C of 10 CFR 20.1001 to 20.2402, [~~2001-ed.~~](2007), which is incorporated by reference; or

(2) Containers holding licensed or registered material in concentrations less than those specified in Table III of Appendix B of 10 CFR 20.1001 to 20.2402, [~~2001-ed.~~](2007), which is incorporated by reference; or

(3) Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by Rule R313-15; or

(4) Containers when they are in transport and packaged and labeled in accordance with the rules of the U.S. Department of Transportation; or

(5) Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

(6) Installed manufacturing or process equipment, such as piping and tanks.

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

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

(a) The material is readily soluble, or is readily dispersible biological material, in water; and

(b) The quantity of licensed or registered radioactive material that the licensee or registrant releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee or registrant does not exceed the concentration listed in Table III of Appendix B of 10 CFR 20.1001 to 20.2402, [~~2001 ed.~~](2007), which is incorporated by reference; and

(c) If more than one radionuclide is released, the following conditions shall also be satisfied:

(i) The licensee or registrant shall determine the fraction of the limit in Table III of Appendix B of 10 CFR 20.1001 to 20.2402, [~~2001 ed.~~](2007), which is incorporated by reference, represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee or registrant into the sewer by the concentration of that radionuclide listed in Table III of Appendix B of 10 CFR 20.1001 to 20.2402, [~~2001 ed.~~](2007), which is incorporated by reference; and

(ii) The sum of the fractions for each radionuclide required by Subsection R313-15-1003(1)(c)(i) does not exceed unity; and

(d) The total quantity of licensed or registered radioactive material that the licensee or registrant releases into the sanitary sewerage system in a year does not exceed 185 GBq (five Ci) of hydrogen-3, 37 GBq (one Ci) of carbon-14, and 37 GBq (one Ci) of all other radioactive materials combined.

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

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

(1) The requirements of Section R313-15-1006 and Appendix G of 10 CFR 20.1001 to 20.2402, [~~2001 ed.~~](2006), which are incorporated into these rules by reference, are designed to:

(a) control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in Appendix G in 10 CFR 20.1001 to 20.2402, [~~2001~~

~~ed.]~~(2006), who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility as defined in Section R313-25-2;

(b) establish a manifest tracking system; and

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

(2) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G to 10 CFR 20.1001 to 20.2402, [~~2001-ed.]~~(2006), which is incorporated into these rules by reference.

(3) Each shipment manifest shall include a certification by the waste generator as specified in Section II of Appendix G to 10 CFR 20.1001 to 20.2402, [~~2001-ed.]~~(2006), which is incorporated by reference.

(4) Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix G to 10 CFR 20.1001 to 20.2402, [~~2001-ed.]~~(2006), which is incorporated by reference.

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

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

(a) Immediately after its occurrence becomes known to the licensee or registrant, stolen, lost, or missing licensed or registered radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C of 10 CFR 20.1001 to 20.2402, [~~2001-ed.]~~(2007), which is incorporated by reference, under such circumstances that it appears to the licensee or registrant that an exposure could result to individuals in unrestricted areas;

(b) Within 30 days after its occurrence becomes known to the licensee or registrant, lost, stolen, or missing licensed or registered radioactive material in an aggregate quantity greater than ten times the quantity specified in Appendix C of 10 CFR 20.1001 to 20.2402, [~~2001-ed.]~~(2007), which is incorporated by reference, that is still missing.

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

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

(a) A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind,

quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;

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

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

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

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

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

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

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

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2007]2008

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R313. Environmental Quality, Radiation Control.

R313-22. Specific Licenses.

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

(9) Manufacture, preparation, or transfer for commercial [and] distribution of radioactive drugs [radiopharmaceuticals] containing radioactive material for medical use under R313-32 [~~group licenses~~].

(a) An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to Rule R313-32 will be approved if:

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

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

(A) registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;

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

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

(D) operating as a nuclear pharmacy within a medical institution.

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

(iv) the applicant satisfies the following labeling requirements:

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

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

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

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

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

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

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

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

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

(iv) May designate a pharmacist, as defined in Rule R313-32 (incorporating 10 CFR 35.2 by reference), as an authorized nuclear pharmacist if the individual is identified as of January 1, 1997 as an "authorized user" on a nuclear pharmacy license issued by the Executive Secretary under Subsection R313-22-75(9).

