

land disposal of radioactive material are subject to the requirements of Rule R313-25, and license tracer studies are subject to the requirements of Rule R313-38.

R313-19-5. Deliberate Misconduct.

(1) Any licensee, certificate of registration holder, applicant for a license or certificate of registration holder or applicant; or any contractor, including a supplier or consultant, subcontractor or subcontractor of any licensee or certificate of registration holder or applicant for a license or certificate of registration holder, contractor, or subcontractor, any component or services that relate to a licensee's, certificate holder's or applicant's activities in these rules, may

(a) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate of registration holder, applicant to be in violation of any rule or order; or any term, condition, or limitation of any license issued by the Executive Secretary;

(b) Deliberately submit to the Executive Secretary, a licensee, certificate of registration holder, applicant, contractor or subcontractor, information that the person submitting the information is inaccurate in some respect material to the Executive Secretary.

(2) A person who violates Subsections R313-19-5(1)(a) or (b) may be subject to enforcement action by the Executive Secretary.

(3) For the purposes of Subsection R313-19-5(1)(a), deliberate misconduct by a person means a person knows:

(a) Would cause a licensee, certificate of registration holder or applicant to be in violation of any rule or order, term, condition, or limitation, of any license issued by the Executive Secretary; or

(b) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or purchase order, of any licensee, certificate of registration holder, applicant, contractor, or subcontractor.

R313-19-13. Exemptions.

(1) Source material.

(a) A person is exempt from Rules R313-19, R313-21, and R313-22 to the extent that the person transfers source material in a chemical mixture, compound, solution or alloy in which the source material is less than one percent (0.05 percent) of the mixture, compound, solution, or alloy.

(b) A person is exempt from Rules R313-19, R313-21, and R313-22 to the extent that the person transfers unrefined and unprocessed ore containing source material; provided, that, except as authorized in this section, the person may not refine or process the ore.

(c) A person is exempt from Rules R313-19, R313-21, and R313-22 to the extent that the person transfers

(i) any quantities of thorium contained in:

(A) incandescent gas mantles,

(B) vacuum tubes,

(C) welding rods,

(D) electric lamps for illuminating purposes: provided that, each lamp does not contain more than

(E) germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp contains not more than 100 micrograms of thorium,

(F) rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight combination of these, or

(G) personnel neutron dosimeters provided that each dosimeter does not contain more than 50 micrograms of source material

(ii) source material contained in the following products:

(A) glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight of source material;

(B) piezoelectric ceramic containing not more than two percent by weight source material, or

(C) glassware containing not more than ten percent by weight source material, but not including window or pane glass, ceramic tile, or other glass or ceramic used in construction;

(iii) photographic film, negatives and prints containing uranium or thorium;

(iv) a finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloy provided that the concentration of the alloy does not exceed four percent by weight and that this exemption shall not be deemed to authorize metallurgical treatment or processing of the product or part;

(v) uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or in the installation or removal of the counterweights, provided that:

(A) the counterweights are manufactured in accordance with a specific license issued by the U.S. Department of Energy authorizing distribution by the licensee pursuant to 10 CFR Part 40,

(B) each counterweight has been impressed with the following legend clearly legible through any plating: "CAUTION - URANIUM",

(C) each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the words "UNAUTHORIZED ALTERATIONS PROHIBITED",

(D) The requirements specified in Subsections R313-19-13(1)(c)(v)(B) and (C) need not be met by counterweights manufactured before December 31, 1969, provided that such counterweights are impressed with the legend, "CAUTION - URANIUM", as previously required by the rules, and

(E) the exemption contained in Subsection R313-19-13(1)(c)(v) shall not be deemed to authorize treatment or processing of counterweights other than repair or restoration of any plating or other coating.

(vi) natural or depleted uranium metal used as shielding constituting part of a shipping container provided that the metal is impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM" and the uranium metal is surrounded by an equally fire resistant metal of minimum wall thickness of one eighth inch (3.2 mm);

(vii) thorium contained in finished optical lenses, provided that each lens does not contain more than 100 micrograms of thorium and that this exemption shall not be deemed to authorize either:

- (A) the shaping, grinding, or polishing of a lens or manufacturing processes other than the assembly of devices without alteration of the lens, or
- (B) the receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacle optical instruments;
- (viii) uranium contained in detector heads for use in fire detection units, provided that each detector contains not more than one microcurie (185.0 Bq) of uranium; or
- (ix) thorium contained in a finished aircraft engine part containing nickel-thoria alloy, provided that
 - (A) the thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide);
 - (B) the thorium content in the nickel-thoria alloy does not exceed four percent by weight.
- (d) The exemptions in Subsection R313-19-13(1)(c) do not authorize the manufacture of any of the following:
 - (2) Radioactive material other than source material.
 - (a) Exempt concentrations.
 - (i) Except as provided in Subsection R313-19-13(2)(a)(ii) a person is exempt from Rules R313-19-13(1)(c) if the person receives, possesses, uses, transfers, owns or acquires products or materials containing:
 - (A) radioactive material introduced in concentrations not in excess of those listed in Section R313-19-13(1)(c);
 - (B) natural occurring radioactive materials containing less than 15 picocuries per gram radium-226 or less than 150 picocuries per gram uranium-235.
 - (ii) A person may not introduce radioactive material into a product or material knowing or having reason to believe that the material will be transferred to persons exempt under Subsection R313-19-13(2)(a)(i) or equivalent regulations of a Licensing Commission or an Agreement State, except in accordance with a specific license issued pursuant to a general license provided in Section R313-19-30.
 - (b) Exempt quantities.
 - (i) Except as provided in Subsections R313-19-13(2)(b)(ii) and (iii) a person is exempt from these Rules if the person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities not in excess of the quantity set forth in Section R313-19-71.
 - (ii) Subsection R313-19-13(2)(b) does not authorize the production, packaging or repackaging of radioactive material for commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.
 - (iii) A person may not, for purposes of commercial distribution, transfer radioactive material in the quantities listed in Section R313-19-71, knowing or having reason to believe that the quantities of radioactive material will be in excess of the quantities listed in Subsection R313-19-13(2)(b) or equivalent regulations of a Licensing State, the U.S. Nuclear Regulatory Commission, or the U.S. Nuclear Regulatory Commission, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission by the Executive Secretary pursuant to Subsection R313-22-75(2), which license states that the license is limited to the licensee to persons exempt under Subsection R313-19-13(2)(b) or the equivalent regulations of a Licensing Commission or an Agreement State.
 - (iv) A person who possesses radioactive material received or acquired prior to September 25, 1971, is exempt from these Rules if the person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities not in excess of the quantity set forth in Section R313-19-71.

provided in 10 C.F.R. Part 31.5 is exempt from the requirements for a license set forth in Rule R3 possesses, uses, transfers or owns the radioactive material. This exemption does not apply for ra

(c) Exempt items.

(i) Certain items containing radioactive material. Except for persons who apply radioactive materi radioactive material into the following products, a person is exempt from these rules to the extent transfers, owns or acquires the following products:

(A) Timepieces or hands or dials containing not more than the following specified quantities of rad following specified levels of radiation:

(I) 25 millicuries (925.0 MBq) of tritium per timepiece;

(II) five millicuries (185.0 MBq) of tritium per hand;

(III) 15 millicuries (555.0 MBq) of tritium per dial. Bezels when used shall be considered as part of

(IV) 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of pro

(V) 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) c hand;

(VI) 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) dial. Bezels when used shall be considered as part of the dial;

(VII) the radiation dose rate from hands and dials containing promethium-147 will not exceed, wh square centimeter of absorber:

for wrist watches, 0.1 millirad (1.0 uGy) per hour at ten centimeters from any surface;

for pocket watches, 0.1 millirad (1.0 uGy) per hour at one centimeter from any surface;

for other timepieces, 0.2 millirad (2.0 uGy) per hour at ten centimeters from any surface;

(VIII) one microcurie (37.0 kBq) of radium-226 per timepiece in timepieces manufactured prior to

(B) Lock illuminators containing not more than 15 millicuries (555.0 MBq) of tritium or not more th promethium-147 installed in automobile locks. The levels of radiation from each lock illuminator o one millirad (10 uGy) per hour at one centimeter from any surface when measured through 50 mi absorber.

(C) Precision balances containing not more than one millicurie (37.0 MBq) of tritium per balance c of tritium per balance part.

(D) Automobile shift quadrants containing not more than 25 millicuries (925 MBq) of tritium.

(E) Marine compasses containing not more than 750 millicuries (27.8 GBq) of tritium gas and oth containing not more than 250 millicuries (9.25 GBq) of tritium gas.

(F) Thermostat dials and pointers containing not more than 25 millicuries (925.0 MBq) of tritium p

(G) Electron tubes, including spark gap tubes, power tubes, gas tubes including glow lamps, rectifier tubes, pick-up tubes, radiation detection tubes, and other completely sealed tubes that are designed for low currents; provided that each tube does not contain more than one of the following specified quantities:

(I) 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or ten millicuries (370 kBq) per tube;

(II) one microcurie (37.0 kBq) of cobalt-60;

(III) five microcuries (185.0 kBq) of nickel-63;

(IV) 30 microcuries (1.11 MBq) of krypton-85;

(V) five microcuries (185.0 kBq) of cesium-137;

(VI) 30 microcuries (1.11 MBq) of promethium-147;

(VII) one microcurie (37.0 kBq) of radium-226;

and provided further, that the radiation dose rate from each electron tube containing radioactive material shall not exceed 0.05 μ Gy per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of lead.

(H) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, a source of radioactive material, provided that:

(I) each source contains no more than one exempt quantity set forth in Section R313-19-71; and

(II) each instrument contains no more than ten exempt quantities. For purposes of this requirement, a source may contain either one type or different types of radionuclides and an individual exempt quantity may be computed as a fraction of the exempt quantities in Section R313-19-71, provided that the sum of the fractions shall not exceed one.

(III) for purposes of Subsection R313-19-13(2)(c)(i)(H), 0.05 microcurie (1.85 kBq) of americium-241 per instrument under Section R313-19-71.

(I) Spark gap irradiators containing not more than one microcurie (37.0 kBq) of cobalt-60 per spark gap tube and igniters for spark-ignited fuel oil burners having a firing rate of at least three gallons (11.4 liters) per hour.

(ii) Self-luminous products containing radioactive material.

(A) Tritium, krypton-85 or promethium-147. Except for persons who manufacture, process or produce self-luminous products containing tritium, krypton-85 or promethium-147, a person is exempt from these rules to the extent that the person transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed or produced in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission under Part 32.22, which license authorizes the transfer of the product to persons who are exempt from the rules in Subsection R313-19-13(2)(c)(ii) does not apply to tritium, krypton-85, or promethium-147 used in toys or adornments.

(B) Radium-226. A person is exempt from these rules, to the extent that such person receives, processes or produces self-luminous products containing less than 0.1 microcurie (3.7 kBq) of radium-226 which were acquired prior to the effective date of these rules.

(iii) Gas and aerosol detectors containing radioactive material.

(A) Except for persons who manufacture, process, or produce gas and aerosol detectors containi exempt from these rules to the extent that the person receives, possesses, uses, transfers, owns and aerosol detectors designed to protect life or property from fires and airborne hazards, provide material shall have been manufactured, imported, or transferred in accordance with a specific lice Regulatory Commission pursuant to 10 C.F.R. Part 32.26, or a Licensing State pursuant to Subse requirements, which authorizes the transfer of the detectors to persons who are exempt from regi

(B) Gas and aerosol detectors previously manufactured and distributed to general licensees in ac by an Agreement State shall be considered exempt under Subsection R313-19- 13(2)(c)(iii)(A), pr accordance with the specific license authorizing distribution of the general licensed device, and pr requirements of Subsection R313-22-75(3).

(C) Gas and aerosol detectors containing naturally occurring and accelerator-produced radioactiv manufactured and distributed in accordance with a specific license issued by a Licensing State st Subsection R313-19-13(2)(c)(iii)(A), provided that the device is labeled in accordance with the sp provided further that they meet the requirements of Subsection R313-22- 75(3).

(iv) Capsules containing carbon-14 urea for "in vivo" diagnostic use for humans.

(A) Except as provided in Subsection R313-19-13(2)(c)(iv)(B), any person is exempt from the req provided that the person receives, possesses, uses, transfers, owns, or acquires capsules contain (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo

(B) Any person who desires to use the capsules for research involving human subjects shall appl pursuant to Rule R313-32.

(C) Nothing in Subsection R313-19-13(2)(c)(iv) relieves persons from complying with applicable L Administration, other Federal, and State requirements governing receipt, administration, and use

(v) Resins containing scandium-46 and designed for sand consolidation in oil wells. A person is e the person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins contain sand consolidation in oil wells. The resins shall have been manufactured or imported in accordan U.S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the sp license issued by the Executive Secretary or an Agreement State to the manufacturer of resins pr equivalent to those in 10 C.F.R. Part 32.16 and 32.17. This exemption does not authorize the ma scandium-46.

(vi) With respect to Subsections R313-19-13(2)(b)(iii), R313-19-13(2)(c)(i), (iii) and (iv), the author the manufacturer, processor, or producer of equipment, devices, commodities, or other products subsequent possession, use, transfer, and disposal by other persons is exempted from regulatory from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

R313-19-20. Types of Licenses.

Licenses for radioactive materials are of two types: general and specific.

(1) General licenses provided in Rule R313-21 are effective without the filing of applications with 1 of licensing documents to the particular persons, although the filing of a registration certificate wit required by the particular general license. The general licensee is subject to the other applicable |

the general license.

(2) Specific licenses require the submission of an application to the Executive Secretary and the Executive Secretary. The licensee is subject to applicable portions of these rules as well as limita

R313-19-25. Prelicensing Inspection.

The Executive Secretary may verify information contained in applications and secure additional information by a reasonable determination as to whether to issue a license and whether special conditions should be imposed or location where radioactive materials would be possessed or used, and by discussing details of radioactive materials with the applicant or representatives designated by the applicant. Such visits shall be made by the Board or the Executive Secretary.

R313-19-30. Reciprocal Recognition of Licenses.

(1) Subject to these rules, a person who holds a specific license from the U.S. Nuclear Regulatory Commission, a Licensing State, and issued by the agency having jurisdiction where the licensee maintains an office at which radiation safety records are normally maintained, is hereby granted a general license to possess, use, or transfer a licensing document within this state, except in areas of exclusive federal jurisdiction, for a period of one year provided that:

(a) the licensing document does not limit the activity authorized by the document to specified instances;

(b) the out-of-state licensee notifies the Executive Secretary in writing at least three days prior to the proposed activity and shall indicate the location, period, and type of proposed possession and use within the state, and the applicable licensing document. If, for a specific case, the three-day period would impose an undue burden on the licensee, the licensee may, upon application to the Executive Secretary, obtain permission to proceed sooner. There shall be no requirement for filing additional written notifications during the remainder of the calendar year following the issuance of a license from a person engaging in activities under the general license provided in Subsection R313-19-30(1);

(c) the out-of-state licensee complies with all applicable rules of the Board and with the terms and conditions of the licensing document except those terms and conditions which may be inconsistent with applicable rules of the Board;

(d) the out-of-state licensee supplies other information as the Executive Secretary may request; and

(e) the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license in Subsection R313-19-30(1) except by transfer to a person:

(i) specifically licensed by the Executive Secretary or by the U.S. Nuclear Regulatory Commission, a Licensing State to receive the material, or

(ii) exempt from the requirements for a license for material under Subsection R313-19-13(2)(a).

(2) Notwithstanding the provisions of Subsection R313-19-30(1), a person who holds a specific license from the U.S. Nuclear Regulatory Commission, a Licensing State, or an Agreement State authorizing the holder to manufacture, install, transfer, demonstrate, or service a device described in Subsection R313-21-22(4) within the areas subject to the jurisdiction of the licensing State shall be granted a general license to install, transfer, demonstrate, or service a device in this state provided that:

(a) the person shall file a report with the Executive Secretary within thirty days after the end of a calendar year in which a device is transferred to or installed in this state. Reports shall identify each general licensee to whom a device is transferred, the type of device transferred, and the quantity and type of radioactive material contained in the device.

(b) the device has been manufactured, labeled, installed, and serviced in accordance with applica issued to the person by the Nuclear Regulatory Commission, a Licensing State, or an Agreement

(c) the person shall assure that any labels required to be affixed to the device under rules of the a the device bear a statement that "Removal of this label is prohibited"; and

(d) the holder of the specific license shall furnish to the general licensee to whom the device is tra is installed a copy of the general license contained in Subsection R313-21-22(4) or in equivalent i over the manufacture and distribution of the device.

(3) The Executive Secretary may withdraw, limit, or qualify his acceptance of a specific license or the U.S. Nuclear Regulatory Commission, a Licensing State or an Agreement State, or a product document, upon determining that the action is necessary in order to prevent undue hazard to pub

R313-19-34. Terms and Conditions of Licenses.

(1) Licenses issued pursuant to Rule R313-19 shall be subject to provisions of the Act, now or he orders of the Executive Secretary.

(2) Licenses issued or granted under Rules R313-21 and R313-22 and rights to possess or utilize issued pursuant to Rules R313-21 and R313-22 shall not be transferred, assigned, or in any man involuntarily, directly or indirectly, through transfer of control of a license to a person unless the E. full information find that the transfer is in accordance with the provisions of the Act now or hereaft the Executive Secretary, and shall give his consent in writing.

(3) Persons licensed by the Executive Secretary pursuant to Rules R313-21 and R313-22 shall c licensed to the locations and purposes authorized in the license.

(4) Licensees shall notify the Executive Secretary in writing and request termination of the license activities involving materials authorized under the license.

(5) Licensees shall notify the Executive Secretary in writing immediately following the filing of a vc bankruptcy under any Chapter of Title 11, Bankruptcy, of the United States Code by or against:

(a) the licensee;

(b) an entity, as that term is defined in 11 U.S.C.101(14), controlling the licensee or listing the lice or

(c) an affiliate, as that term is defined in 11 U.S.C.101(2), of the licensee.

(6) The notification specified in Subsection R313-19-34(5) shall indicate:

(a) the bankruptcy court in which the petition for bankruptcy was filed; and

(b) the date of the filing of the petition.

(7) Licensees required to submit emergency plans pursuant to Subsection R313-22-32(8) shall fo Executive Secretary. The licensee may change the approved plan without the Executive Secretar decrease the effectiveness of the plan. The licensee shall furnish the change to the Executive Se

organizations within six months after the change is made. Proposed changes that decrease, or preclude, the approved emergency plan may not be implemented without prior application to and prior approval of the Executive Secretary.

R313-19-41. Transfer of Material.

(1) Licensees shall not transfer radioactive material except as authorized pursuant to Section R313-19-41.

(2) Except as otherwise provided in the license and subject to the provisions of Subsections R313-19-41(3) through R313-19-41(5), a licensee shall not transfer radioactive material:

(a) to the Executive Secretary, if prior approval from the Executive Secretary has been received;

(b) to the U.S. Department of Energy;

(c) to persons exempt from the rules in Rule R313-19 to the extent permitted under the exemption;

(d) to persons authorized to receive the material under terms of a general license or its equivalent licensing document, issued by the Executive Secretary, the U.S. Nuclear Regulatory Commission, an Agreement State, or to a person otherwise authorized to receive the material by the federal government or an Agreement State or a Licensing State; or

(e) as otherwise authorized by the Executive Secretary in writing.

(3) Before transferring radioactive material to a specific licensee of the Executive Secretary, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, or to a general licensee who is required to register with the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State prior to receipt of the radioactive material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of material to be transferred.

(4) The following methods for the verification required by Subsection R313-19-41(3) are acceptable:

(a) the transferor may possess, and read a current copy of the transferee's specific license or registration certificate;

(b) the transferor may possess a written certification by the transferee that the transferee is authorized to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;

(c) for emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date, provided that the oral certification is confirmed by the Executive Secretary, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State;

(d) the transferor may obtain other information compiled by a reporting service from official records of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State regarding the identity and expiration dates of licenses and registration; or

(e) when none of the methods of verification described in Subsection R313-19-41(4) are readily available, to verify that information received by one of the methods is correct or up-to-date, the transferor may obtain approval from the Executive Secretary, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to receive the radioactive material.

(5) Shipment and transport of radioactive material shall be in accordance with the provisions of Subsection R313-19-41(5).

R313-19-50. Reporting Requirements.

(1) Licensees shall notify the Executive Secretary as soon as possible but not later than four hours after an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials or releases of licensed material that could exceed regulatory limits. Events may include fires, explosions, or other accidents.

(2) The following events involving licensed material require notification of the Executive Secretary:

(a) an unplanned contamination event that:

(i) requires access to the contamination area, by workers or the public, to be restricted for more than 24 hours; or radiological controls or by prohibiting entry into the area;

(ii) involves a quantity of material greater than five times the lowest annual limit on intake specified through 20.2402 (2000), which is incorporated by reference, for the material; and

(iii) has access to the area restricted for a reason other than to allow radionuclides with a half-life greater than 30 days to be decontaminated; or

(b) an event in which equipment is disabled or fails to function as designed when:

(i) the equipment is required by rule or license condition to prevent releases exceeding regulatory limits or radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(ii) the equipment is required by rule or license condition to be available and operable; and

(iii) no redundant equipment is available and operable to perform the required safety function; or

(c) an event that requires unplanned medical treatment at a medical facility of an individual with contamination on the individual's clothing or body; or

(d) an unplanned fire or explosion damaging licensed material or a device, container, or equipment:

(i) the quantity of material involved is greater than five times the lowest annual limit on intake specified through 20.2402 (2000), which is incorporated by reference, for the material; and

(ii) the damage affects the integrity of the licensed material or its container.

(3) Preparation and submission of reports. Reports made by licensees in response to the requirements of this section shall be made as follows:

(a) licensees shall make reports required by Subsections R313-19-50(1) and (2) by telephone to the Executive Secretary as soon as possible but not later than four hours after the event, so that the information is available at the time of notification, the information provided in these reports shall include:

(i) the caller's name and call back telephone number;

(ii) a description of the event, including date and time;

(iii) the exact location of the event;

- (iv) the radionuclides, quantities, and chemical and physical form of the licensed material involved
- (v) available personnel radiation exposure data.

(b) Written report. A licensee who makes a report required by Subsections R313-19-50(1) or (2) shall submit a written report within 30 days of the initial report. Written reports prepared pursuant to other rules may be submitted if they contain all of the necessary information and the appropriate distribution is made. These written reports shall be submitted to the Executive Secretary. The report shall include the following:

- (i) A description of the event, including the probable cause and the manufacturer and model number of the equipment that failed or malfunctioned;
- (ii) the exact location of the event;
- (iii) the radionuclides, quantities, and chemical and physical form of the licensed material involved;
- (iv) date and time of the event;
- (v) corrective actions taken or planned and results of evaluations or assessments; and
- (vi) the extent of exposure of individuals to radiation or radioactive materials without identification.

R313-19-61. Modification, Revocation, and Termination of Licenses.

- (1) The terms and conditions of all licenses shall be subject to amendment, revision, or modification, and may be revoked by reason of amendments to the Act, or by reason of rules, and orders issued by the Executive Secretary.
- (2) Licenses may be revoked, suspended, or modified, in whole or in part, for any material false statement of fact required under provisions of the Act, or because of conditions revealed by the a report, record, or inspection or other means which would warrant the Executive Secretary to refuse application, or for violation of, or failure to observe any of the terms and conditions of the Act, or for any other cause in the discretion of the Executive Secretary.
- (3) Administrative reviews, modifications, revocations or terminations of licenses will be in accordance with the rules.
- (4) The Executive Secretary may terminate a specific license upon written request submitted by the licensee.

R313-19-70. Exempt Concentrations of Radioactive Materials.

Refer to Subsection R313-19-13(2)(a)

TABLE

Element (Atomic Number)	Radionuclide	Column I Concentration Material Normally Used		Column II Concentration
		As	Gas (uCi/ml)	Liquid (uCi/ml) Solid (uCi/g)
Antimony (51)	Sb-122			3 E-4
	Sb-124			2 E-4
	Sb-125			1 E-3
Argon (18)	Ar-37	1	E-3	
	Ar-41	4	E-7	
Arsenic (33)	As-73			5 E-3

	As-74		5 E-4
	As-76		2 E-4
	As-77		8 E-4
Barium (56)	Ba-131		2 E-3
	Ba-140		3 E-4
Beryllium (4)	Be-7		2 E-2
Bismuth (83)	Bi-206		4 E-4
Bromine (35)	Br-82	4 E-7	3 E-3
Cadmium (48)	Cd-109		2 E-3
	Cd-115m		3 E-4
	Cd-115		3 E-4
Calcium (20)	Ca-45		9 E-5
	Ca-47		5 E-4
Carbon (6)	C-14	1 E-6	8 E-3
Cerium (58)	Ce-141		9 E-4
	Ce-143		4 E-4
	Ce-144		1 E-4
Cesium (55)	Cs-131		2 E-2
	Cs-134m		6 E-2
	Cs-134		9 E-5
Chlorine (17)	Cl-38	9 E-7	4 E-3
Chromium (24)	Cr-51		2 E-2
Cobalt (27)	Co-57		5 E-3
	Co-58		1 E-3
	Co-60		5 E-4
Copper (29)	Cu-64		3 E-3
Dysprosium (66)	Dy-165		4 E-3
	Dy-166		4 E-4
Erbium (68)	Er-169		9 E-4
	Er-171		1 E-3
Europium (63)	Eu-152		6 E-4
	(T = 9.2 h)		
	Eu-155		2 E-3
Fluorine (9)	F-18	2 E-6	8 E-3
Gadolinium (64)	Gd-153		2 E-3
	Gd-159		8 E-4
Gallium (31)	Ga-72		4 E-4
Germanium (32)	Ge-71		2 E-2
Gold (79)	Au-196		2 E-3
	Au-198		5 E-4
	Au-199		2 E-3
Hafnium (72)	Hf-181		7 E-4
Hydrogen (1)	H-3	5 E-6	3 E-2
Indium (49)	In-113m		1 E-2
	In-114m		2 E-4
Iodine (53)	I-126	3 E-9	2 E-5
	I-131	3 E-9	2 E-5
	I-132	8 E-8	6 E-4
	I-133	1 E-8	7 E-5
	I-134	2 E-7	1 E-3
Iridium (77)	Ir-190		2 E-3
	Ir-192		4 E-4
	Ir-194		3 E-4
Iron (26)	Fe-55		8 E-3
	Fe-59		6 E-4
Krypton (36)	Kr-85m	1 E-6	
	Kr-85	3 E-6	
Lanthanum (57)	La-140		2 E-4
Lead (82)	Pb-203		4 E-3
Lutetium (71)	Lu-177		1 E-3
Manganese (25)	Mn-52		3 E-4
	Mn-54		1 E-3
	Mn-56		1 E-3
Mercury (80)	Hg-197m		2 E-3
	Hg-197		3 E-3

	Hg-203		2 E-4
Molybdenum (42)	Mo-99		2 E-3
Neodymium (60)	Nd-147		6 E-4
	Nd-149		3 E-3
Nickel (28)	Ni-65		1 E-3
Niobium	Nb-95		1 E-3
(Columbium) (41)	Nb-97		9 E-3
Osmium (76)	Os-185		7 E-4
	Os-191m		3 E-2
	Os-191		2 E-3
	Os-193		6 E-4
Palladium (46)	Pd-103		3 E-3
	Pd-109		9 E-4
Phosphorus (15)	P-32		2 E-4
Platinum (78)	Pt-191		1 E-3
	Pt-193m		1 E-2
	Pt-197m		1 E-2
	Pt-197		1 E-3
Potassium (19)	K-42		3 E-3
Praseodymium (59)	Pr-142		3 E-4
	Pr-143		5 E-4
Promethium (61)	Pm-147		2 E-3
	Pm-149		4 E-3
Rhenium (75)	Re-183		6 E-4
	Re-186		9 E-3
	Re-188		6 E-4
Rhodium (45)	Rh-103m		1 E-1
	Rh-105		1 E-3
Rubidium (37)	Rb-86		7 E-4
Ruthenium (44)	Ru-97		4 E-4
	Ru-103		8 E-4
	Ru-105		1 E-3
	Ru-106		1 E-4
Samarium (62)	Sm-153		8 E-4
Scandium (21)	Sc-46		4 E-4
	Sc-47		9 E-4
	Sc-48		3 E-4
Selenium (34)	Se-75		3 E-3
Silicon (14)	Si-31		9 E-3
Silver (47)	Ag-105		1 E-3
	Ag-110m		3 E-4
	Ag-111		4 E-4
Sodium (11)	Na-24		2 E-3
Strontium (38)	Sr-85		1 E-4
	Sr-89		1 E-4
	Sr-91		7 E-4
	Sr-92		7 E-4
Sulfur (16)	S-35	9 E-8	6 E-4
Tantalum (73)	Ta-182		4 E-4
Technetium (43)	Tc-96m		1 E-1
	Tc-96		1 E-3
Tellurium (52)	Te-125m		2 E-3
	Te-127m		6 E-4
	Te-127		3 E-3
	Te-129m		3 E-4
	Te-131m		6 E-4
	Te-132		3 E-4
Terbium (65)	Tb-160		4 E-4
Thallium (81)	Tl-200		4 E-3
	Tl-201		3 E-3
	Tl-202		1 E-3
	Tl-204		1 E-3
Thulium (69)	Tm-170		5 E-4
	Tm-171		5 E-3
Tin (50)	Sn-113		9 E-4

	Sn-125		2 E-4
Tungsten	W-181		4 E-3
(Wolfram) (74)	W-187		7 E-4
Vanadium (23)	V-48		3 E-4
Xenon (54)	Xe-131m	4 E-6	
	Xe-133	3 E-6	
	Xe-135	1 E-6	
Ytterbium (70)	Yb-175		1 E-3
Yttrium (39)	Y-90		2 E-4
	Y-91m		3 E-2
	Y-91		3 E-4
	Y-92		6 E-4
	Y-93		3 E-4
Zinc (30)	Zn-65		1 E-3
	Zn-69m		7 E-4
	Zn-69		2 E-2
Zirconium (40)	Zr-95		6 E-4
	Zr-97		2 E-4
Beta or gamma emitting radioactive material not listed above with half-life less than 3 years		1 E-10	1 E-6

(1) In expressing the concentrations in Section R313-19-70, the activity stated and takes into account the radioactive decay products, because many radionuclides disintegrate also radioactive.

(2) For purposes of Subsection R313-19-13(2)(a) where there is involved a combination the combination should be derived as follows: Determine for each radionuclide in the combination the radioactivity concentration present in the product and the exempt radioactivity concentration for the specific radionuclide when not in combination. The sum of the ratios may not exceed 1.

(3) To convert microcuries (uCi) to SI units of kilobecquerels (kBq), multiply the microcuries by 37.

R313-19-71. Exempt Quantities of Radioactive Materials.

Refer to Subsection R313-19-13(2)(b)

TABLE

RADIOACTIVE MATERIAL	MICROCURIES
Antimony-122 (Sb-122)	100
Antimony-124 (Sb-124)	10
Antimony-125 (Sb-125)	10
Arsenic-73 (As-73)	100
Arsenic-74 (As-74)	10
Arsenic-76 (As-76)	10
Arsenic-77 (As-77)	100
Barium-131 (Ba-131)	10
Barium-133 (Ba-133)	10
Barium-140 (Ba-140)	10
Bismuth-210 (Bi-210)	1
Bromine-82 (Br-82)	10
Cadmium-109 (Cd-109)	10
Cadmium-115m (Cd-115m)	10
Cadmium-115 (Cd-115)	100
Calcium-45 (Ca-45)	10
Calcium-47 (Ca-47)	10
Carbon-14 (C-14)	100
Cerium-141 (Ce-141)	100
Cerium-143 (Ce-143)	100

Cerium-144 (Ce-144)	1
Cesium-129 (Cs-129)	100
Cesium-131 (Cs-131)	1,000
Cesium-134m (Cs-134m)	100
Cesium-134 (Cs-134)	1
Cesium-135 (Cs-135)	10
Cesium-136 (Cs-136)	10
Cesium-137 (Cs-137)	10
Chlorine-36 (Cl-36)	10
Chlorine-38 (Cl-38)	10
Chromium-51 (Cr-51)	1,000
Cobalt-57 (Co-57)	100
Cobalt-58m (Co-58m)	10
Cobalt-58 (Co-58)	10
Cobalt-60 (Co-60)	1
Copper-64 (Cu-64)	100
Dysprosium-165 (Dy-165)	10
Dysprosium-166 (Dy-166)	100
Erbium-169 (Er-169)	100
Erbium-171 (Er-171)	100
Europium-152 (Eu-152) 9.2h	100
Europium-152 (Eu-152) 13 yr	1
Europium-154 (Eu-154)	1
Europium-155 (Eu-155)	10
Fluorine-18 (F-18)	1,000
Gadolinium-153 (Gd-153)	10
Gadolinium-159 (Gd-159)	100
Gallium-67 (Ga-67)	100
Gallium-72 (Ga-72)	10
Germanium-68 (Ge-68)	10
Germanium-71 (Ge-71)	100
Gold-195 (Au 195)	10
Gold-198 (Au-198)	100
Gold-199 (Au-199)	100
Hafnium-181 (Hf-181)	10
Holmium-166 (Ho-166)	100
Hydrogen-3 (H-3)	1,000
Indium-111 (In-111)	100
Indium-113m (In-113m)	100
Indium-114m (In-114m)	10
Indium-115m (In-115m)	100
Indium-115 (In-115)	10
Iodine-123 (I-123)	100
Iodine-125 (I-125)	1
Iodine-126 (I-126)	1
Iodine-129 (I-129)	0.1
Iodine-131 (I-131)	1
Iodine-132 (I-132)	10
Iodine-133 (I-133)	1
Iodine-134 (I-134)	10
Iodine-135 (I-135)	10
Iridium-192 (Ir-192)	10
Iridium-194 (Ir-194)	100
Iron-52 (Fe-52)	10
Iron-55 (Fe-55)	100
Iron-59 (Fe-59)	10
Krypton-85 (Kr-85)	100
Krypton-87 (Kr-87)	10
Lanthanum-140 (La-140)	10
Lutetium-177 (Lu-177)	100
Manganese-52 (Mn-52)	10
Manganese-54 (Mn-54)	10
Manganese-56 (Mn-56)	10
Mercury-197m (Hg-197m)	100
Mercury-197 (Hg-197)	100

Mercury-203 (Hg-203)	10
Molybdenum-99 (Mo-99)	100
Neodymium-147 (Nd-147)	100
Neodymium-149 (Nd-149)	100
Nickel-59 (Ni-59)	100
Nickel-63 (Ni-63)	10
Nickel-65 (Ni-65)	100
Niobium-93m (Nb-93m)	10
Niobium-95 (Nb-95)	10
Niobium-97 (Nb-97)	10
Osmium-185 (Os-185)	10
Osmium-191m (Os-191m)	100
Osmium-191 (Os-191)	100
Osmium-193 (Os-193)	100
Palladium-103 (Pd-103)	100
Palladium-109 (Pd-109)	100
Phosphorus-32 (P-32)	10
Platinum-191 (Pt-191)	100
Platinum-193m (Pt-193m)	100
Platinum-193 (Pt-193)	100
Platinum-197m (Pt-197m)	100
Platinum-197 (Pt-197)	100
Polonium-210 (Po-210)	0.1
Potassium-42 (K-42)	10
Potassium-43 (K-43)	10
Praseodymium-142 (Pr-142)	100
Praseodymium-143 (Pr-143)	100
Promethium-147 (Pm-147)	10
Promethium-149 (Pm-149)	10
Rhenium-186 (Re-186)	100
Rhenium-188 (Re-188)	100
Rhodium-103m (Rh-103m)	100
Rhodium-105 (Rh-105)	100
Rubidium-81 (Rb-81)	10
Rubidium-86 (Rb-86)	10
Rubidium-87 (Rb-87)	10
Rubidium-97 (Ru-97)	100
Ruthenium-103 (Ru-103)	10
Ruthenium-105 (Ru-105)	10
Ruthenium-106 (Ru-106)	1
Samarium-151 (Sm-151)	10
Samarium-153 (Sm-153)	100
Scandium-46 (Sc-46)	10
Scandium-47 (Sc-47)	100
Scandium-48 (Sc-48)	10
Selenium-75 (Se-75)	10
Silicon-31 (Si-31)	100
Silver-105 (Ag-105)	10
Silver-110m (Ag-110m)	1
Silver-111 (Ag-111)	100
Sodium-22 (Na-22)	10
Sodium-24 (Na-24)	10
Strontium-85 (Sr-85)	10
Strontium-89 (Sr-89)	1
Strontium-90 (Sr-90)	0.1
Strontium-91 (Sr-91)	10
Strontium-92 (Sr-92)	10
Sulfur-35 (S-35)	100
Tantalum-182 (Ta-182)	10
Technetium-96 (Tc-96)	10
Technetium-97m (Tc-97m)	100
Technetium-97 (Tc-97)	100
Technetium-99m (Tc-99m)	100
Technetium-99 (Tc-99)	10
Tellurium-125m (Te-125m)	10

Tellurium-127m (Te-127m)	10
Tellurium-127 (Te-127)	100
Tellurium-129m (Te-129m)	10
Tellurium-129 (Te-129)	100
Tellurium 131m (Te-131m)	10
Tellurium-132 (Te-132)	10
Terbium-160 (Tb-160)	10
Thallium-200 (Tl-200)	100
Thallium-201 (Tl-201)	100
Thallium-202 (Tl-202)	100
Thallium-204 (Tl-204)	10
Thulium-170 (Tm-170)	10
Thulium-171 (Tm-171)	10
Tin-113 (Sn-113)	10
Tin-125 (Sn-125)	10
Tungsten-181 (W-181)	10
Tungsten-185 (W-185)	10
Tungsten-187 (W-187)	100
Vanadium-48 (V-48)	10
Xenon-131m (Xe-131m)	1,000
Xenon-133 (Xe-133)	100
Xenon-135 (Xe-135)	100
Ytterbium-175 (Yb-175)	100
Yttrium-87 (Y-87)	10
Yttrium-88 (Y-88)	10
Yttrium-90 (Y-90)	10
Yttrium-91 (Y-91)	10
Yttrium-92 (Y-92)	100
Yttrium-93 (Y-93)	100
Zinc-65 (Zn-65)	10
Zinc-69m (Zn-69m)	100
Zinc-69 (Zn-69)	1,000
Zirconium-93 (Zr-93)	10
Zirconium-95 (Zr-95)	10
Zirconium-97 (Zr-97)	10
Any radioactive material not listed above other than alpha emitting radioactive material.	0.1

(1) To convert microcuries (uCi) to SI units of kilobecquerels (kBq), multiply t

R313-19-100. Transportation.

For purposes of Section R313-19-100, 10 CFR 71.4, 71.10, 71.12, 71.13(a) and (b) through 71.14, 71.97 (1998), and Appendix A to part 71 are incorporated by reference with the following clarifications:

(1) The substitution of the following:

- (a) "Issued by the Executive Secretary" for reference to "issued by the Commission" in 10 CFR 71.4;
- (b) "Licensee" for reference to "licensee of the Commission";
- (c) "Subsection R313-19-100(3)" for reference to "10 CFR 71.5";
- (d) "Subsection R313-15-906(5)" for reference to "10 CFR 20.1906(e)";
- (e) "Section R313-15-502" for reference to "10 CFR 20.1502"; and

(f) "Utah" for reference to "the United States" in 10 CFR 71.10(b)(3);

(2) The exclusion of the following:

(a) "close reflection by water" and "optimum interspersed hydrogenous moderation" in 10 CFR 71

(b) "10 CFR 71.12(b)", "10 CFR 71.14(b)", and "10 CFR 71.16(b)"; and

(c) "subpart H" in 10 CFR 71.12(c)(2), 71.14(c)(2), 71.16(d)(2), and 71.81;

(3) Transportation of licensed material.