~~(v) Shall provide to the Executive Secretary a copy of each individual's certification by the Board of Pharmaceutical Specialties, the Nuclear Regulatory Commission or Agreement State license, or the permit issued by a licensee of broad scope, and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to Subsections R313-22-75(9)(b)(ii)(A) and (B), the individual to work as an authorized nuclear pharmacist.]~~

(v) Shall provide to the Executive Secretary:

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

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

(C) the permit issued by a licensee of broad scope; and

(D) and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the

licensee allows, pursuant to Subsections R313-22-75(9)(b)(ii)(A) and R313-22-75(9)(b)(ii)(C), the individual to work as an authorized nuclear pharmacist.

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

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

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

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

(10) Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed [~~pursuant to~~] under Rule R313-32 [~~(incorporating 10 CFR 35.18)~~] for use as a calibration, transmission, or reference source or for the uses listed in Rule R313-32 (incorporating 10 CFR 35.400, 10 CFR 35.500, [~~and~~] 10 CFR 35.600, and 35.1000 by reference) will be approved if:

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

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

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

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

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

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

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

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

(vii) legend and methods for labeling sources and devices as

to their radioactive content, and

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

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

(d) 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.

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

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R313. Environmental Quality, Radiation Control.

R313-32. Medical Use of Radioactive Material.

R313-32-1. Purpose and Authority.

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

(2) The rules set forth herein are adopted pursuant to the provisions of Subsections 19-3-104(4) and 19-3-104(8).

R313-32-2. Clarifications or Exceptions.

For the purposes of Rule R313-32, 10 CFR 35.2 through 35.7; and 35.10 through 35.3067 [~~January 1, 2006~~](January 1, 2007) are incorporated by reference with the following clarifications or exceptions:

- (1) The exclusion of the following:
 - (a) In 10 CFR 35.2, exclude definitions for "Address of Use," "Agreement State," "Area of Use," "Dentist," "Pharmacist," "Physician," "Podiatrist," and "Sealed Source"; and
 - (b) In 10 CFR 35.3067, exclude "with a copy to the Director, Office of Nuclear Material Safety and Safeguards."
- (2) The substitution of the following date references:
 - ~~[(a) "October 25, 2006" for "October 25, 2005";]~~
 - ~~[(b) "October 24, 2006" for "October 24, 2005";]~~
 - [(a) [+e)] "May 13, 2005" for "October 24, 2002"; and
 - [(b) [+d)] "May 10, 2006" for "April 29, 2005."
- (3) The substitution of the following rule references:
 - (a) "Rule R313-15" for reference to "10 CFR Part 20" or for reference to "Part 20 of this chapter";
 - (b) "Rule R313-19" for reference to "Part 30 of this chapter" or for reference to "10 CFR Part 30" except for the reference to "Part 30 of this chapter" found in 10 CFR 35.65(d);
 - (c) "10 CFR 30" for reference to "Part 30 of this chapter" found in 10 CFR 35.65(d);
 - (d) "Rules R313-15 and R313-19" for reference to "parts 20 and 30 of this chapter";
 - (e) "Section R313-12-110" for reference to "Sec. 30.6 of this chapter" or for reference to "Sec. 30.6(a)" or for reference to "Sec. 30.6(a) of this chapter";
 - (f) "Section R313-15-101" for reference to "Sec. 20.1101 of this chapter";
 - (g) "Subsection R313-15-301(1)(a)" for reference to "Sec. 20.1301(a)(1) of this chapter";
 - (h) "Subsection R313-15-301(1)(c)" for reference to "Sec. 20.1301(c) of this chapter";
 - (i) "Section R313-15-501" for reference to "Sec. 20.1501 of this chapter";

(j) "Section R313-18-12" for reference to "Sec. 19.12 of this chapter";

(k) "Subsection R313-22-75(10) or equivalent U.S. Nuclear Regulatory Commission or Agreement State regulations" for reference to "Sec. 32.74 of this chapter," found in 10 CFR 35.65(b);

(l) "Subsection R313-22-75(10)" for reference to "10 CFR 32.74 of this chapter," or for reference to "Sec. 32.74 of this chapter" except for the reference to "Sec. 32.74 of this chapter" found in 10 CFR 35.65(b);

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

(n) "Section R313-19-34(2)" for reference to "Sec. 30.34(b) of this chapter";

(o) "Rule R313-22" for reference to "Part 33 of this chapter";

(p) "Subsection R313-22-50(2)" for reference to "Sec. 33.13 of this chapter";

(q) "Subsection R313-22-75(9)(b)(iv)" for reference to "Sec. 32.72(b)(4)";

(r) "Subsection R313-22-75(9)" for reference to "Sec. 32.72 of this chapter"; ~~and~~

(s) "Subsection R313-22-75(9)(b)(v)" for reference to "Sec. 32.72(b)(5)"

[~~s~~](t) "(c)(1) or (c)(2)" for reference to "(c)(1)" in 10 CFR 35.50(d); and

(u) "35.600 or 35.1000" for reference to "35.600" in 10 CFR 35.41(b)(1).