(a) Each licensee who transports licensed material outside the site of usage, as specified in the li highways, or who delivers licensed material to a carrier for transport, shall comply with the applica of Transportation (DOT) regulations in 49 CFR 170 through 189 (1998) appropriate to the mode c

(i) The licensee shall particularly note DOT regulations in the following areas:

(A) Packaging--49 CFR 173.1 through 173.13, 173.21 through 173.40, and 173.401 through 173.

(B) Marking and labeling--49 CFR 172.300 through 172.338, 172.400 through 172.407, 172.436 t 172.450;

(C) Placarding--49 CFR 172.500 through 172.560 and Appendices B and C;

(D) Accident reporting--49 CFR 171.15 and 171.16;

(E) Shipping papers and emergency information--49 CFR 172.200 through 172.205 and 172.600

(F) Hazardous material employee training--49 CFR 172.700 through 172.704; and

(G) Hazardous material shipper/carrier registration--49 CFR 107.601 through 107.620.

(ii) The licensee shall also note DOT regulations pertaining to the following modes of transportati

(A) Rail--49 CFR 174.1 through 174.86 and 174.700 through 174.750;

(B) Air--49 CFR 175;

(C) Vessel--49 CFR 176.1 through 176.99 and 176.700 through 176.715; and

(D) Public Highway--49 CFR 177 and 390 through 397.

(b) If DOT regulations are not applicable to a shipment of licensed material, the licensee shall cor of the DOT specified in paragraph (a) of this section to the same extent as if the shipment or tran regulations. A request for modification, wavier, or exemption from those requirements, and any no requirements, must be filed with, or made to, the Executive Secretary.

KEY

license, reciprocity, transportation, exemptions

Date of Enactment or Last Substantive Amendment

January 26, 2001

Notice of Continuation

May 1, 1997

Authorizing, Implemented, or Interpreted Law

19-3-104; 19-3-108;

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Rule R313-22. Specific Licenses.

As in effect on July 1, 2001

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- R313-22-75. Special Requirements for a Specific License to Manufacture, Assemble, Repair Devices Which Contain Radioactive Material.
- R313-22-90. Quantities of Radioactive Materials Requiring Consideration of the Need for an Release. Refer to Subsection R313-22-32(8).
- R313-22-100. Limits for Broad Licenses. Refer to Section R313-22-50.
- R313-22-210. Registration of Product Information.
- KEY
- Date of Enactment or Last Substantive Amendment
- Notice of Continuation
- Authorizing, Implemented, or Interpreted Law

R313-22-1. Purpose and Authority.

- (1) The purpose of this rule is to prescribe the requirements for the issuance of specific licenses.
- (2) The rules set forth herein are adopted pursuant to the provisions of Subsections 19-3-104(3) :

R313-22-2. General.

The provisions and requirements of Rule R313-22 are in addition to, and not in substitution for, of particular the provisions of Rule R313-19 apply to applications and licenses subject to Rule R313

R313-22-4. Definitions.

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

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

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

R313-22-30. Specific License by Rule.

A license by rule is issued in the following circumstances, without the necessity of filing an application, under Subsection R313-22-32(1), and the licensee shall be subject to the applicable provisions of Sections 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 this section but are unlicensed;

(2) When radioactive materials existing as a result of improper handling, spillage, accidental contamination, possession, transfer, or receipt, must be stored and those materials have not been licensed under this section.

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, issue statements in order to enable the Executive Secretary to determine whether the application should be modified or revoked.

(3) Applications shall be signed by the applicant or licensee or a person duly authorized to act for the applicant or licensee.

(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 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 device shall identify the source or device by manufacturer and model number as registered with the applicant under 10 CFR 32.210, 2000 ed. or the equivalent regulations of an Agreement State.

(7) As provided by Section R313-22-35, certain applications for specific licenses filed under these sections shall include a decommissioning funding plan or a certification of financial assurance for decommissioning. In the case of applications filed before January 1, 1995, this submittal may follow the renewal application but shall be submitted concurrently with the application.

(8)(a) Applications to possess radioactive materials in unsealed form, on foils or plated sources, or in quantities in excess of those listed in Section R313-22-90, "Quantities of Radioactive Materials Requiring Consideration of 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 material is not greater than 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 S

(i) The radioactive material is physically separated so that only a portion could be involved in an a

(ii) All or part of the radioactive material is not subject to release during an accident because of th

(iii) The release fraction in the respirable size range would be lower than the release fraction show
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
R313-22-90;

(vi) Operating restrictions or procedures would prevent a release fraction as large as that shown i

(vii) Other factors appropriate for the specific facility.

(c) An emergency plan for responding to a release of radioactive material submitted under Subse
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 p

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

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

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

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

(vii) Responsibilities. A brief description of the responsibilities of licensee personnel should an ac
personnel responsible for promptly notifying off-site response organizations and the Executive Se
developing, maintaining, and updating the plan.

(viii) Notification and coordination. A commitment to and a brief description of the means to prom
and request off-site assistance, including medical assistance for the treatment of contaminated in
A control point shall be established. The notification and coordination shall be planned so that un
the facility, and some equipment will not prevent the notification and coordination. The licensee sl
Secretary immediately after notification of the appropriate off-site response organizations and not
declares an emergency.

NOTE: These reporting requirements do not supersede or release licensees of complying with the
Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499 or other state or
40 CFR 302, 1992 ed.

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

(x) Training. A brief description of the frequency, performance objectives and plans for the training; how to respond to an emergency including special instructions and orientation tours the licensee or other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures and thoroughly prepare site personnel for their responsibilities in the event of accident scenarios post 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 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 biennial exercises. Participation of off-site response organizations in biennial exercises although not required shall use accident scenarios postulated as most probable for the specific site and the scenarios shall be varied to include all participants. The licensee shall critique each exercise using individuals not having direct implementation of the exercise. Critiques of exercises shall evaluate the appropriateness of the plan, emergency procedures, facilities 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 Right-to-Know Act of 1986, Title III, Public Law 99-499, if applicable to the applicant's activities at the site involving radioactive material.

(d) The licensee shall allow the off-site response organizations expected to respond in case of an accident to participate in the licensee's emergency plan before submitting it to the Executive Secretary. The licensee shall provide 30 days to the Executive Secretary with the emergency plan.

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

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

(a) the applicant and all personnel who will be handling the radioactive material are qualified by experience to handle the material in question for the purpose requested in accordance with these rules in a manner as to protect public safety or the environment;

(b) the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to the public and environment;

(c) the applicant's facilities are permanently located in Utah, otherwise the applicant shall seek review under Section R313-19-30;

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

(e) the applicant satisfies applicable special requirements in Sections R313-22-50 and R313-22-70, R313-34, R313-36, or R313-38; and

(f) in the case of an application for a license to receive and possess radioactive material for commercial use or for the conduct of other activities which the Executive Secretary determines will significantly affect the public interest, the Executive Secretary, before commencement of construction of the plant or facility in which the activity is to be conducted, after weighing the environmental, economic, technical and other benefits against environmental costs, shall determine whether the action called for is the issuance of the proposed license, with any appropriate conditions. The Executive Secretary shall respond to the application within 60 days. Commencement

conclusion shall be grounds for denial of a license to receive and possess radioactive material in paragraph the term "commencement of construction" means clearing of land, excavation, or other activity that affects the environment of a site. The term does not mean site exploration, necessary borings to do preconstruction monitoring or testing to establish background information related to the suitability 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 shall issue a specific license authorizing the proposed activity in a form and containing conditions and terms that the Executive Secretary deems appropriate or necessary.

(2) The Executive Secretary may incorporate in licenses at the time of issuance, additional requirements relating to the licensee's receipt, possession, use and transfer of radioactive material subject to Rule R313-22 as follows:

- (a) minimize danger to public health and safety or the environment;
- (b) require reports and the keeping of records, and to provide for inspections of activities under the license as necessary; and
- (c) prevent loss or theft of material subject to Rule R313-22.

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

(1) Applicants for a specific license authorizing the possession and use of unsealed radioactive material in quantities exceeding 10^5 times the applicable quantities set forth in Appendix B of 10 CFR incorporated by reference, shall submit a decommissioning funding plan as described in Subsection R313-22-35(4). A decommissioning funding plan shall also be submitted when a combination of radionuclides is involved if the ratio of the quantity of each radionuclide to the applicable value is greater than or equal to 30.72, 2000 ed., which is incorporated by reference.

(2) Applicants for a specific license authorizing possession and use of radioactive material of half-life greater than 30 years and in quantities specified in Subsection R313-22-35(4) shall either:

- (a) submit a decommissioning funding plan as described in Subsection R313-22-35(5); or
- (b) submit a certification that financial assurance for decommissioning has been provided in the form of a financial instrument as described in Subsection R313-22-35(6). For an applicant for a license for unsealed radioactive material, appropriate assurance will be obtained after the application has been approved and the license is issued. If the applicant defers execution of the financial instrument until after the license has been issued, the financial instrument obtained to satisfy the requirements of Subsection R313-22-35(6) shall be submitted to the Executive Secretary before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit a signed original of the financial instrument to the Executive Secretary, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of Subsection R313-22-35(6).

(3)(a) Holders of a specific license issued on or after January 1, 1995, which is of a type described in Subsection R313-22-35(4), shall provide financial assurance for decommissioning in accordance with the criteria set forth in Subsection R313-22-35(5).

(b) Holders of a specific license issued before January 1, 1995, and of a type described in Subsection R313-22-35(4), shall provide financial assurance for decommissioning in accordance with the criteria set forth in Subsection R313-22-35(5).

before January 1, 1995, a decommissioning funding plan as described in Subsection R313-22-35 assurance for decommissioning in an amount at least equal to \$750,000 in accordance with the c the licensee submits the certification of financial assurance rather than a decommissioning fundir 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 Subse before January 1, 1995, a decommissioning funding plan as described in Subsection R313-22-35 assurance for decommissioning in accordance with the criteria set forth in Section R313-22-35.

(d) A licensee who has submitted an application before January 1, 1995, for renewal of license in shall provide financial assurance for decommissioning in accordance with Subsections R313-22- submitted before January 1, 1997.

(4) Table of required amounts of financial assurance for decommissioning by quantity of material:

TABLE

Greater than 10 ⁴ but less than or equal to 10 ⁵ times the applicable quantities of radioactive material, as defined in Appendix B of 10 CFR 30.1 through 30.72, 2000 ed., which is incorporated by reference, in unsealed form. For a combination of radionuclides, if R, as defined in Subsection R313-22-35(1) divided by 10 ⁴ is greater than one but R divided by 10 ⁵ is less than or equal to one:	\$750,000
Greater than 10 ³ but less than or equal to 10 ⁴ times the applicable quantities of radioactive material, as defined in Appendix B of 10 CFR 30.1 through 30.72, 2000 ed., which is incorporated by reference, in unsealed form. For a combination of radionuclides, if R, as defined in Subsection R313-22-35(1) divided by 10 ³ is greater than one but R divided by 10 ⁴ is less than or equal to one:	\$150,000
Greater than 10 ¹⁰ times the applicable quantities of radioactive material, as defined in Appendix B of 10 CFR 30.1 through 30.72, 2000 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 des for decommissioning from Subsection R313-22-35(6), including means for adjusting cost estimate periodically over the life of the facility. The decommissioning funding plan shall also contain a cer assurance for decommissioning has been provided in the amount of the cost estimate for decom financial instrument obtained to satisfy the requirements of Subsection R313-22-35(6).

(6) Financial assurance for decommissioning shall be provided by one or more of the following m

(a) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated under 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 other financial assurance.

(b) A surety method, insurance, or other guarantee method. These methods shall guarantee that the licensee will be able to pay decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Subsection R313-22-35(9). A guarantee by the applicant or licensee for decommissioning costs based on a financial test may not be used in combination with other financial methods to satisfy the requirements of Section R313-22-35. A guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test and test are as contained in Subsection R313-22-35(9). A guarantee by the applicant or licensee in combination with any other financial methods to satisfy the requirements of Section R313-22-35 shall be acceptable to the Executive Secretary if the licensee has a parent company holding majority control of the voting stock of the company. A surety method or insurance 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 automatically renew unless 90 days or more prior to the renewal date the issuer notifies the Executive Secretary of its intention not to renew. The surety method or insurance shall also provide that the funds shall be automatically forfeited prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement surety method or insurance 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 or other purpose acceptable to the Executive Secretary. An acceptable trustee includes an appropriate state or federal agency which has the authority to act as a trustee and whose trust operations are regulated and examined by the Executive Secretary,

(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, may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund in which the licensee sets aside funds periodically in an account segregated from licensee assets and outside the licensee's control so that the total amount of funds would be sufficient to pay decommissioning costs at the time termination of the license. The sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or other financial assurance. The surety or insurance provisions shall be as stated in Subsection R313-22-35(6)(b);

(d) In the case of Federal, State or local government licensees, a statement of intent containing a statement of intent based on the Table in Subsection R313-22-35(4) and indicating that funds for decommissioning costs are being set aside or

(e) When a governmental entity is assuming custody and ownership of a site, an arrangement that provides for the decommissioning of the site by the governmental entity.

(7) Persons licensed under Rule R313-22 shall keep records of information important to the decommissioning of a facility until the site is released for unrestricted use. Before licensed activities are transferred or terminated under R313-19-34(2), licensees shall transfer all records described in Subsections R313-22-35(7)(a) through (7)(d). In the case, the new licensee will be responsible for maintaining these records until the license is terminated. Records of decommissioning of a facility are kept for other purposes, reference to these records and their location shall be provided to the Executive Secretary if 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. These records may be limited to instances when contamination remains after any cleanup procedure has been completed and there is a likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into concrete. These records shall include any known information on identification of involved nuclides

(b) as-built drawings and modification of structures and equipment in restricted areas where radiological locations of possible inaccessible contamination such as buried pipes which may be subject to referenced, each relevant document need not be indexed individually. If drawings are not available, 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 other radioactive materials having only half-lives of less than 65 days, a list contained in a single document including all of the following:

(i) all areas designated and formerly designated as restricted areas as defined under Section R313-15-1109;

(ii) all areas outside of restricted areas that require documentation under Subsection R313-22-35(6)(b);

(iii) all areas outside of restricted areas where current and previous wastes have been buried as defined in Section R313-15-1109; and

(iv) all areas outside of restricted areas which contain material such that, if the license expired, the licensee shall decontaminate the area to meet the criteria for decommissioning in Sections R313-15-401 through R313-15-403 or disposal under Section R313-15-1002; and

(d) records of the cost estimate performed for the decommissioning funding plan or of the amount 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 decommissioning.

(a) To pass the financial test referred to in Subsection R313-22-35(6)(b), the parent company shall have:

(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 total depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.0;

(B) Net working capital and tangible net worth each at least six times the current decommissioning cost estimate, 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 90 percent of the current decommissioning cost estimate, 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 & Poor's or Moody's;

(B) Tangible net worth at least six times the current decommissioning cost estimate, or prescribed amount if a certification is used; and

(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 cost estimates, or prescribed amount if certification is used.

(b) The parent company's independent certified public accountant shall have compared the data to the financial test, which is derived from the independently audited, year end financial statements for the fiscal year of such financial statement. In connection with that procedure the licensee shall inform the Executive Secretary of any coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test for 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 the succeeding fiscal year.

(ii) If the parent company no longer meets the requirements of Subsection R313-22-35(8)(a) the licensee shall notify the Executive Secretary of intent to establish alternative financial assurance as specified in Section R313-22-35(8)(b) by certified mail within 90 days after the end of the fiscal year for which the year end financial data shall be provided. If the licensee meets the financial test requirements. The licensee shall provide alternate financial assurance within the succeeding fiscal year.

(d) The terms of a parent company guarantee which an applicant or licensee obtains shall provide for the following:

(i) The parent company guarantee will remain in force unless the guarantor sends notice of cancellation to the Executive Secretary. Cancellation may not occur, however, during the 120 days beginning with the date of cancellation by both the licensee and the Executive Secretary, as evidenced by the return receipt.

(ii) If the licensee fails to provide alternate financial assurance as specified in Section R313-22-35(8)(b) the licensee and Executive Secretary of a notice of cancellation of the parent company guarantee from the date of 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 issues a new license.

(iv) If a trust is established for decommissioning costs, the trustee and trust shall be acceptable to the Executive Secretary if the trustee includes an appropriate State or Federal Government agency or an entity which has the authority to regulate 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 shall be:

(a) To pass the financial test referred to in Subsection R313-22-35(6)(b), a company shall meet a minimum of:

(i) Tangible net worth at least ten times the total current decommissioning cost estimate, or the current amount required, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor; and

(ii) Assets located in the United States amounting to at least 90 percent of total assets or at least the 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 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 Act of 1933.
- (ii) The company's independent certified public accountant shall have compared the data used by the company in its financial statements with the data derived from the independently audited, yearend financial statements for the latest fiscal year, and shall certify that the data specified in the financial statements is derived from the independently audited, yearend financial statements for the latest fiscal year, and shall inform the Executive Secretary of the attention of the auditor that cause the auditor to believe that the data specified in the financial statements 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 end of each fiscal year.
- (c) If the licensee no longer meets the requirements of Subsection R313-22-35(9)(a), the licensee shall give the Executive Secretary of its intent to establish alternate financial assurance as specified in Section R313-22-35(9)(b) by written 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 by the Executive Secretary, as evidenced by the return receipt.
 - (ii) The licensee shall provide alternative financial assurance as specified in Section R313-22-35(9)(b) by written notice of a cancellation of the guarantee.
 - (iii) The guarantee and financial test provisions shall remain in effect until the Executive Secretary determines that another financial assurance method acceptable to the Executive Secretary has been put in effect.
 - (iv) The licensee shall promptly forward to the Executive Secretary and the licensee's independent certified public accountant a copy of the financial statements for each fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to 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 better by Standard and Poor's and Moody's, the licensee shall provide notice in writing of such fact to the Executive Secretary within 30 days of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in a category of "A" or better by Standard and Poor's and Moody's, the licensee no longer meets the requirements of Subsection R313-22-35(9)(a).
 - (vi) The applicant or licensee shall provide to the Executive Secretary a written guarantee, a written agreement to fund and carry out the required decommissioning activities or, if the licensee is not a corporation, the licensee shall set up and fund a trust in the amount of the current cost estimates for decommissioning activities.

R313-22-36. Expiration and Termination of Licenses and Decommissioning of Outdoor Areas.

- (1) A specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed for renewal under Section R313-22-37 no less than 30 days before the expiration date stated in the license, and the renewal has been filed at least 30 days prior to the expiration date stated in the existing license, then the day on which the Executive Secretary makes a final determination to deny the renewal application. If the licensee does not file for renewal, the 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 determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided in the determination.

the Executive Secretary.

(3) A specific license continues in effect, beyond the expiration date if necessary, with respect to the Executive Secretary notifies the licensee in writing that the license is terminated. During this time:

(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 no undue hazard to public health, 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 of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that the building or outdoor area is suitable for release so that there is not an undue hazard to public health, safety or the environment, or submit within 12 months of notification a decommissioning plan, if required by Subsection R313-22-36(4), upon approval of that plan if:

(a) the license has expired pursuant to Subsections R313-22-36(1) or (2); or

(b) the licensee has decided to permanently cease principal activities at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release because of an undue hazard to public health, 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, safety or the environment.

(5) Coincident with the notification required by Subsection R313-22-36(4), the licensee shall maintain the financial assurances established by the licensee pursuant to Section R313-22-35 in conjunction with the decommissioning plan required by Section R313-22-36. The amount of the financial assurance must be increased, or modified, to reflect the detailed cost estimate for decommissioning established pursuant to Subsection R313-22-36(4).

(a) A licensee who has not provided financial assurance to cover the detailed cost estimate submitted by the licensee must 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 if the radiological contamination is reduced at the site with the approval of the Executive Secretary.

(6) The Executive Secretary may grant a request to extend the time periods established in Subsection R313-22-36(4) if the Executive Secretary determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. A request for relief must be submitted no later than 30 days before notification pursuant to Subsection R313-22-36(4) and the decommissioning plan set forth in Subsection R313-22-36(4) may not commence until the Executive Secretary has made a determination.

(7)(a) A decommissioning plan shall be submitted if required by license condition or if the procedures for decommissioning of the site or separate building or outdoor area have not been previously approved and the decommissioning procedures could increase potential health and safety impacts to workers or to the public, such as:

(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 radiological hazards are present.

routinely encountered during operation;

(iii) procedures could result in significantly greater airborne concentrations of radioactive material;

(iv) procedures could result in significantly greater releases of radioactive material to the environment during operation.

(b) The Executive Secretary may approve an alternate schedule for submittal of a decommissioning plan under R313-22-36(4) if the Executive Secretary determines that the alternative schedule is necessary to complete decommissioning operations and presents no undue risk from radiation to the public health and safety.

(c) Procedures such as those listed in Subsection R313-22-36(7)(a) with potential health and safety risks require the 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 proposed decommissioning plan;

(ii) a description of planned decommissioning activities;

(iii) a description of methods used to ensure protection of workers and the environment against radiation;

(iv) a description of the planned final radiation survey; and

(v) an updated detailed cost estimate for decommissioning, comparison of that estimate with previous estimates, 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 initiation, a justification for the delay based on the criteria in Subsection R313-22-36(8).

(e) The proposed decommissioning plan will be approved by the Executive Secretary if the information shows that decommissioning will be completed as soon as practical and that the health and safety of workers and the public will be protected.

(8)(a) Except as provided in Subsection R313-22-36(9), licensees shall complete decommissioning of a building or outdoor area as soon as practical but no later than 24 months following the initiation of decommissioning.

(b) Except as provided in Subsection R313-22-36(9), when decommissioning involves the entire site, licensees shall complete decommissioning 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 a building or outdoor area, and license termination if appropriate, if the Executive Secretary determines that the request warrants 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 an alternative schedule.

(d) whether a significant reduction in radiation exposure to workers can be achieved by allowing s

(e) other site-specific factors which the Executive Secretary may consider appropriate on a case-l requirements of other government agencies, lawsuits, ground-water treatment activities, monitore actions that could result in more environmental harm than deferred cleanup, and other factors be

(10) As the final step in decommissioning, the licensee shall:

(a) certify the disposition of all licensed material, including accumulated wastes, by submitting a c information; and

(b) conduct a radiation survey of the premises where the licensed activities were carried out and s survey, unless the licensee demonstrates in some other manner that the premises are suitable fo for decommissioning in Sections R313-15-401 through R313-15-406. The licensee shall, as appr

(i) report levels of gamma radiation in units of millisieverts (microrentgen) per hour at one meter radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or i centimeters--removable and fixed-- for surfaces, megabecquerels (microcuries) per milliliter for w gram for solids such as soils or concrete; and

(ii) specify the survey instrument(s) used and certify that each instrument is properly calibrated ar

(11) Specific licenses, including expired licenses, will be terminated by written notice to the licens determines that:

(a) radioactive material has been properly disposed;

(b) reasonable effort has been made to eliminate residual radioactive contamination, if present; a

(c) documentation is provided to the Executive Secretary that:

(i) a radiation survey has been performed which demonstrates that the premises are suitable for r decommissioning in Sections R313-15-401 through R313-15-406; or

(ii) other information submitted by the licensee is sufficient to demonstrate that the premises are s the criteria for decommissioning in Sections R313-15-401 through R313-15-406.

R313-22-37. Renewal of Licenses.

Application for renewal of a specific license shall be filed on a form prescribed by the Executive S R313-22-32.

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

Applications for amendment of a license shall be filed in accordance with Section R313-22-32 an 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 Secretar R313-22-33, R313-22-50, and R313-22-75 and in Rules R313-25, R313-32, R313-34, R313-36, c

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 product containing byproduct material whose subsequent possession, use, transfer and disposal from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission

(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 of any chemical or physical form of the radioactive material specified in the license, but not exceed 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 of any chemical or physical form of radioactive material specified in Section R313-22-100 for any for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified in R313-22-100, Column I. If two or more radionuclides are possessed thereunder, the possession of each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in R313-22-100, Column I. The sum of the ratios for the radionuclides possessed under the license shall not exceed 1.0.

(c) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition of any chemical or physical form of radioactive material specified in Section R313-22-100, for any limit for a Type C broad license, if only one radionuclide is possessed thereunder, is the quantity specified in R313-22-100, Column II. If two or more radionuclides are possessed thereunder, the possession of each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified for that radionuclide. The sum of the ratios for the radionuclides possessed under the license shall not exceed 1.0.

(2) An application for a Type A specific license of broad scope shall be approved if all of the following:

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

(b) the applicant has engaged in a reasonable number of activities involving the use of radioactive material;

(c) the applicant has established administrative controls and provisions relating to organization and recordkeeping, material control and accounting, and management review that are necessary to assure:

(i) the establishment of a radiation safety committee composed of such persons as a radiation safety officer, 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 safety 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 the design of facilities and equipment, training and experience of the user, and the operating or handling procedures;

(C) review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses of radioactive material 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 follow

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

(b) the applicant has established administrative controls and provisions relating to organization and recordkeeping, material control and accounting, and management review that are necessary to assure:

(i) the appointment of a radiation safety officer who is qualified by training and experience in radiation 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 of facilities and equipment, training and experience of the user, and the operating or handling procedures

(C) review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses of radioactive material prior to use of the radioactive material.

(4) An application for a Type C specific license of broad scope shall be approved, if:

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

(b) the applicant submits a statement that radioactive material will be used only by, or under the control of, a person who has received:

(i) a college degree at the bachelor level, or equivalent training and experience, in the physical or chemical sciences, and

(ii) at least forty hours of training and experience in the safe handling of radioactive material, and units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of 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, recordkeeping, material control and accounting, and management review necessary to assure safe use.

(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) of radioactive sources used for irradiation of materials;

(iii) conduct activities for which a specific license issued by the Executive Secretary under Section 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

inhalation by, or application to, a human being.

(b) Type A specific licenses of broad scope issued under Rule R313-22 shall be subject to the conditions of use. The license possessed under the license may only be used by, or under the direct supervision of, individuals approved by the safety committee.

(c) Type B specific license of broad scope issued under Rule R313-22 shall be subject to the conditions of use. The license under the license may only be used by, or under the direct supervision of, individuals approved by the safety committee.

(d) Type C specific license of broad scope issued under Rule R313-22 shall be subject to the conditions of use. The license possessed under the license may only be used, by or under the direct supervision of, individuals approved by the safety committee. Subsection R313-22-50(4).

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

(1) Licensing the introduction of radioactive material into products in exempt concentrations.

(a) In addition to the requirements set forth in Section R313-22-33, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to another person pursuant to 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 is introduced, the amount of radioactive material and the product or material into which it is introduced, method of introduction of radioactive material in the product or material, control methods to assure that no more than the specified concentration of radioactive material in the product or material, estimated time interval between introduction and transfer of the product or material, a description of the product or material, a description 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 introduction are in concentrations in Section R313-19-70, that reconcentration of the radioactive material in concentrations in Section R313-19-70 is not likely, that use of lower concentrations is not feasible, and that the product or material is not a food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation.

(b) Persons licensed under Subsection R313-22-75(1) shall file an annual report with the Executive Director of the Department of Health and Human Services and the quantity of products or materials into which radioactive material has been introduced during the reporting period; the person who owned or possessed the product and material, into which radioactive material has been introduced; the type and quantity of radionuclide introduced into the product or material; and the concentration of radioactive material in the product or material at time of transfer of the radioactive material by the licensee. If no transfer of radioactive material was made pursuant to Subsection R313-22-75(1) during the reporting period, the report shall so indicate. The report shall be filed by June 30, and shall be filed within thirty days thereafter.

(2) Licensing the distribution of radioactive material in exempt quantities. Authority to transfer possession of radioactive material to a processor or producer of equipment, devices, commodities or other products containing byproducts of radioactive material, possession, use, transfer, and disposal by other persons who are exempted from regulatory requirements of the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(a) An application for a specific license to distribute naturally occurring and accelerator-produced radionuclides shall be exempted from these rules pursuant to Subsection R313-19-13(2)(b) will be approved if:

(i) the radioactive material is not contained in a food, beverage, cosmetic, drug or other commodity or product designed for ingestion or application to, a human being;

(ii) the radioactive material is in the form of processed chemical elements, compounds, or mixture counting standards, plated or encapsulated sources, or similar substances, identified as radioactive properties, but is not incorporated into a manufactured or assembled commodity, product, or device and

(iii) the applicant submits copies of prototype labels and brochures and the Executive Secretary a

(b) The license issued under Subsection R313-22-75(2)(a) is subject to the following conditions:

(i) No more than ten exempt quantities shall be sold or transferred in a single transaction. However, fractional parts of one or more of the exempt quantities provided the sum of the fractions shall

(ii) Exempt quantities shall be separated and individually packaged. No more than ten packaged quantities shall be placed in any outer package for transfer to persons exempt pursuant to Subsection R313-19-13(2)(b). The radiation level at the external surface of the package shall not 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 label which:

(A) identifies the radionuclide and the quantity of radioactivity; and

(B) bears the words "Radioactive Material."

(iv) In addition to the labeling information required by Subsection R313-22-75(2)(b)(iii), the label and 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, and Medicines into Products Manufactured for Commercial Distribution is Prohibited - Exempt Quantities Should Be Labeled as Such";

(C) set forth appropriate additional radiation safety precautions and instructions relating to the handling of the radioactive material.

(c) Persons licensed under Subsection R313-22-75(2) shall maintain records identifying, by name and quantity, the radioactive material transferred for use under Subsection R313-19-13(2)(b) or the equivalent regulations. An annual summary report stating the kinds and quantities of radioactive material transferred. An annual summary report stating the kinds and quantities of radioactive material transferred under the specific license shall be filed with the Executive Secretary. Reports shall be filed within thirty days thereafter. If no transfers of radioactive material have been made pursuant to the reporting period, the report shall so indicate.

(3) Licensing the incorporation of naturally occurring and accelerator-produced radioactive materials into gas and liquid detectors. An application for a specific license authorizing the incorporation of NARM into gas and liquid detectors to persons exempt under Subsection R313-19-13(2)(c)(iii) will be approved if the application satisfies the requirements contained in 10 CFR 32.26. The maximum quantity of radium-226 in each device shall not exceed 10 micrograms.

(4) Licensing the manufacture and distribution of devices to persons generally licensed under Subsection R313-21-22(4) or equivalent regulations:

(a) An application for a specific license to manufacture or distribute devices containing radioactive material, to persons generally licensed under Subsection R313-21-22(4) or equivalent regulations

Commission, an Agreement State or a Licensing State will be approved if:

- (i) the applicant satisfies the general requirements of Section R313-22-33;
- (ii) the applicant submits sufficient information relating to the design, manufacture, prototype test installation, servicing, leak testing, operating and safety instructions, and potential hazards of the 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 released or inadvertently removed from the device, and it is unlikely that a person will receive in c of the annual limits specified in Subsection R313-15-201(1), and
 - (C) under accident conditions, such as fire and explosion, associated with handling, storage and i person would receive an external radiation dose or dose commitment in excess of the following o

TABLE

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	150.0 mSv (15 rems)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter	2.0 Sv (200 rems)
Other organs	500.0 mSv (50 rems); and

- (iii) each device bears a durable, legible, clearly visible label or labels approved by the Executive identified and separate statement:
 - (A) instructions and precautions necessary to assure safe installation, operation and servicing of t 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 ; time interval for testing, and the identification of radioactive material by radionuclide, quantity of r the quantity, and
 - (C) the information called for in one of the following statements, as appropriate, in the same or su
 - (I) "The receipt, possession, use and transfer of this device, Model No., Serial No., equivalent, and the regulations of the U.S. Nuclear Regulatory Commission or a state with which has entered into an agreement for the exercise of regulatory authority. This label shall be maintai Removal of this label is prohibited." The label shall be printed with the words "CAUTION -RADIO/ manufacturer or distributor shall appear on the label. The model, serial number, and name of the omitted from this label provided the information is elsewhere specified in labeling affixed to the de
 - (II) "The receipt, possession, use and transfer of this device, Model No., Serial No. equivalent, and the regulations of a Licensing State. This label shall be maintained on the device label is prohibited." The label shall be printed with the words "CAUTION - RADIOACTIVE MATEF

or distributor shall appear on the label. The model, serial number, and name of the manufacturer 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 operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material or application sufficient information to demonstrate that a longer interval is justified by performance of devices and by design features which have a significant bearing on the probability or consequence of the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval, the Executive Secretary will consider information which includes, but is not limited to:

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

(c) In the event the applicant desires that the general licensee under Subsection R313-21-22(4), or U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State be authorized to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the device, or remove the device from installation, the applicant shall include in the application written instructions for the estimated calendar quarter doses associated with this activity or activities, and basis for these estimates to demonstrate that performance of this activity or activities by an individual untrained in radiological storage, and use of devices under the general license, is unlikely to cause that individual to receive annual limits specified in Subsection R313-15-201(1).

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

(i) furnish a copy of the general license contained in Subsection R313-21-22(4) to each person to whom an intermediate person transfers radioactive material in a device for use pursuant to the general license in Subsection R313-21-22(4);

(ii) furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's, or Agreement State, regulation equivalent to Subsection R313-21-22(4), or alternatively, furnish a copy of the general license in Subsection R313-21-22(4) to each person to whom he directly or through an intermediate person transfers radioactive material pursuant to the general license of the U.S. Nuclear Regulatory Commission, the Agreement State or the Agreement State general license in Subsection R313-21-22(4) is furnished to such a person, it shall be accompanied by a copy of the general license in Subsection R313-21-22(4) if the device is regulated by the U.S. Nuclear Regulatory Commission, Agreement State or Licensing State.

the same as those in Subsection R313-21-22(4);

(iii) report to the Executive Secretary all transfers of such devices to persons for use under the general license in Subsection R313-21-22(4). The reports shall identify the general licensee by name and address, an individual by name and address, a point of contact between the Executive Secretary and the general licensee, the type and model of the device, 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 and address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under Subsection R313-21-22(4) during the reporting period, the report shall so indicate. The report shall cover each transfer and be submitted 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 a general license in 10 CFR 31.5.

(B) Report to the responsible State agency all transfers of devices manufactured and distributed for use under a general license in that State's regulations equivalent to Subsection R313-21-22(4).

(C) The reports shall identify each general licensee by name and address, an individual by name and address, a point of contact between the responsible agency and general licensee, the type and model of the device, 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 and address, contact, and relationship to the intended user. The report shall be submitted within thirty days after the end of the reporting period or the 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, the report shall so indicate.

(E) If transfers have not been made to general licensees within a particular state during the reporting period, the report shall so indicate upon request of that agency; and

(v) keep records showing the name, address and the point of contact for each general licensee to whom radioactive material is transferred, the name and address of each intermediate person transfers radioactive material in devices for use pursuant to the general license in Subsection R313-21-22(4), or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement with the U.S. Nuclear Regulatory Commission, records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device, the name and address of each intermediate person, and compliance with the report requirements of Subsection R313-22-75(4)

(5) Special requirements for the manufacture, assembly or repair of luminous safety devices for use under a general license to manufacture, assemble or repair luminous safety devices containing tritium or promethium-147 to persons generally licensed under Subsection R313-21-22(5) will be approved if:

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

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

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

- (a) the applicant satisfies the general requirements of Section R313-22-33; and
- (b) the applicant satisfies the requirements of 10 CFR 32.57 through 32.59, 32.102 and 10 CFR 7

(7) Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory tests for a specific license to manufacture or distribute radioactive material for use under the general license be approved if:

- (a) the applicant satisfies the general requirements specified in Section R313-22-33;
- (b) the radioactive material is to be prepared for distribution in prepackaged units of:
 - (i) iodine-125 in units not exceeding ten microcuries (370.0 kBq) each;
 - (ii) iodine-131 in units not exceeding ten microcuries (370.0 kBq) each;
 - (iii) carbon-14 in units not exceeding ten microcuries (370.0 kBq) each;
 - (iv) hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each;
 - (v) iron-59 in units not exceeding 20 microcuries (740.0 kBq) each;
 - (vi) cobalt-57 in units not exceeding ten microcuries (370.0 kBq) each;
 - (vii) selenium-75 in units not exceeding ten microcuries (370.0 kBq) each; or
 - (viii) mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 r each;

- (c) prepackaged units bear a durable, clearly visible label:
 - (i) identifying the radioactive contents as to chemical form and radionuclide, and indicating that they exceed ten microcuries (370.0 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-hydrogen-3 (tritium); 20 microcuries (740.0 kBq) of iron-59; or Mock Iodine-125 in units not exceeding iodine-129 and 0.005 microcurie (185.0 Bq) of americium-241 each; and
 - (ii) displaying the radiation caution symbol described in Section R313-15-901 and the words, "CAUTION - 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 following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet package:

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

..... Name of Manufacturer"

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

..... Name of Manufacturer"

(e) the label affixed to the unit, or the leaflet or brochure which accompanies the package, contain precautions to be observed in handling and storing radioactive material. In the case of the Mock I source, the information accompanying the source shall also contain directions to the licensee as set out in Section R313-15-1001.

(8) Licensing the manufacture and distribution of ice detection devices. An application for a specific license for ice detection devices to persons generally licensed under Subsection R313-21-22(10) will be approved if:

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

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

(9) Manufacture and distribution of radiopharmaceuticals containing radioactive material for medical use:

(a) An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material to 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 manufacturer, generator, or other container of the radioactive drug; and the shielding provided by the packaging for the 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, 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"; the name of the radioactive drug or its activity; and the date and time of the radioactive drug's activity at a specified date and time. For radioactive drugs with a half life greater than 100 days:

(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" and an identifier that ensures that the syringe, vial, or other container can be correlated to the radiation shield label.

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

(i) May prepare radioactive drugs for medical use, as defined in Section R313-32-2, provided that either an authorized nuclear pharmacist, as specified in Subsections R313-22-75(9)(b)(ii) and (iii) of an authorized nuclear pharmacist as specified in Section R313-32-25.

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

(A) this individual qualifies as an authorized nuclear pharmacist as defined in Section R313-32-2

(B) this individual meets the requirements specified in Subsection R313-32-980(2) and Section R received an approved license amendment identifying this individual as an authorized nuclear pha

(C) this individual is designated as an authorized nuclear pharmacist in accordance with Subsecti

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

(iv) May designate a pharmacist, as defined in Section R313-32-2, as an authorized nuclear phar January 1, 1997 as an "authorized user" on a nuclear pharmacy license issued by the Executive : R313-22-75(9).

(v) Shall provide to the Executive Secretary a copy of each individual's certification by the Board c Nuclear Regulatory Commission or Agreement State license, or the permit issued by a licensee o pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, p 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 d for use of the instrumentation. The licensee shall measure, by direct measurement or by combin the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior addition, the licensee shall:

(i) perform tests before initial use, periodically, and following repair, on each instrument for accur 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 FD governing radioactive drugs.

(10) Manufacture and distribution of sources or devices containing radioactive material for medic license to manufacture and distribute sources and devices containing radioactive material to pers R313-32-18 for use as a calibration or reference source or for the uses listed in Sections R313-32 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 t 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 meet the conditions 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 same 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; a durable label attached to the source or device or attached to a permanent storage container for instructions which are too lengthy for a label may be summarized on the label and printed in detail on the label;
- (c) the label affixed to the source or device, or to the permanent storage container for the source, shall include the radionuclide, quantity and date of assay, and a statement that the source or device is licensed by the State of Utah to persons licensed pursuant to Sections R313-32-18, R313-32-400, and R313-32-500 or under a Compact with the Regulatory Commission, an Agreement State or a Licensing State; provided that labeling for sources in permanent 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 longer than six months, the applicant shall include in the application sufficient information to demonstrate the safety by performance characteristics of the source or device or similar sources or devices and by design and construction 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 Director shall include, 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,

furnish a copy of the general license contained in Subsection R313-21-21(5) and a copy of form [the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement & the same as those in Subsection R313-21- 21(5);

(v) report to the Executive Secretary all transfers of industrial products or devices to persons for u Subsection R313-21-21(5). The report shall identify each general licensee by name and address, may constitute a point of contact between the Executive Secretary and the general licensee, the t transferred, and the quantity of depleted uranium contained in the product or device. The report s the end of the calendar quarter in which the product or device is transferred to the generally licen: made to persons generally licensed under Subsection R313-21-21(5) during the reporting period,

(vi) provide certain other reports as follows:

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

(B) report to the responsible state agency all transfers of devices manufactured and distributed pu use under a general license in that state's regulations equivalent to Subsection R313-21-21(5),

(C) reports shall identify each general licensee by name and address, an individual by name or p contact between the agency and the general licensee, the type and model number of the device t uranium contained in the product or device. The report shall be submitted within thirty days after t 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 reported to the U.S. Nuclear Regulatory Commission, and

(E) if no transfers have been made to general licensees within a particular Agreement State durin shall be reported to the responsible Agreement State agency upon the request of that agency; an

(vii) records shall be kept showing the name, address and point of contact for each general licens depleted uranium in industrial products or devices for use pursuant to the general license provide equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The re two years and shall show the date of each transfer, the quantity of depleted uranium in the produ with the report requirements of Subsection R313-22- 75(11).