(4) The substitution of the following terms:

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

(b) "original" for "original and one copy";

(c) "(801) 536-4250 or after hours, (801) 536-4123" for "(301) 951-0550";

(d) "Form DRC-~~[02]01~~, [~~'Application for Medical Use of'~~] 'Radioactive Material License Application'" for reference to "NRC Form 313, 'Application for Material License'";

(e) "State of Utah radioactive materials" for reference to "NRC" in 10 CFR 35.6(c);

(f) "the Executive Secretary, the U.S. Nuclear Regulatory Commission, or an Agreement State" for reference to "the Commission or Agreement State" or for reference to "the Commission or an Agreement State";

(g) "an Executive Secretary, the U.S. Nuclear Regulatory Commission, or an Agreement State" for reference to "a Commission or Agreement State";

(h) "Equivalent U.S. Nuclear Regulatory Commission or Agreement State" for reference to "equivalent Agreement State" as found in 10 CFR 35.63(b)(2)(i), 10 CFR 35.63(c)(3), 10 CFR 35.65(a), 10 CFR 35.100(a), 10 CFR 35.200(a), and 10 CFR

35.300(a);

(i) "Executive Secretary" for reference to "NRC Operations Center" in 10 CFR 35.3045(c) and 10 CFR 35.3047(c);

(j) "Utah Division of Radiation Control" for reference to "NRC Operations Center" in Footnote 3 to 10 CFR 35.3045;

(k) "Executive Secretary" for reference to "appropriate NRC Regional Office listed in Sec. 30.6 of this chapter";

(l) "Utah Radiation Control Board" for reference to "Commission" in 10 CFR 35.18(a)(3)(second instance) and 10 CFR 35.19;

(m) "Executive Secretary" for reference to "Commission" in 10 CFR 35.10(b), 10 CFR 35.12(d)(2), 10 CFR 35.14(a)(first instance), 10 CFR 35.14(b), 10 CFR 35.18(a), 10 CFR 35.18(a)(3)(first instance), 10 CFR 35.18(b), 10 CFR 35.24(a)(1), 10 CFR 35.24(c), 10 CFR 35.26(a), and 10 CFR 35.1000(b);

(n) "the Executive Secretary" for reference to "NRC" in 10 CFR 35.13(b)(4)(i), 10 CFR 35.3045(g)(1), and 10 CFR 35.3047(f)(1);

(o) "the U.S. Nuclear Regulatory Commission or an Agreement State" for reference to "an Agreement State" in 10 CFR 35.49(a) and 10 CFR 35.49(c); and

(p) "Executive Secretary, a U.S. Nuclear Regulatory Commission, or Agreement State" for reference to "NRC or Agreement State" in 10 CFR 35.63(b)(2)(ii), 10 CFR 35.100(c), 10 CFR 35.200(c), and 10 CFR 35.300(c);

(q) In 10 CFR 35.2, Definitions, "Medium dose-rate remote afterloader," substitute "remotely delivers a dose rate of greater than 2 gray (200 rads) per hour, but less than or equal to 12 gray (1200 rads) per hour" for "remotely delivers a dose rate of greater than 2 gray (200 rads), but less than 12 gray (1200 rads) per hour."

(r) In 10 CFR 35.75(a) "Footnote 1", substitute "The current version of NUREG-1556, Vol. 9" for "NUREG-1556 Vol. 9,";

(s) In 10 CFR 35.92(a) substitute "less than or equal to" for "less than";

(t) In 10 CFR 35.190, paragraph (a)(1), substitute "as described in paragraphs (c)(1)(i) through (c)(1)(ii)(F) of this section; and" for "that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section; and"

(u) In 10 CFR 35.290, paragraph (a)(1), substitute "as described in paragraphs (c)(1)(i) through (c)(1)(ii)(G) of this section; and" for "that includes the topics listed in (c)(1)(i) and (c)(1)(ii) of this section."

KEY: radioactive materials, radiopharmaceutical, brachytherapy, nuclear medicine

Date of Enactment or Last Substantive Amendment: ~~May 10, 2006~~ 2009

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