R313-22-90. Quantities of Radioactive Materials Requiring Consideration of the Responding to a Release. Refer to Subsection R313-22-32(8).

TABLE

Radioactive Material(1)	Release Fraction	Quantity (curies)
Actinium-228	0.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600

Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252 (20 mg)	.001	9
Carbon-14	.01	50,000
	Non CO	
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Germanium-68	.01	2,000
Gadolinium-153	.01	5,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holmium-166m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10
Indium-114m	.01	1,000
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000

Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment, beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma(2)	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha(2)	.0001	20
Combinations of radioactive materials listed above(1)	-----	-----

(1) For combinations of radioactive materials, consideration of the need for an of the ratios of the quantity of each radioactive material authorized to the quantity R313-22-90 exceeds one.

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

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

TABLE

RADIOACTIVE MATERIAL	COLUMN I	COLUMN II
	CURIES	
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	1	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1
Cesium-134m	100	1
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1

Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1
Chromium-51	100	1
Cobalt-57	10	0.1
Cobalt-58m	100	1
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 (9.2h)	10	0.1
Europium-152 (13y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1
Indium-113m	100	1
Indium-114m	1	0.01
Indium-115m	100	1
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.01
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1
Krypton-87	10	0.1
Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1
Osmium-185	1	0.01
Osmium-191m	100	1
Osmium-191	10	0.1

Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1
Platinum-193	10	0.1
Platinum-197m	100	1
Platinum-197	10	0.1
Polonium-210	0.01	0.0001
Potassium-42	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-186	10	0.1
Rhenium-188	10	0.1
Rhodium-103m	1,000	10
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1
Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85m	1,000	10
Strontium-85	1	0.01
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulphur-35	10	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1
Technetium-99	1	0.01
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01

Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-187	10	0.1
Vanadium-48	1	0.01
Xenon-131m	1,000	10
Xenon-133	100	1
Xenon-135	100	1
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01
Zinc-69m	10	0.1
Zinc-69	100	1
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01
Any radioactive material other than source material, special nuclear material, or alpha-emitting radioactive material not listed above	0.1	0.001

R313-22-210. Registration of Product Information.

Licenses who manufacture or initially distribute a sealed source or device containing a sealed source under a specific license or general license are deemed to have provided reasonable assurance that source or device are adequate to protect health and minimize danger to life and the environment evaluated in accordance with 10 CFR 32.210, 2000 ed. or equivalent regulations of an Agreement

KEY

specific licenses, decommissioning, broad scope, radioactive material

Date of Enactment or Last Substantive Amendment

March 10, 2000

Notice of Continuation

May 1, 1997

Authorizing, Implemented, or Interpreted Law

19-3-104; 19-3-108;

Rule converted into HTML by the Division of Administrative Rules.

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Home: <http://www.rules.state.ut.us/>
Last modified: 07/06/2001 12:53 PM

From: Bill Sinclair
To: "sellis@myriad.com".MAIL.MNET
Subject: Re: Envirocare

Governor Leavitt has asked me to respond to your electronic mail of July 27, 2001 concerning the Envirocare of Utah issue. As you are aware, Envirocare submitted a license application on November 1, 1999, to receive and dispose of containerized Class A, B, and C low-level radioactive waste in a new landfill cell at their facility in western Tooele County. The licensing process requires that the Division of Radiation Control determine the technical adequacy of the application. The license review process has been ongoing, public comment has been received, and a final decision was made by the Executive Secretary of the Utah Radiation Control Board on July 9, 2001. The next step in the process is to await any appeals to the Executive Secretary decision. Interested parties have until August 7, 2001 to file appeals in accordance with Radiation Control rule R313-17. To date (August 6th), one appeal has been filed but it is anticipated that at least two others may be filed before the deadline. These appeals invokes a review of the licensing decision by the Utah Radiation Control Board and must be resolved before either the Legislature or Governor can act in their approval capacity. Envirocare has requested that the Division pursue the appeals process until a final agency action is reached.

Governor Leavitt has taken no position in terms of his role in the licensing process but is letting the process move forward as prescribed in state law. At the appropriate time, Governor Leavitt will weigh in on this issue. Since appeals must be considered, the approval process will not be available for the legislature and Governor until the decision of the Executive Secretary is upheld, modified, or rejected by the Board. The Governor appreciates your input into this important question and will consider such input when it is the appropriate time for him to make a decision concerning this issue.

>>> Sandra Ellis <sellis@myriad.com> 07/27/01 04:24PM >>>
7/27/01

Governor,

I am very proud of the work that you have done to help prevent PFS from bringing Nuclear wastes into the Skull Valley area. Having nuclear wastes stored so close to the population center of Utah concerns me greatly. I am afraid for the future of our land with so many industries lobbying to store spent reactor rods etc. in the area.

I am still more concerned about your interests with Envirocare. Envirocare would like to bring class B and C wastes into Utah which would remain hot for several generations. I am afraid that you are allowing political contributions to sway your decisions with these critical issues. The wastes that Envirocare wants to bring into the state are essentially as toxic as the ones that PFS would like to bring in. It does not matter if the waste is hot for 500 or 10,000 years. I am also deeply concerned with ground water contamination from leaking containers and transportation of the wastes over the railways or even worse the highways. The risks from these issues seems too high to allow these wastes to come into Utah.

Please consider your stance against PFS and the good things that you are trying to accomplish by opposing the Skull Valley storage site. Envirocare needs the same attention. Utah families don't want nuclear waste stored a mere 45 miles from their homes. Future generations of Utah families can't be jeopardized by industrial greediness.

Please don't let Envirocare obtain the permit to store class B and C nuclear wastes. Our future rests on your decision.

Thanks for your time,

Sandra Ellis
sellis@myriad.com

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Rule R313-25. License Requirements for Land Disposal of Radioactive Waste - General Provisions.

As in effect on July 1, 2001

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- Authorizing, Implemented, or Interpreted Law

R313-25-1. Purpose and Scope.

The rules in this chapter establish procedures, criteria, and terms and conditions upon which the Department issues licenses for the land disposal of wastes received from other persons. The requirements of R313-25 are in addition to, and not in substitution for, other applicable requirements of these rules.

R313-25-2. Definitions.

As used in R313-25, the following definitions apply:

"Active maintenance" means significant activity needed during the period of institutional control to maintain a reasonable assurance that the performance objectives in R313-25-19 and R313-25-20 are met. Active maintenance may include the pumping and treatment of water from a disposal unit, the replacement of a disposal unit cover, or other episodic or continuous measures. Active maintenance does not include custodial activities like repair of fencing, repair or replacement of monitoring equipment, revegetation, minor additions to soil cover, minor repair of disposal unit covers, and general disposal site upkeep.

"Buffer zone" means a portion of the disposal site that is controlled by the licensee and that lies under the disposal units and between the disposal units and the boundary of the site.

"Commencement of construction" means clearing of land, excavation, or other substantial action that could adversely affect the environment of a land disposal facility. The term does not mean disposal site exploration, necessary roads for disposal site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the disposal site or the protection of environmental values.

"Custodial agency" means an agency of the government designated to act on behalf of the government owner of the disposal site.

"Disposal" means the isolation of wastes from the biosphere by placing them in a land disposal facility.

"Disposal site" means that portion of a land disposal facility which is used for disposal of waste. It consists of disposal units and a buffer zone.

"Disposal unit" means a discrete portion of the disposal site into which waste is placed for disposal. For near-surface disposal, the disposal unit may be a trench.

"Engineered barrier" means a man-made structure or device intended to improve the land disposal facility's performance under R313-25.

"Hydrogeologic unit" means a soil or rock unit or zone that has a distinct influence on the storage or movement of ground water.

"Inadvertent intruder" means a person who may enter the disposal site after closure and engage in activities unrelated to post closure management, such as agriculture, dwelling construction, or other pursuits which could, by disturbing the site, expose individuals to radiation.

"Intruder barrier" means a sufficient depth of cover over the waste that inhibits contact with waste and helps to ensure that radiation exposures to an inadvertent intruder will meet the performance objectives set forth in R313-25, or engineered structures that provide equivalent protection to the inadvertent intruder.

"Land disposal facility" means the land, buildings and structures, and equipment which are intended to be used for the disposal of radioactive waste.

"Monitoring" means observing and making measurements to provide data to evaluate the performance and characteristics of the disposal site.

"Near-surface disposal facility" means a land disposal facility in which waste is disposed of within approximately the upper 30 meters of the earth's surface.

"Site closure and stabilization" means those actions that are taken upon completion of operations that prepare the disposal site for custodial care, and that assure that the disposal site will remain stable and will not need ongoing active maintenance.

"Stability" means structural stability.

"Surveillance" means monitoring and observation of the disposal site to detect needs for maintenance or custodial care, to observe evidence of intrusion, and to ascertain compliance with other license and regulatory requirements.

"Treatment" means the stabilization or the reduction in volume of waste by a chemical or a physical process.

"Waste" means those low-level radioactive wastes as defined in Section 19-3-102 that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as it does in the Low-Level Radioactive Waste Policy Act, Pub.L. 96-573, 94 Stat. 3347; thus, the term denotes radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, waste does not mean byproduct material as defined in 42 U.S.C. 2011(e)(2) of the Atomic Energy Act, uranium or thorium tailings and waste.

R313-25-3. Siting Criteria and Pre-licensing Plan Approval for Commercial Radioactive Waste Disposal Facilities.

(1) Persons proposing to construct or operate commercial radioactive waste disposal facilities, including waste incinerators, shall obtain a plan approval from the Executive Secretary before applying for a license. Plans shall meet the siting criteria and plan approval requirements of Section R313-25-3 and Section 19-3-105.

(2) The siting criteria and plan approval requirements in R313-25-3 apply to prelicensing plan approval applications.

(3) Treatment and disposal facilities, including commercial radioactive waste incinerators, shall not be located:

(a) within or underlain by:

- (i) national, state, and county parks, monuments, and recreation areas; designated wilderness and wilderness study areas; wild and scenic river areas;
 - (ii) ecologically and scientifically significant natural areas, including wildlife management areas and habitats for listed or proposed endangered species as designated by federal law;
 - (iii) 100 year floodplains;
 - (iv) areas 200 feet from Holocene faults;
 - (v) underground mines, salt domes and salt beds;
 - (vi) dam failure flood areas;
 - (vii) areas subject to landslide, mud flow, or other earth movement, unless adverse impacts can be mitigated;
 - (viii) farmlands classified or evaluated as "prime", "unique", or of "statewide importance" by the U.S. Department of Agricultural Soil Conservation Service under the Prime Farmland Protection Act;
 - (ix) areas five miles of existing permanent dwellings, residential areas, and other habitable structures, including schools, churches, and historic structures;
 - (x) areas five miles of surface waters including intermittent streams, perennial streams, rivers, lakes, reservoirs, and wetlands;
 - (xi) areas 100 feet of uranium mill tailings;
 - (xii) areas 1000 feet of archeological sites to which adverse impacts cannot reasonably be mitigated;
 - (xiii) recharge zones of aquifers containing ground water which has a total dissolved solids content of less than 10,000 mg/l; or
 - (xiv) drinking water source protection areas designated by the State Drinking Water Committee;
- (b) in areas:
- (i) above or underlain by aquifers containing ground water which has a total dissolved solids content of less than 500 mg/l and which aquifers do not exceed state ground water standards for pollutants;
 - (ii) above or underlain by aquifers containing ground water which has a total dissolved solids content between 3000 and 10,000 mg/l when the distance from the surface to the ground water is less than 100 ft.;
 - (iii) areas, such as areas of extensive withdrawal of water, gas, or oil;
 - (iv) above or underlain by weak and unstable soils, including soils that lose their ability to support

foundations as a result of hydrocompaction, expansion, or shrinkage;

(v) above or underlain by karst terrains.

(4) Incinerators associated with land disposal facilities may not be located above aquifers containing ground water which has a total dissolved solids content below 3000 mg/l. Incinerators not associated with ground disposal facilities shall not be located above aquifers containing ground water which has a total dissolved solids content below 500 mg/l.

(5) Facilities may not be located within a distance to existing drinking water wells and watersheds for public water supplies of one year ground water travel time plus 1000 feet for incinerators and of five years ground water travel time plus 1000 feet for land disposal facilities.

(6) The plan approval application shall include hydraulic conductivity and other information necessary to estimate adequately the ground water travel distance.

(7) The plan approval application shall include the results of studies adequate to identify the presence of ground water aquifers in the area of the proposed site and to assess the quality of the ground water of all aquifers identified in the area of the proposed site.

(8) The Executive Secretary may require the applicant to conduct vadose zone or other near surface monitoring.

(9) Emergency response and safety.

(a) The plan approval application shall demonstrate the availability and adequacy of emergency services, including medical and fire response. The application shall provide evidence that the applicant has coordinated emergency response plans with local and regional emergency response resources.

(b) The plan approval application shall include plans for responding to emergencies both at the site and those involving the transport of wastes within the state. Details of the proposed emergency response plan shall be given in the plan approval application and will be stipulated in the plan approval and radioactive materials license.

(c) The plan approval application shall show proposed routes for transportation of radioactive wastes within the state. The Executive Secretary will not approve plans that propose radioactive waste transportation routes over roads or bridges where weight restrictions would be exceeded. The Executive Secretary will not approve plans that pose adverse impact or risk of harm to inhabited areas. The plan approval application shall address risks to inhabited areas, including both residential and non-residential areas; the width, condition, and types of roads to be used; roadside development on proposed routes; seasonal and climatic factors which may affect safety; alternate emergency access to the facility; the type, size, and configuration of vehicles proposed to haul wastes; transportation restrictions on proposed routes; and the transportation means and routes available to evacuate the population at risk in the event of accidents, including spills and fires.

(10) Siting Authority. The Executive Secretary recognizes that Titles 10 and 17 of the Utah Code give cities and counties authority for local use planning and zoning. Nothing in R313-25-3 precludes cities and counties from establishing additional requirements as provided by applicable state and federal law.

R313-25-4. License Required.

- (1) Persons shall not receive, possess, or dispose of waste at a land disposal facility unless authorized by a license issued by the Executive Secretary pursuant to R313-25 and R313-22.
- (2) Persons shall file an application with the Executive Secretary pursuant to R313-22-32 and obtain a license as provided in R313-25 before commencement of construction of a land disposal facility. Failure to comply with this requirement may be grounds for denial of a license and other penalties established by law and rules.

R313-25-5. Content of Application.

In addition to the requirements set forth in R313-22-33, an application to receive from others, possess, and dispose of wastes shall consist of general information, specific technical information, institutional information, and financial information as set forth in R313-25-6 through R313-25-10.

R313-25-6. General Information.

The general information shall include the following:

(1) identity of the applicant including:

(a) the full name, address, telephone number, and description of the business or occupation of the applicant;

(b) if the applicant is a partnership, the names and addresses of the partners and the principal location where the partnership does business;

(c) if the applicant is a corporation or an unincorporated association;

(i) the state where it is incorporated or organized and the principal location where it does business; and

(ii) the names and addresses of its directors and principal officers; and

(d) if the applicant is acting as an agent or representative of another person in filing the application, the applicant shall provide, with respect to the other person, information required under R313-25-6(1).

(2) Qualifications of the applicant shall include the following:

(a) the organizational structure of the applicant, both offsite and onsite, including a description of lines of authority and assignments of responsibilities, whether in the form of administrative directives, contract provisions, or otherwise;

(b) the technical qualifications, including training and experience of the applicant and members of the applicant's staff, to engage in the proposed activities. Minimum training and experience requirements for personnel filling key positions described in R313-25-6(2)(a) shall be provided;

- (c) a description of the applicant's personnel training program; and
 - (d) the plan to maintain an adequate complement of trained personnel to carry out waste receipt, handling, and disposal operations in a safe manner.
- (3) A description of:
- (a) the location of the proposed disposal site;
 - (b) the general character of the proposed activities;
 - (c) the types and quantities of waste to be received, possessed, and disposed of;
 - (d) plans for use of the land disposal facility for purposes other than disposal of wastes; and
 - (e) the proposed facilities and equipment; and
- (4) proposed schedules for construction, receipt of waste, and first emplacement of waste at the proposed land disposal facility.

R313-25-7. Specific Technical Information.

The application shall include certain technical information. The following information is needed to determine whether or not the applicant can meet the performance objectives and the applicable technical requirements of R313-25:

- (1) A description of the natural and demographic disposal site characteristics shall be based on and determined by disposal site selection and characterization activities. The description shall include geologic, geochemical, geotechnical, hydrologic, ecologic, archaeologic, meteorologic, climatologic, and biotic features of the disposal site and vicinity.
- (2) Descriptions of the design features of the land disposal facility and of the disposal units for near-surface disposal shall include those design features related to infiltration of water; integrity of covers for disposal units; structural stability of backfill, wastes, and covers; contact of wastes with standing water; disposal site drainage; disposal site closure and stabilization; elimination to the extent practicable of long-term disposal site maintenance; inadvertent intrusion; occupational exposures; disposal site monitoring; and adequacy of the size of the buffer zone for monitoring and potential mitigative measures.
- (3) Descriptions of the principal design criteria and their relationship to the performance objectives.
- (4) Descriptions of the natural events or phenomena on which the design is based and their relationship to the principal design criteria.
- (5) Descriptions of codes and standards which the applicant has applied to the design, and will apply to construction of the land disposal facilities.
- (6) Descriptions of the construction and operation of the land disposal facility. The description shall include as a minimum the methods of construction of disposal units; waste emplacement; the procedures for and areas of waste segregation; types of intruder barriers; onsite traffic and

drainage systems; survey control program; methods and areas of waste storage; and methods to control surface water and ground water access to the wastes. The description shall also include a description of the methods to be employed in the handling and disposal of wastes containing chelating agents or other non-radiological substances which might affect meeting the performance objectives of R313-25

(7) A description of the disposal site closure plan, including those design features which are intended to facilitate disposal site closures and to eliminate the need for active maintenance after closure.

(8) Identification of the known natural resources at the disposal site whose exploitation could result in inadvertent intrusion into the wastes after removal of active institutional control.

(9) Descriptions of the kind, amount, classification and specifications of the radioactive material proposed to be received, possessed, and disposed of at the land disposal facility.

(10) Descriptions of quality assurance programs, tailored to low-level waste disposal, including audit and managerial controls, for the determination of natural disposal site characteristics and for quality control during the design, construction, operation, and closure of the land disposal facility and the receipt, handling, and emplacement of waste.

(11) A description of the radiation safety program for control and monitoring of radioactive effluents to ensure compliance with the performance objective in R313-25-19 and monitoring of occupational radiation exposure to ensure compliance with the requirements of R313-15 and to control contamination of personnel, vehicles, equipment, buildings, and the disposal site. The applicant shall describe procedures, instrumentation, facilities, and equipment appropriate to both routine and emergency operations.

(12) A description of the environmental monitoring program to provide data and to evaluate potential health and environmental impacts and the plan for taking corrective measures if migration is indicated.

(13) Descriptions of the administrative procedures that the applicant will apply to control activities at the land disposal facility.

(14) A description of the facility electronic recordkeeping system as required in R313-25-33.

R313-25-8. Technical Analyses.

The specific technical information shall also include the following analyses needed to demonstrate that the performance objectives of R313-25 will be met:

(1) Analyses demonstrating that the general population will be protected from releases of radioactivity shall consider the pathways of air, soil, ground water, surface water, plant uptake, and exhumation by burrowing animals. The analyses shall clearly identify and differentiate between the roles performed by the natural disposal site characteristics and design features in isolating and segregating the wastes. The analyses shall clearly demonstrate a reasonable assurance that the exposures to humans from the release of radioactivity will not exceed the limits set forth in R313-25-19.

(2) Analyses of the protection of inadvertent intruders shall demonstrate a reasonable assurance

that the waste classification and segregation requirements will be met and that adequate barriers to inadvertent intrusion will be provided.

(3) Analysis of the protection of individuals during operations shall include assessments of expected exposures due to routine operations and likely accidents during handling, storage, and disposal of waste. The analysis shall provide reasonable assurance that exposures will be controlled to meet the requirements of R313-15.

(4) Analyses of the long-term stability of the disposal site shall be based upon analyses of active natural processes including erosion, mass wasting, slope failure, settlement of wastes and backfill, infiltration through covers over disposal areas and adjacent soils, and surface drainage of the disposal site. The analyses shall provide reasonable assurance that there will not be a need for ongoing active maintenance of the disposal site following closure.

R313-25-9. Institutional Information.

The institutional information submitted by the applicant shall include:

(1) A certification by the federal or state agency which owns the disposal site that the agency is prepared to accept transfer of the license when the provisions of R313-25-16 are met and will assume responsibility for institutional control after site closure and for post-closure observation and maintenance.

(2) Evidence, if the proposed disposal site is on land not owned by the federal or a state government, that arrangements have been made for assumption of ownership in fee by the federal or a state agency.

R313-25-10. Financial Information.

This information shall demonstrate that the applicant is financially qualified to carry out the activities for which the license is sought. The information shall meet other financial assurance requirements of R313- 25.

R313-25-11. Requirements for Issuance of a License.

A license for the receipt, possession, and disposal of waste containing radioactive material will be issued by the Executive Secretary upon finding that:

(1) the issuance of the license will not constitute an unreasonable risk to the health and safety of the public;

(2) the applicant is qualified by reason of training and experience to carry out the described disposal operations in a manner that protects health and minimizes danger to life or property;

(3) the applicant's proposed disposal site, disposal design, land disposal facility operations, including equipment, facilities, and procedures, disposal site closure, and post-closure institutional control, are adequate to protect the public health and safety as specified in the performance objectives of R313-25-19;

(4) the applicant's proposed disposal site, disposal site design, land disposal facility operations, including equipment, facilities, and procedures, disposal site closure, and post-closure

institutional control are adequate to protect the public health and safety in accordance with the performance objectives of R313-25-20;

(5) the applicant's proposed land disposal facility operations, including equipment, facilities, and procedures, are adequate to protect the public health and safety in accordance with R313-15;

(6) the applicant's proposed disposal site, disposal site design, land disposal facility operations, disposal site closure, and post-closure institutional control plans are adequate to protect the public health and safety in that they will provide reasonable assurance of the long-term stability of the disposed waste and the disposal site and will eliminate to the extent practicable the need for continued maintenance of the disposal site following closure;

(7) the applicant's demonstration provides reasonable assurance that the requirements of R313-25 will be met;

(8) the applicant's proposal for institutional control provides reasonable assurance that control will be provided for the length of time found necessary to ensure the findings in R313-25-11(3) through (6) and that the institutional control meets the requirements of R313-25-28.

(9) the financial or surety arrangements meet the requirements of R313-25.

R313-25-12. Conditions of Licenses.

(1) A license issued under R313-25, or a right thereunder, may not be transferred, assigned, or disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to a person, unless the Executive Secretary finds, after securing full information, that the transfer is in accordance with the provisions of the Radiation Control Act and Rules and gives his consent in writing in the form of a license amendment.

(2) The Executive Secretary may require the licensee to submit written statements under oath.

(3) The license will be terminated only on the full implementation of the final closure plan, including post-closure observation and maintenance, as approved by the Executive Secretary.

(4) The licensee shall submit to the provisions of the Act now or hereafter in effect, and to all findings and orders of the Executive Secretary. The terms and conditions of the license are subject to amendment, revision, or modification, by reason of amendments to, or by reason of rules, and orders issued in accordance with the terms of the Act and these rules.

(5) Persons licensed by the Executive Secretary pursuant to R313-25 shall confine possession and use of the materials to the locations and purposes authorized in the license.

(6) The licensee shall not dispose of waste until the Executive Secretary has inspected the land disposal facility and has found it to conform with the description, design, and construction described in the application for a license.

(7) The Executive Secretary may incorporate, by rule or order, into licenses at the time of issuance or thereafter, additional requirements and conditions with respect to the licensee's receipt, possession, and disposal of waste as the Executive Secretary deems appropriate or necessary in order to:

- (a) protect health or to minimize danger to life or property;
 - (b) require reports and the keeping of records, and to provide for inspections of licensed activities as the Executive Secretary deems necessary or appropriate to effectuate the purposes of the Radiation Control Act and Rules.
- (8) The authority to dispose of wastes expires on the expiration date stated in the license. An expiration date on a license applies only to the above ground activities and to the authority to dispose of waste. Failure to renew the license shall not relieve the licensee of responsibility for implementing site closure, post-closure observation, and transfer of the license to the site owner.

R313-25-13. Application for Renewal or Closure.

- (1) An application for renewal or an application for closure under R313-25-14 shall be filed at least 90 days prior to license expiration.
- (2) Applications for renewal of a license shall be filed in accordance with R313-25-5 through 25-10. Applications for closure shall be filed in accordance with R313-25-14. Information contained in previous applications, statements, or reports filed with the Executive Secretary under the license may be incorporated by reference if the references are clear and specific.
- (3) If a licensee has filed an application in proper form for renewal of a license, the license shall not expire unless and until the Executive Secretary has taken final action to deny application for renewal.
- (4) In evaluating an application for license renewal, the Executive Secretary will apply the criteria set forth in R313-25-11.

R313-25-14. Contents of Application for Site Closure and Stabilization.

- (1) Prior to final closure of the disposal site, or as otherwise directed by the Executive Secretary, the licensee shall submit an application to amend the license for closure. This closure application shall include a final revision and specific details of the disposal site closure plan included in the original license application submitted and approved under R313-25-7(7). The plan shall include the following:
- (a) additional geologic, hydrologic, or other data pertinent to the long-term containment of emplaced wastes obtained during the operational period;
 - (b) the results of tests, experiments, or other analyses relating to backfill of excavated areas, closure and sealing, waste migration and interaction with emplacement media, or other tests, experiments, or analyses pertinent to the long-term containment of emplaced waste within the disposal site;
 - (c) proposed revision of plans for:
 - (i) decontamination or dismantlement of surface facilities;
 - (ii) backfilling of excavated areas; or
 - (iii) stabilization of the disposal site for post-closure care.

(d) Significant new information regarding the environmental impact of closure activities and long-term performance of the disposal site.

(2) Upon review and consideration of an application to amend the license for closure submitted in accordance with R313-25-14(1), the Executive Secretary shall issue an amendment authorizing closure if there is reasonable assurance that the long-term performance objectives of R313-25 will be met.

R313-25-15. Post-Closure Observation and Maintenance.

The licensee shall observe, monitor, and carry out necessary maintenance and repairs at the disposal site until the site closure is complete and the license is transferred by the Executive Secretary in accordance with R313-25-16. The licensee shall remain responsible for the disposal site for an additional five years. The Executive Secretary may approve closure plans that provide for shorter or longer time periods of post-closure observation and maintenance, if sufficient rationale is developed for the variance.

R313-25-16. Transfer of License.

Following closure and the period of post-closure observation and maintenance, the licensee may apply for an amendment to transfer the license to the disposal site owner. The license shall be transferred when the Executive Secretary finds:

(1) that the disposal site was closed according to the licensee's approved disposal site closure plan;

(2) that the licensee has provided reasonable assurance that the performance objectives of R313-25 have been met;

(3) that funds for care and records required by R313-25-33(4) and (5) have been transferred to the disposal site owner;

(4) that the post-closure monitoring program is operational and can be implemented by the disposal site owner; and

(5) that the Federal or State agency which will assume responsibility for institutional control of the disposal site is prepared to assume responsibility and ensure that the institutional requirements found necessary under R313-25-11(8) will be met.

R313-25-17. Termination of License.

(1) Following the period of institutional control needed to meet the requirements of R313-25-11, the licensee may apply for an amendment to terminate the license.

(2) This application will be reviewed in accordance with the provisions of R313-22-32.

(3) A license shall be terminated only when the Executive Secretary finds:

(a) that the institutional control requirements of R313-25-11(8) have been met;

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

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

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

R313-25-18. General Requirement.

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

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

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

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

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

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

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

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

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

R313-25-23. Disposal Site Suitability Requirements for Land Disposal - Near-Surface Disposal.

- (1) The primary emphasis in disposal site suitability is given to isolation of wastes and to disposal site features that ensure that the long-term performance objectives are met.
- (2) The disposal site shall be capable of being characterized, modeled, analyzed and monitored.
- (3) Within the region where the facility is to be located, a disposal site should be selected so that projected population growth and future developments are not likely to affect the ability of the disposal facility to meet the performance objectives of R313-25.
- (4) Areas shall be avoided having known natural resources which, if exploited, would result in failure to meet the performance objectives of R313-25.
- (5) The disposal site shall be generally well drained and free of areas of flooding or frequent ponding. Waste disposal shall not take place in a 100-year flood plain, coastal high-hazard area or wetland, as defined in Executive Order 11988, "Floodplain Management Guidelines."
- (6) Upstream drainage areas shall be minimized to decrease the amount of runoff which could erode or inundate waste disposal units.
- (7) The disposal site shall provide sufficient depth to the water table that ground water intrusion, perennial or otherwise, into the waste will not occur. The Executive Secretary will consider an exception to this requirement to allow disposal below the water table if it can be conclusively shown that disposal site characteristics will result in molecular diffusion being the predominant means of radionuclide movement and the rate of movement will result in the performance objectives being met. In no case will waste disposal be permitted in the zone of fluctuation of the water table.
- (8) The hydrogeologic unit used for disposal shall not discharge ground water to the surface within the disposal site.
- (9) Areas shall be avoided where tectonic processes such as faulting, folding, seismic activity, vulcanism, or similar phenomena may occur with such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives of R313-25 or may preclude defensible modeling and prediction of long-term impacts.
- (10) Areas shall be avoided where surface geologic processes such as mass wasting, erosion, slumping, landsliding, or weathering occur with sufficient such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives of R313-25, or may preclude defensible modeling and prediction of long-term impacts.
- (11) The disposal site shall not be located where nearby facilities or activities could adversely impact the ability of the site to meet the performance objectives of R313-25 or significantly mask the environmental monitoring program.

R313-25-24. Disposal Site Design for Near-Surface Land Disposal.

- (1) Site design features shall be directed toward long-term isolation and avoidance of the need for continuing active maintenance after site closure.
- (2) The disposal site design and operation shall be compatible with the disposal site closure and

stabilization plan and lead to disposal site closure that provides reasonable assurance that the performance objectives will be met.

(3) The disposal site shall be designed to complement and improve, where appropriate, the ability of the disposal site's natural characteristics to assure that the performance objectives will be met.

(4) Covers shall be designed to minimize, to the extent practicable, water infiltration, to direct percolating or surface water away from the disposed waste, and to resist degradation by surface geologic processes and biotic activity.

(5) Surface features shall direct surface water drainage away from disposal units at velocities and gradients which will not result in erosion that will require ongoing active maintenance in the future.

(6) The disposal site shall be designed to minimize to the extent practicable the contact of water with waste during storage, the contact of standing water with waste during disposal, and the contact of percolating or standing water with wastes after disposal.

R313-25-25. Near Surface Land Disposal Facility Operation and Disposal Site Closure.

(1) Wastes designated as Class A pursuant to R313-15-307 of these rules shall be segregated from other wastes by placing them in disposal units which are sufficiently separated from disposal units for the other waste classes so that any interaction between Class A wastes and other wastes will not result in the failure to meet the performance objectives of R313-25. This segregation is not necessary for Class A wastes if they meet the stability requirements of R313-15-308(2).

(2) Wastes designated as Class C pursuant to R313-15-307 shall be disposed of so that the top of the waste is a minimum of five meters below the top surface of the cover or shall be disposed of with intruder barriers that are designed to protect against an inadvertent intrusion for at least 500 years.

(3) Except as provided in R313-25-1(1), only waste classified as Class A, B, or C shall be acceptable for near-surface disposal. Wastes shall be disposed of in accordance with the requirements of R313-25-25(4) through 11.

(4) Wastes shall be emplaced in a manner that maintains the package integrity during emplacement, minimizes the void spaces between packages, and permits the void spaces to be filled.

(5) Void spaces between waste packages shall be filled with earth or other material to reduce future subsidence within the fill.

(6) Waste shall be placed and covered in a manner that limits the radiation dose rate at the surface of the cover to levels that at a minimum will permit the licensee to comply with all provisions of R313-15-105 at the time the license is transferred pursuant to R313-25-16.

(7) The boundaries and locations of disposal units shall be accurately located and mapped by means of a land survey. Near-surface disposal units shall be marked in such a way that the

boundaries of the units can be easily defined. Three permanent survey marker control points, referenced to United States Geological Survey or National Geodetic Survey control stations, shall be established on the site to facilitate surveys. The United States Geological Survey or National Geodetic Survey control stations shall provide horizontal and vertical controls as checked against United States Geological Survey or National Geodetic Survey record files.

(8) A buffer zone of land shall be maintained between any buried waste and the disposal site boundary and beneath the disposed waste. The buffer zone shall be of adequate dimensions to carry out environmental monitoring activities specified in R313-25-26(4) and take mitigative measures if needed.

(9) Closure and stabilization measures as set forth in the approved site closure plan shall be carried out as the disposal units are filled and covered.

(10) Active waste disposal operations shall not have an adverse effect on completed closure and stabilization measures.

(11) Only wastes containing or contaminated with radioactive material shall be disposed of at the disposal site.

(12) Proposals for disposal of waste that are not generally acceptable for near-surface disposal because the wastes form and disposal methods shall be different and, in general, more stringent than those specified for Class C waste, may be submitted to the Executive Secretary for approval.

R313-25-26. Environmental Monitoring.

(1) At the time a license application is submitted, the applicant shall have conducted a preoperational monitoring program to provide basic environmental data on the disposal site characteristics. The applicant shall obtain information about the ecology, meteorology, climate, hydrology, geology, geochemistry, and seismology of the disposal site. For those characteristics that are subject to seasonal variation, data shall cover at least a 12-month period.

(2) During the land disposal facility site construction and operation, the licensee shall maintain an environmental monitoring program. Measurements and observations shall be made and recorded to provide data to evaluate the potential health and environmental impacts during both the construction and the operation of the facility and to enable the evaluation of long-term effects and need for mitigative measures. The monitoring system shall be capable of providing early warning of releases of waste from the disposal site before they leave the site boundary.

(3) After the disposal site is closed, the licensee responsible for post-operational surveillance of the disposal site shall maintain a monitoring system based on the operating history and the closure and stabilization of the disposal site. The monitoring system shall be capable of providing early warning of releases of waste from the disposal site before they leave the site boundary.

(4) The licensee shall have plans for taking corrective measures if the environmental monitoring program detects migration of waste which would indicate that the performance objectives may not be met.

R313-25-27. Alternative Requirements for Design and Operations.

The Executive Secretary may, upon request or on his own initiative, authorize provisions other than those set forth in R313-25-24 and 25-26 for the segregation and disposal of waste and for the design and operation of a land disposal facility on a specific basis, if it finds reasonable assurance of compliance with the performance objectives of R313-25.

R313-25-28. Institutional Requirements.

(1) Land Ownership. Disposal of waste received from other persons may be permitted only on land owned in fee by the Federal or a State government.

(2) Institutional Control. The land owner or custodial agency shall conduct an institutional control program to physically control access to the disposal site following transfer of control of the disposal site from the disposal site operator. The institutional control program shall also include, but not be limited to, conducting an environmental monitoring program at the disposal site, periodic surveillance, minor custodial care, and other equivalents as determined by the Executive Secretary, and administration of funds to cover the costs for these activities. The period of institutional controls will be determined by the Executive Secretary, but institutional controls may not be relied upon for more than 100 years following transfer of control of the disposal site to the owner.

R313-25-30. Applicant Qualifications and Assurances.

The applicant shall show that it either possesses the necessary funds, or has reasonable assurance of obtaining the necessary funds, or by a combination of the two, to cover the estimated costs of conducting all licensed activities over the planned operating life of the project, including costs of construction and disposal.

R313-25-31. Funding for Disposal Site Closure and Stabilization.

(1) The applicant shall provide assurances prior to the commencement of operations that sufficient funds will be available to carry out disposal site closure and stabilization, including:

(a) decontamination or dismantlement of land disposal facility structures, and

(b) closure and stabilization of the disposal site so that following transfer of the disposal site to the site owner, the need for ongoing active maintenance is eliminated to the extent practicable and only minor custodial care, surveillance, and monitoring are required. These assurances shall be based on Executive Secretary approved cost estimates reflecting the Executive Secretary approved plan for disposal site closure and stabilization. The applicant's cost estimates shall take into account total costs that would be incurred if an independent contractor were hired to perform the closure and stabilization work.

(2) In order to avoid unnecessary duplication and expense, the Executive Secretary will accept financial sureties that have been consolidated with earmarked financial or surety arrangements established to meet requirements of Federal or other State agencies or local governmental bodies for decontamination, closure, and stabilization. The Executive Secretary will accept these arrangements only if they are considered adequate to satisfy the requirements of R313-25-31 and if they clearly identify that the portion of the surety which covers the closure of the disposal site is clearly identified and committed for use in accomplishing these activities.

(3) The licensee's financial or surety arrangement shall be submitted annually for review by the Executive Secretary to assure that sufficient funds will be available for completion of the closure plan.

(4) The amount of the licensee's financial or surety arrangement shall change in accordance with changes in the predicted costs of closure and stabilization. Factors affecting closure and stabilization cost estimates include inflation, increases in the amount of disturbed land, changes in engineering plans, closure and stabilization that have already been accomplished, and other conditions affecting costs. The financial or surety arrangement shall be sufficient at all times to cover the costs of closure and stabilization of the disposal units that are expected to be used before the next license renewal.

(5) The financial or surety arrangement shall be written for a specified period of time and shall be automatically renewed unless the person who issues the surety notifies the Executive Secretary; the beneficiary, the site owner; and the principal, the licensee, not less than 90 days prior to the renewal date of its intention not to renew. In such a situation, the licensee shall submit a replacement surety within 30 days after notification of cancellation. If the licensee fails to provide a replacement surety acceptable to the Executive Secretary, the beneficiary may collect on the original surety.

(6) Proof of forfeiture shall not be necessary to collect the surety so that, in the event that the licensee could not provide an acceptable replacement surety within the required time, the surety shall be automatically collected prior to its expiration. The conditions described above shall be clearly stated on surety instruments.

(7) Financial or surety arrangements generally acceptable to the Executive Secretary include surety bonds, cash deposits, certificates of deposit, deposits of government securities, escrow accounts, irrevocable letters or lines of credit, trust funds, and combinations of the above or other types of arrangements as may be approved by the Executive Secretary. Self-insurance, or an arrangement which essentially constitutes self-insurance, will not satisfy the surety requirement for private sector applicants.

(8) The licensee's financial or surety arrangement shall remain in effect until the closure and stabilization program has been completed and approved by the Executive Secretary, and the license has been transferred to the site owner.

R313-25-32. Financial Assurances for Institutional Controls.

(1) Prior to the issuance of the license, the applicant shall provide for Executive Secretary approval, a binding arrangement, between the applicant and the disposal site owner that ensures that sufficient funds will be available to cover the costs of monitoring and required maintenance during the institutional control period. The binding arrangement shall be reviewed annually by the Executive Secretary to ensure that changes in inflation, technology, and disposal facility operations are reflected in the arrangements.

(2) Subsequent changes to the binding arrangement specified in R313-25-32(1) relevant to institutional control shall be submitted to the Executive Secretary for prior approval.

R313-25-33. Maintenance of Records, Reports, and Transfers.

(1) Licensees shall maintain records and make reports in connection with the licensed activities

as may be required by the conditions of the license or by the rules and orders of the Executive Secretary.

(2) Records which are required by these rules or by license conditions shall be maintained for a period specified by the appropriate rules or by license condition. If a retention period is not otherwise specified, these records shall be maintained and transferred to the officials specified in R313-25-33(4) as a condition of license termination unless the Executive Secretary otherwise authorizes their disposition.

(3) Records which shall be maintained pursuant to R313-25 may be the original or a reproduced copy or microfilm if this reproduced copy or microfilm is capable of producing copy that is clear and legible at the end of the required retention period.

(4) Notwithstanding R313-25-33(1) through (3), copies of records of the location and the quantity of wastes contained in the disposal site shall be transferred upon license termination to the chief executive of the nearest municipality, the chief executive of the county in which the facility is located, the county zoning board or land development and planning agency, the State Governor, and other state, local, and federal governmental agencies as designated by the Executive Secretary at the time of license termination.

(5) Following receipt and acceptance of a shipment of waste, the licensee shall record the date that the shipment is received at the disposal facility, the date of disposal of the waste, a traceable shipment manifest number, a description of any engineered barrier or structural overpack provided for disposal of the waste, the location of disposal at the disposal site, the condition of the waste packages as received, discrepancies between the materials listed on the manifest and those received, the volume of any pallets, bracing, or other shipping or onsite generated materials that are contaminated, and are disposed of as contaminated or suspect materials, and evidence of leakage or damaged packages or radiation or contamination levels in excess of limits specified in U.S. Department of Transportation and Executive Secretary regulations or rules. The licensee shall briefly describe repackaging operations of the waste packages included in the shipment, plus other information required by the Executive Secretary as a license condition.

(6) Licensees authorized to dispose of waste received from other persons shall file a copy of their financial report or a certified financial statement annually with the Executive Secretary in order to update the information base for determining financial qualifications.

(7)(a) Licensees authorized to dispose of waste received from other persons, pursuant to R313-25, shall submit annual reports to the Executive Secretary. Reports shall be submitted by the end of the first calendar quarter of each year for the preceding year.

(b) The reports shall include:

(i) specification of the quantity of each of the principal contaminants released to unrestricted areas in liquid and in airborne effluents during the preceding year;

(ii) the results of the environmental monitoring program;

(iii) a summary of licensee disposal unit survey and maintenance activities;

(iv) a summary, by waste class, of activities and quantities of radionuclides disposed of;

(v) instances in which observed site characteristics were significantly different from those described in the application for a license; and

(vi) other information the Executive Secretary may require.

(c) If the quantities of waste released during the reporting period, monitoring results, or maintenance performed are significantly different from those predicted, the report shall cover this specifically.

(8) In addition to the other requirements in R313-25-33, the licensee shall store, or have stored, manifest and other information pertaining to receipt and disposal of radioactive waste in an electronic recordkeeping system.

(a) The manifest information that must be electronically stored is:

(i) that required in Appendix G of 10 CFR 20.1001 to 20.2402, 1997 ed., which is incorporated into these rules by reference, with the exception of shipper and carrier telephone numbers and shipper and consignee certifications; and

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

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

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

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

(1) wastes;

(2) facilities used for the receipt, storage, treatment, handling or disposal of wastes;

(3) radiation detection and monitoring instruments; or

(4) other equipment and devices used in connection with the receipt, possession, handling, treatment, storage, or disposal of waste.

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

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

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

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Rule R313-32. Medical Use of Radioactive Material.

As in effect on July 1, 2001

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- R313-32-18. License Issuance.
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- R313-32-49. Suppliers for Sealed Sources or Devices for Medical Use.
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- R313-32-57. Authorization for Calibration and Reference Sources.
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- R313-32-60. Syringe Shields and Labels.
- R313-32-61. Vial Shields and Labels.
- R313-32-70. Surveys for Contamination and Ambient Radiation Exposure Rate.
- R313-32-75. Release of Individuals Containing Radiopharmaceuticals or Permanent Implants.
- R313-32-80. Technical Requirements that Apply to the Providers of Mobile Nuclear Medicine Service.
- R313-32-90. Storage of Volatiles and Gases.
- R313-32-92. Decay-In-Storage.
- R313-32-100. Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies.

- R313-32-120. Possession of Survey Instrument.
- R313-32-200. Use of Unsealed Radioactive Material for Imaging and Localization Studies.
- R313-32-204. Permissible Molybdenum-99 Concentration.
- R313-32-205. Control of Aerosols and Gases.
- R313-32-220. Possession of Survey Instruments.
- R313-32-300. Use of Unsealed Radioactive Material for Therapeutic Administration.
- R313-32-310. Safety Instruction.
- R313-32-315. Safety Precautions.
- R313-32-320. Possession of Survey Instruments.
- R313-32-400. Use of Sources for Brachytherapy.
- R313-32-404. Release of Patients or Human Research Subjects Treated With Temporary Implants.
- R313-32-406. Brachytherapy Sources Inventory.
- R313-32-410. Safety Instruction.
- R313-32-415. Safety Precautions.
- R313-32-420. Possession of Survey Instrument.
- R313-32-500. Use of Sealed Sources for Diagnosis.
- R313-32-520. Availability of Survey Instrument.
- R313-32-600. Use of a Sealed Source in a Teletherapy Unit.
- R313-32-605. Maintenance and Repair Restrictions.
- R313-32-606. License Amendments.
- R313-32-610. Safety Instruction.
- R313-32-615. Safety Precautions.
- R313-32-620. Possession of Survey Instrument.
- R313-32-630. Dosimetry Equipment.
- R313-32-632. Full Calibration Measurements.
- R313-32-634. Periodic Spot-Checks.
- R313-32-636. Safety Checks for Teletherapy Facilities.
- R313-32-641. Radiation Surveys for Teletherapy Facilities.
- R313-32-643. Modification of Teletherapy Unit or Room Before Beginning a Treatment Program.
- R313-32-645. Reports of Teletherapy Surveys, Checks, Tests and Measurements.
- R313-32-647. Five-Year Inspection.
- R313-32-900. Radiation Safety Officer.
- R313-32-901. Training for Experienced Radiation Safety Officer.
- R313-32-910. Training for Uptake, Dilution, and Excretion Studies.
- R313-32-920. Training for Imaging and Localization Studies.
- R313-32-930. Training for Therapeutic Use of Unsealed Radioactive Material.
- R313-32-932. Training for Treatment of Hyperthyroidism.
- R313-32-934. Training for Treatment of Thyroid Carcinoma.
- R313-32-940. Training for Use of Brachytherapy Sources.
- R313-32-941. Training for Ophthalmic Use of Strontium-90.
- R313-32-950. Training for Use of Sealed Sources for Diagnosis.
- R313-32-960. Training for Teletherapy.
- R313-32-961. Training for Teletherapy Physicist.
- R313-32-970. Training for Experienced Authorized Users.
- R313-32-971. Physician Training in a Three Month Program.
- R313-32-972. Recentness of Training.
- R313-32-980. Training for an Authorized Nuclear Pharmacist.
- R313-32-981. Training for Experienced Nuclear Pharmacists.
- R313-32-999. Resolution of Conflicting Requirements During Transition Period.

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

R313-32-1. Purpose and Authority.

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

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

R313-32-2. Definitions.

"Authorized nuclear pharmacist" means a pharmacist who is:

- (a) board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties;
- (b) identified as an authorized nuclear pharmacist on a Nuclear Regulatory Commission or Agreement State license that authorizes the use of radioactive material in the practice of nuclear pharmacy; or
- (c) identified as an authorized nuclear pharmacist on a permit issued by a Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of radioactive material in the practice of nuclear pharmacy.

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

- (a) board certified by at least one of the boards listed in Paragraph (1) of R313-32-910, R313-32-920, R313-32-930, R313-32-940, R313-32-950, or R313-32-960;
- (b) identified as an authorized user on a Nuclear Regulatory Commission or Agreement State license that authorizes the medical use of radioactive material; or
- (c) identified as an authorized user on a permit issued by a Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material.

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

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

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

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

"Diagnostic clinical procedures manual" means a collection of written procedures that describes each method, other instructions, and precautions, by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

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

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

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

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

"Misadministration" means the administration of:

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

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

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

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

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

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

(c) A gamma stereotactic radiosurgery radiation dose:

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

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

(d) A teletherapy radiation dose:

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

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

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

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

(e) A brachytherapy radiation dose:

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

(ii) involving a sealed source that is leaking;

(iii) when, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

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

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

(i) involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

(ii) when the dose to the individual exceeds 0.05 Sv (five rems) effective dose equivalent or 0.5 Sv (50 rems) dose equivalent to any individual organ.

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

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

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

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

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

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

(a) in a written directive; or

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

"Prescribed dose" means:

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

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

"Recordable event" means the administration of:

- (a) a radiopharmaceutical or radiation without a written directive where a written directive is required;
- (b) a radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;
- (c) a radiopharmaceutical dosage greater than 1.11 MBq (30 uCi) of either sodium iodide I-125 or I-131 when both:
 - (i) the administered dosage differs from the prescribed dosage by more than ten percent of the prescribed dosage, and
 - (ii) the difference between the administered dosage and prescribed dosage exceed 555 kBq (15 uCi);
- (d) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than ten percent of the prescribed dosage;
- (e) A teletherapy radiation dose when the calculated weekly administered dose exceeds the weekly prescribed dose by 15 percent or more of the weekly prescribed dose; or
- (f) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than ten percent of the prescribed dose.

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

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

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

"Written directive" means an order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or

radiation, except as specified in paragraph (f) of this definition, containing the following information:

- (a) for any administration of quantities greater than 1.11 MBq (30 uCi) of either sodium iodide I-125 or I-131: the dosage;
- (b) for a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;
- (c) for gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;
- (d) for teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;
- (e) for high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or
- (f) for all other brachytherapy:
 - (i) prior to implantation: the radionuclide, number of sources, and source strengths; and
 - (ii) after implantation but prior to completion of the procedure: the radionuclide, treatment site, and total source strength and exposure time, or equivalently, the total dose.

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

A licensee may conduct research involving human subjects using radioactive material provided that the research is conducted, funded, supported, or regulated by a Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its Utah license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

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

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

R313-32-11. License Required.

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

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

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

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

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

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

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

R313-32-13. License Amendment.

A licensee shall apply for and receive a license amendment:

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

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

(a) an authorized user certified by the organizations specified in paragraph (1) of R313-32-910, R313-32-920, R313-32-930, R313-32-940, R313-32-950, or R313-32-960;

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

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

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

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

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

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

R313-32-14. Notifications.

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

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

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

(b) the licensee's mailing address changes.

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

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

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

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

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

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

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

R313-32-18. License Issuance.

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

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

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

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

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

(a) the applicant has appointed a radiation safety committee to coordinate the use of radioactive

material throughout that institution and to maintain surveillance over the institution's radiation safety program; and

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

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

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

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

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

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

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

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

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

(C) the performance of in vitro diagnostic studies;

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

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

(iii) the medical institution does not hold a radioactive material license issued pursuant to the provisions of R313-32-18(4).

R313-32-19. Specific Exemptions.

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

R313-32-20. ALARA Program.

- (1) The licensee shall develop and implement a written radiation protection program that includes provisions for keeping doses ALARA.
- (2) To satisfy the requirement of R313-32-20(1) one of the following shall be implemented:
 - (a) At a medical institution, management, the Radiation Safety Officer, and authorized users shall participate in the program as requested by the Radiation Safety Committee.
 - (b) For licensees that are not medical institutions, management and authorized users shall participate in the program as requested by the Radiation Safety Officer.
- (3) The program shall include notice to workers of the program's existence and workers' responsibility to help keep dose equivalents ALARA, a review of summaries of the types and amounts of radioactive material used, occupational doses, changes in radiation safety procedures and safety measures, and continuing education and training for personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that licensees make a reasonable effort to maintain individual and collective occupational doses ALARA.

R313-32-21. Radiation Safety Officer.

- (1) A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.
- (2) The Radiation Safety Officer shall:
 - (a) investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, misadministrations, and other deviations from approved radiation safety practices and implement corrective actions as necessary;
 - (b) establish, collect in one binder or file, and implement written policy and procedures for:
 - (i) authorizing the purchase of radioactive material;
 - (ii) receiving and opening packages of radioactive material;
 - (iii) storing radioactive material;
 - (iv) keeping an inventory record of radioactive material;
 - (v) using radioactive material safely;
 - (vi) taking emergency action if control of radioactive material is lost;
 - (vii) performing periodic radiation surveys;
 - (viii) performing checks of survey instruments and other safety equipment;

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

R313-32-22. Radiation Safety Committee.

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

- (1) The Committee shall meet the following administrative requirements:
 - (a) Membership shall consist of at least three individuals and shall include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.
 - (b) The Committee shall meet at least quarterly.
 - (c) To establish a quorum and to conduct business, at least one-half of the Committee's membership shall be present, including the Radiation Safety Officer and the management's representative.
 - (d) The minutes of each Radiation Safety Committee meeting shall include:
 - (i) the date of the meeting;
 - (ii) members present;
 - (iii) members absent;
 - (iv) summary of deliberations and discussions;

(v) recommended actions and the numerical results of all ballots; and

(vi) ALARA program reviews described in R313-32-20.

(e) The Committee shall promptly provide the members with copies of the meeting minutes, and retain one copy for the duration of the license.

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

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

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

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

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

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

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

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

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

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

(a) identify radiation safety problems;

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

(c) verify implementation of corrective actions.

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

the Executive Secretary terminates the license.

R313-32-25. Supervision.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

R313-32-31. Radiation Safety Program Changes.

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

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

R313-32-32. Quality Management Program.

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

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

(i) teletherapy radiation doses;

(ii) gamma stereotactic radiosurgery radiation doses;

(iii) brachytherapy radiation doses;

(iv) administration of quantities greater than 1.11 MBq (30 uCi) of either sodium iodide I-125 or I-131;

(v) therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131;

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

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

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

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

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

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

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

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

(2) The licensee shall:

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

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

(ii) all recordable events, and

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

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

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

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

(a) assembling the relevant facts including the cause;

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

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

(4) The licensee shall retain:

(a) a written directive; and

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

administration.

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

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

(b) Existing licensees, as applicable, shall submit to the Executive Secretary in accordance with R313-12-110, prior to March 1, 1995, a written certification that the quality management program has been implemented along with a copy of the program.

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

(1) For a misadministration:

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

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

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

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

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

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

(2) The licensee shall retain a record of each misadministration for five years. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual who received the misadministration, and that individual's referring physician, if applicable), the individual's social security number or other identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the individual, improvements needed to prevent recurrence, and the actions taken to prevent recurrence.

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

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

A licensee may use for medical use only:

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

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

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

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

(2) A licensee shall:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- (a) a description of the calibration procedure; and
- (b) the date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the signature of the individual who performed the calibration.

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

- (1) R313-32-52 does not apply to unit dosages of alpha- or beta-emitting radionuclides that are obtained from a manufacturer or preparer licensed pursuant to R313-22-75(9) or equivalent requirements of the Nuclear Regulatory Commission or an Agreement State.
- (2) For other than unit dosages obtained pursuant to R313-32-52(1), a licensee shall possess and use instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha- or beta-emitting radionuclides prior to administration to each patient or human research subject. In addition, the licensee shall:
 - (a) perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and
 - (b) check each instrument for constancy and proper operation at the beginning of each day of use.

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

A licensee shall:

- (1) measure the activity of each dosage of a photon-emitting radionuclide prior to medical use;
- (2) measure, by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha- or beta-emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to R313-22-75(9) or equivalent requirements of the Nuclear Regulatory Commission or an Agreement State; and
- (3) retain a record of the measurements required by R313-32-53 for three years. To satisfy this requirement, the record shall contain the following:
 - (a) generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;
 - (b) patient's or human research subject's name, and identification number if one has been assigned;
 - (c) prescribed dosage and activity of the dosage at the time of measurement, or a notation that

the total activity is less than 1.1 MBq (30 uCi);

(d) date and time of the measurement; and

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

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

Persons authorized by R313-32-11 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, and reference use:

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

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

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

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

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

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

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

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

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

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

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

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

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

of radioactive material on the sample.

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

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

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

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

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

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

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

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

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

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

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

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

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

R313-32-60. Syringe Shields and Labels.

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

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

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

R313-32-61. Vial Shields and Labels.

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

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

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

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

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

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

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

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

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

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

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

analyze the samples, and the initials of the individual who performed the survey.

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

(1) The licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

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

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

- (a) guidance on the interruption or discontinuation of breast-feeding, and
- (b) information on the consequences of failure to follow the guidance.

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

- (a) using the retained activity rather than the activity administered,
- (b) using an occupancy factor less than 0.25 at 1 meter,
- (c) using the biological or effective half-life, or
- (d) considering the shielding by tissue.

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

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

A licensee providing mobile nuclear medicine service shall:

- (1) transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;
- (2) bring into each address of use all radioactive material to be used and, before leaving, remove

all unused radioactive material and all associated waste;

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

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

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

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

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

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

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

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

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

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

(c) removes or obliterates all radiation labels; and

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

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

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

Excretion Studies.

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

- (1) obtained from a manufacturer or preparer licensed pursuant to R313-22-75(9) or equivalent requirements of the Nuclear Regulatory Commission or an Agreement State; or
- (2) prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in R313-32-920, or an individual under the supervision of either as specified in R313-32-25.

R313-32-120. Possession of Survey Instrument.

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

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

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

- (1) obtained from a manufacturer or preparer licensed pursuant to R313-22-75(9) or equivalent requirements of the Nuclear Regulatory Commission or an Agreement State; or
- (2) prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in R313-32-920, or an individual under the supervision of either as specified in R313-32-25.

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

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

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

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

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

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

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

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

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

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

R313-32-220. Possession of Survey Instruments.

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

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

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

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

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

R313-32-310. Safety Instruction.

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

- (a) patient or human research subject control;
 - (b) visitor control;
 - (c) contamination control;
 - (d) waste control; and
 - (e) notification of the Radiation Safety Officer in case of the patient's or the human research subjects's death or medical emergency.
- (2) A licensee shall keep for three years a list of individuals receiving instruction required by R313-32-310(1), a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

R313-32-315. Safety Precautions.

- (1) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with R313-32-75, a licensee shall:
- (a) provide a private room with a private sanitary facility;
 - (b) post the patient's or the human research subject's door with a "Radioactive Materials" sign and note on the door or in the patient's or the human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room;
 - (c) authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;
 - (d) promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of R313- 15, and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in microsieverts or millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey;
 - (e) either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste;
 - (f) survey the patient's or the human research subject's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient or human research subject to the room. The room shall not be reassigned until removable contamination is less than 200 disintegrations per minute per 100 square centimeters; and
 - (g) measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage, and retain for the period required by R313-15-1107 a record of each thyroid burden measurement, its date, the name of the individual

whose thyroid burden was measured, and the initials of the individual who made the measurements.

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

R313-32-320. Possession of Survey Instruments.

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

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

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

- (1) Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
- (2) Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
- (3) Gold-198 as a sealed source in seeds for interstitial treatment of cancer;
- (4) Iridium-192 as seeds encased in nylon ribbon for interstitial and intracavitary treatment of cancer and as seeds for topical treatment of cancer;
- (5) Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions;
- (6) Iodine-125 as a sealed source in seeds for topical, interstitial and intracavitary treatment of cancer;
- (7) Palladium-103 as a sealed source in seeds for interstitial treatment of cancer.

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

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

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

human research subject, the survey instrument used, and the initials of the individual who made the survey.

R313-32-406. Brachytherapy Sources Inventory.

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

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

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

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

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

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

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

R313-32-410. Safety Instruction.

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

(a) size and appearance of the brachytherapy sources;

(b) safe handling and shielding instructions in case of a dislodged source;

(c) procedures for patient or human research subject control;

(d) procedures for visitor control; and

(e) procedures for notification of the Radiation Safety Officer if the patient or the human research subject dies or has a medical emergency.

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

R313-32-415. Safety Precautions.

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

- (a) not quarter the patient or the human research subject in the same room with an individual who is not receiving radiation therapy;
- (b) post the patient's or human research subject's door with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;
- (c) authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;
- (d) promptly after implanting the material, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of R313- 15, and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in microsieverts or millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey; and
- (e) provide the patient or the human research subject with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before releasing the individual if the individual was administered a permanent implant.

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

R313-32-420. Possession of Survey Instrument.

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

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

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

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

R313-32-520. Availability of Survey Instrument.

A licensee authorized to use radioactive material as a sealed source for diagnostic purposes

shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range one μSv (0.1 mrem) per hour to one mSv per hour to (100 mrem) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range ten μSv (one mrem) per hour to ten mSv (1000 mrem) per hour. The instrument shall be calibrated in accordance with R313-32-51.

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

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

R313-32-605. Maintenance and Repair Restrictions.

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

- (1) install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source; or
- (2) maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

R313-32-606. License Amendments.

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

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

R313-32-610. Safety Instruction.

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

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

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

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

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

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

R313-32-615. Safety Precautions.

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

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

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

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

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

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

(4) A licensee shall install in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

(a) A radiation monitor shall provide visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source, and shall be observable by an individual entering the teletherapy room.

(b) A radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

(c) A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects.

(d) A licensee shall maintain a record of the check required by R313-32-615(4)(c) for three years. The record shall include the date of the check, notation that the monitor indicates when its detector is and is not exposed, and the initials of the individual who performed the check.

(e) If a radiation monitor is inoperable, the licensee shall require individuals entering the

teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in R313-32-615(4)(d).

(f) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

(5) A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient or the human research subject from the teletherapy unit console during irradiation.

R313-32-620. Possession of Survey Instrument.

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

R313-32-630. Dosimetry Equipment.

(1) A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:

(a) The system shall be calibrated by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration shall have been performed within the previous two years and after any servicing that may have affected system calibration.

(b) The system shall have been calibrated within the previous four years; eighteen to thirty months after that calibration, the system shall have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past twenty-four months by the National Bureau of Standards or by a calibration laboratory accredited by the AAPM. The intercomparison meeting shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM. The results of the intercomparison meeting shall have indicated that the calibration factor of the licensee's system had not changed by more than two percent. The licensee shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.

(2) The licensee shall have available for use a dosimetry system for spot-check measurements. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with R313-32-630(1). This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in R313-32-630(1).

(3) The licensee shall retain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated,

intercompared, or compared as required by R313-32-630(1) and (2), the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by AAPM.

R313-32-632. Full Calibration Measurements.

(1) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

(a) before the first medical use of the unit; and

(b) before medical use under the following conditions:

(i) whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) following replacement of the source or following reinstallation of the teletherapy unit in a new location; or

(iii) following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(c) at intervals not exceeding one year.

(2) To satisfy the requirement of R313-32-632(1), full calibration measurements shall include determination of:

(a) the output within plus or minus three percent for the range of field sizes and for the distance or range of distances used for medical use;

(b) the coincidence of the radiation field and the field indicated by the light beam localizing device;

(c) the uniformity of the radiation field and its dependence on the orientation of the useful beam;

(d) timer constancy and linearity over the range of use;

(e) on-off error; and

(f) the accuracy of all distance measuring and localization devices in medical use.

(3) A licensee shall use the dosimetry system described in R313-32-630(1) to measure the output for one set of exposure conditions. The remaining radiation measurements required in R313-32-632(2)(a) may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by R313-32-632(1) in accordance with either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in Physics in

Medicine and Biology Vol. 16, No. 3, 1971, pp. 379-396, or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics Vol. 10, No. 6, 1983, pp. 741-711, and Vol. 11, No. 2, 1984, p. 213.

(5) A licensee shall correct mathematically the outputs determined in R313-32-632(2)(a) for physical decay for intervals not exceeding one month for cobalt-60 or six months for cesium-137.

(6) Full calibration measurement required in R313-32-632(1) and physical decay corrections required by R313-32-632(5) shall be performed by the licensee teletherapy physicist.

(7) A licensee shall retain a record of each calibration for the duration of the teletherapy unit source. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, an assessment of timer linearity and constancy, the calculated on-off error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.

R313-32-634. Periodic Spot-Checks.

(1) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

(a) timer constancy, and timer linearity over the range of use;

(b) on-off error;

(c) the coincidence of the radiation field and the field indicated by the light beam localizing device;

(d) the accuracy of all distance measuring and localization devices used for medical use;

(e) the output for one typical set of operating conditions measured with the dosimetry system described in R313-32-630(2); and

(f) the difference between the measurement made in R313-32-634(2)(e) and the anticipated output, expressed as a percentage of the anticipated output (the value obtained at last full calibration corrected mathematically for physical decay).

(2) A licensee shall perform measurements required by R313-32-634(1) in accordance with procedures established by the teletherapy physicist. That individual need not actually perform the spot-check measurements.

(3) A licensee shall have the teletherapy physicist review the results of each spot-check within 15 days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each spot-check. The licensee shall keep a copy of each written notification for three years.

(4) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks for each teletherapy facility once in each calendar month that assure proper

operation of:

- (a) electrical interlocks at each teletherapy room entrance;
 - (b) electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);
 - (c) beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;
 - (d) viewing systems;
 - (e) treatment room doors from inside and outside the treatment room; and
 - (f) electrically assisted treatment room doors with the teletherapy unit electrical power turned off.
- (5) A licensee shall arrange for prompt repair of any system identified in R313-32-634(4) that is not operating properly, and shall not use the teletherapy unit following door interlock malfunction until the interlock system has been repaired.
- (6) A licensee shall retain a record of each spot-check required by R313-32-634(1) and (4) for three years. The record shall include the date of the spot-check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, an assessment of linearity and constancy, the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the calculated on-off error, the determined accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot-check.

R313-32-636. Safety Checks for Teletherapy Facilities.

- (1) A licensee shall promptly check all systems listed in R313-32-634(4) for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by R313-32-606(1) through (4).
- (2) If the results of the checks required in R313-32-636(1) indicate the malfunction of a system specified in R313-32-634(4), the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
- (3) A licensee shall retain for three years a record of the facility checks following installation of a source. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, and doors, and the signature of the Radiation Safety Officer.

R313-32-641. Radiation Surveys for Teletherapy Facilities.

- (1) Before medical use, after each installation of a teletherapy source, and after making any

change for which an amendment is required by R313-32-606(1) through (4), the licensee shall perform radiation surveys with a portable radiation measurement survey instrument calibrated in accordance with R313-32-51 to verify that:

- (a) the maximum and average dose rates at one meter from the teletherapy source with the source in the off position and the collimators set for a normal treatment field do not exceed 100 uSv (ten mrem) per hour and 20 uSv (two mrem) per hour, respectively;
 - (b) with the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of the radiation, that:
 - (i) radiation dose quantities per unit time in restricted areas are not likely to cause personnel exposures in excess of the limits specified in R313-15-201; and
 - (ii) radiation dose quantities per unit time in unrestricted areas do not exceed the limits specified in R313-15-301.
- (2) If the results of the surveys required in R313-32-641(1) indicate any radiation dose quantity per unit time in excess of the respective limit specified in R313-32-641(1), the licensee shall lock the control in the off position and not use the unit:

- (a) except as may be necessary to repair, replace, or test the teletherapy unit shielding or the treatment room shielding; or
- (b) until the licensee has received a specific exemption pursuant to R313-12-54.

(3) A licensee shall retain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the off position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microseverts or millirem per hour, the calculated maximum quantity of radiation over a period of one week for each restricted and unrestricted area, and the signature of the Radiation Safety Officer.

R313-32-643. Modification of Teletherapy Unit or Room Before Beginning a Treatment Program.

- (1) If the survey required by R313-32-641 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by R313-15-301, before beginning the treatment program the licensee shall:
- (a) either equip the unit with stops or add additional radiation shielding to ensure compliance with R313-15-301(3);
 - (b) perform the survey required by R313-32-641 again; and
 - (c) include in the report required by R313-32-645 the results of the initial survey, a description of the modification made to comply with R313-32-643(1)(a), and the results of the second survey.

(2) As an alternative to the requirements set out in R313-32-643(1), a licensee may request a license amendment under R313-15-301(3) that authorizes radiation levels in unrestricted areas greater than those permitted by R313-15-301(1). A licensee shall not begin the treatment program until the license amendment has been issued.

R313-32-645. Reports of Teletherapy Surveys, Checks, Tests and Measurements.

A licensee shall mail a copy of the records required in R313-32-636, R313-32-641, R313-32-643, and the output from the teletherapy source expressed as coulombs/kilogram (roentgens) or gray (rad) per hour at one meter from the source and determined during the full calibration required in R313-32-632 to the Executive Secretary within thirty days following completion of the action that initiated the record requirement.

R313-32-647. Five-Year Inspection.

(1) A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(2) This inspection and servicing shall only be performed by persons specifically licensed to do so by the Executive Secretary, the Nuclear Regulatory Commission, or an Agreement State.

(3) A licensee shall keep a record of the inspection and servicing for the duration of the license. The record shall contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

R313-32-900. Radiation Safety Officer.

Except as provided in R313-32-901, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in R313-32-21 to be an individual who:

(1) is certified by:

(a) American Board of Health Physics in comprehensive health physics;

(b) American Board of Radiology;

(c) American Board of Nuclear Medicine;

(d) American Board of Science in nuclear medicine;

(e) Board of Pharmaceutical Specialties in nuclear pharmacy;

(f) American Board of Medical Physics in radiation oncology physics;

(g) Royal College of Physicians and Surgeons of Canada in nuclear medicine;

- (h) American Osteopathic Board of Radiology; or
- (i) American Osteopathic Board of Nuclear Medicine; or
- (2) has had classroom and laboratory training and experience as follows:
 - (a) 200 hours of classroom and laboratory training that includes:
 - (i) radiation physics and instrumentation;
 - (ii) radiation protection;
 - (iii) mathematics pertaining to the use and measurement of radioactivity;
 - (iv) radiation biology; and
 - (v) radiopharmaceutical chemistry; and
 - (b) one year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a license issued by the Executive Secretary, Nuclear Regulatory Commission or Agreement State license that authorizes the medical use of radioactive material; or
- (3) be an authorized user identified on the licensee's license.

R313-32-901. Training for Experienced Radiation Safety Officer.

An individual identified as a Radiation Safety Officer on a license issued by the Executive Secretary, Nuclear Regulatory Commission or Agreement State before January 1, 1989, need not comply with the training requirements of R313-32-900.

R313-32-910. Training for Uptake, Dilution, and Excretion Studies.

Except as provided in R313-32-970 and R313-32-971, the licensee shall require the authorized user of a radiopharmaceutical in R313-32-100(1) to be a physician who:

- (1) is certified in:
 - (a) nuclear medicine by the American Board of Nuclear Medicine;
 - (b) diagnostic radiology by the American Board of Radiology;
 - (c) diagnostic radiology or radiology by the American Osteopathic Board of Radiology;
 - (d) nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or
 - (e) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or
- (2) has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as

follows:

(a) 40 hours of classroom and laboratory training that includes:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity;

(iv) radiation biology; and

(v) radiopharmaceutical chemistry; and

(b) 20 hours of supervised clinical experience under the supervision of an authorized user and that includes:

(i) examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(ii) selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(iii) administering dosages to patients or human research subjects and using syringe radiation shields;

(iv) collaborating with the authorized user in the interpretation of radionuclide test results; and

(v) patient or human research subject follow-up; or

(3) has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in the topics identified in R313-32-910(2).

R313-32-920. Training for Imaging and Localization Studies.

Except as provided in R313-32-970 or R313-32-971, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in R313-32-200(1) to be a physician who:

(1) is certified in:

(a) nuclear medicine by the American Board of Nuclear Medicine;

(b) diagnostic radiology by the American Board of Radiology;

(c) diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

(d) nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(e) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

(2) has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows:

(a) 200 hours of classroom and laboratory training that includes:

- (i) radiation physics and instrumentation;
- (ii) radiation protection;
- (iii) mathematics pertaining to the use and measurement of radioactivity;
- (iv) radiopharmaceutical chemistry; and
- (v) radiation biology; and

(b) 500 hours of supervised work experience under the supervision of an authorized user that includes:

- (i) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (ii) calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;
- (iii) calculating and safely preparing patient or human research subject dosages;
- (iv) using administrative controls to prevent the misadministration of radioactive material;
- (v) using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
- (vi) eluting technetium-99m from generator systems, measuring and testing the elute for molybdenum-99 and alumina contamination, and processing the elute with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

(c) 500 hours of supervised clinical experience under the supervision of the authorized user that includes:

- (i) examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;
- (ii) selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
- (iii) administering dosages to patients or human research subjects and using syringe radiation shields;
- (iv) collaborating with the authorized user in the interpretation of radioisotope test results; and
- (v) patient or human research subject follow-up; or

(3) has successfully completed a six-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in the topics identified in R313-32-920(2).

R313-32-930. Training for Therapeutic Use of Unsealed Radioactive Material.

Except as provided in R313-32-970, the licensee shall require the authorized user of radiopharmaceuticals in R313-32-300 to be a physician who:

(1) is certified by:

(a) the American Board of Nuclear Medicine;

(b) the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology;

(c) nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(d) the American Osteopathic Board of Radiology after 1984; or

(2) has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows:

(a) 80 hours of classroom and laboratory training that includes:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity; and

(iv) radiation biology; and

(b) supervised clinical experience under the supervision of an authorized user at a medical institution that includes:

(i) use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in ten individuals; and

(ii) use of iodine-131 for treatment of thyroid carcinoma in three individuals.

R313-32-932. Training for Treatment of Hyperthyroidism.

Except as provided in R313-32-970, the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows:

- (1) 80 hours of classroom and laboratory training that includes:
 - (a) radiation physics and instrumentation;
 - (b) radiation protection;
 - (c) mathematics pertaining to the use and measurement of radioactivity; and
 - (d) radiation biology; and
- (2) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in ten individuals.

R313-32-934. Training for Treatment of Thyroid Carcinoma.

Except as provided in R313-32-970, the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma, and supervised clinical experience as follows:

- (1) 80 hours of classroom and laboratory training that includes:
 - (a) radiation physics and instrumentation;
 - (b) radiation protection;
 - (c) mathematics pertaining to the use and measurement of radioactivity; and
 - (d) radiation biology; and
- (2) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in three individuals.

R313-32-940. Training for Use of Brachytherapy Sources.

Except as provided in R313-32-970 the licensee shall require the authorized user of a brachytherapy source listed in R313-32-400 for therapy to be a physician who:

- (1) is certified in:
 - (a) radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;
 - (b) radiation oncology by the American Osteopathic Board of Radiology;
 - (c) radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
 - (d) therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(2) is in the active practice of therapeutic radiology, has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows:

(a) 200 hours of classroom and laboratory training that includes:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity; and

(iv) radiation biology;

(b) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

(i) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) checking survey meters for proper operation;

(iii) preparing, implanting, and removing sealed sources;

(iv) maintaining running inventories of material on hand;

(v) using administrative controls to prevent the misadministration of radioactive material; and

(vi) using emergency procedures to control radioactive material; and

(c) three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

(i) examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

(ii) selecting the proper brachytherapy sources and dose and method of administration;

(iii) calculating the dose; and

(iv) post-administration follow-up and review of case histories in collaboration with the authorized user.

R313-32-941. Training for Ophthalmic Use of Strontium-90.

Except as provided in R313-32-970, the licensee shall require the authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of

therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows:

(1) 24 hours of classroom and laboratory training that includes:

- (a) radiation physics and instrumentation;
- (b) radiation protection;
- (c) mathematics pertaining to the use and measurement of radioactivity; and
- (d) radiation biology.

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals that includes:

- (a) examination of each individual to be treated;
- (b) calculation of the dose to be administered;
- (c) administration of the dose; and
- (d) follow-up and review of each individual's case history.

R313-32-950. Training for Use of Sealed Sources for Diagnosis.

Except as provided in R313-32-970, the licensee shall require the authorized user of a sealed source in a device listed in R313-32-500 to be a physician, dentist, or podiatrist who:

(1) is certified in

- (a) radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;
- (b) nuclear medicine by the American Board of Nuclear Medicine;
- (c) diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
- (d) nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(2) has had eight hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes:

- (a) radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;
- (b) radiation biology;
- (c) radiation protection; and

(d) training in the use of the device for the uses requested.

R313-32-960. Training for Teletherapy.

Except as provided in R313-32-970, the licensee shall require the authorized user of a sealed source listed in R313-32-600 in a teletherapy unit to be a physician who:

(1) is certified in:

(a) radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(b) radiation oncology by the American Osteopathic Board of Radiology;

(c) radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(d) therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(2) is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, supervised work experience, and supervised clinical experience as follows:

(a) 200 hours of classroom and laboratory training that includes:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity; and

(iv) radiation biology;

(b) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

(i) review of the full calibration measurements and periodic spot checks;

(ii) preparing treatment plans and calculating treatment times;

(iii) using administrative controls to prevent misadministrations;

(iv) implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and

(v) checking and using survey meters; and

(c) three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in

therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

- (i) examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;
- (ii) selecting the proper dose and how it is to be administered;
- (iii) calculating the teletherapy doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and
- (iv) post-administration follow-up and review of case histories.

R313-32-961. Training for Teletherapy Physicist.

The licensee shall require the teletherapy physicist to be an individual who:

- (1) is certified by the American Board of Radiology in:
 - (a) therapeutic radiological physics;
 - (b) roentgen ray and gamma ray physics;
 - (c) x-ray and radium physics; or
 - (d) radiological physics; or
- (2) is certified by the American Board of Medical Physics in radiation oncology physics; or
- (3) holds a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and has completed one year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of a teletherapy physicist at a medical institution that includes the tasks listed in R313-32-59, R313-32-632, R313-32-634 and R313-32-641.

R313-32-970. Training for Experienced Authorized Users.

Physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of radioactive material on a license issued by the Executive Secretary, Nuclear Regulatory Commission, or Agreement State license issued before January 1, 1989, who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of R313-32-900 to R313-32-961.

R313-32-971. Physician Training in a Three Month Program.

A physician who, before October 1, 1988, began a three month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program need not comply with the requirements of R313-32-910 or R313-32-920.

R313-32-972. Recentness of Training.

The training and experience specified in R313-32-900 through R313-32-981 shall have been obtained within the seven years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

R313-32-980. Training for an Authorized Nuclear Pharmacist.

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(1) has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties, or

(2)(a) has completed 700 hours in a structured educational program consisting of both:

(i) didactic training in the following areas:

(A) radiation physics and instrumentation;

(B) radiation protection;

(C) mathematics pertaining to the use and measurement of radioactivity;

(D) chemistry of radioactive material for medical use; and

(E) radiation biology; and

(ii) supervised experience in a nuclear pharmacy involving the following:

(A) shipping, receiving, and performing related radiation surveys;

(B) using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) using administrative controls to avoid mistakes in the administration of radioactive material;

(E) using procedures to prevent or minimize contamination and using proper decontamination procedures; and

(b) has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

R313-32-981. Training for Experienced Nuclear Pharmacists.

A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work

as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in R313-32-980(2)(a) before January 1, 1998 and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement (See R313-32-980(2)(b)) and recentness of training (See R313-32-972) to qualify as an authorized nuclear pharmacist.

R313-32-999. Resolution of Conflicting Requirements During Transition Period.

If the rules in R313-32 conflict with the licensee's radiation safety program as identified in its license, and if that license was approved by the Bureau of Radiation Control, Department of Health, before January 1, 1989, and has not been renewed since January 1, 1989, then the requirements in the license will apply. However, if the licensee exercises its privilege to make minor changes in its radiation safety procedures that are not potentially important to safety under R313-32-31, the portion changed shall comply with the requirements of R313-32. At the time of license renewal and thereafter, these amendments to R313-32 shall apply.

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