State of Utah
Administrative Rule Analysis

NOTICE OF PROPOSED RULE OR CHANGE

The agency identified below in box 1 provides notice of proposed rule or change pursuant to Utah Code Subsections 63-46a-4(2) and (4). Please address questions regarding information on this notice to the agency. The full text of all rule filings is published in the *Utah State Bulletin* unless excluded because of space constraints. The full text of all rule filings may also be inspected at the Division of Administrative Rules.

State of Utah
Division of Administrative Rules (DAR)
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DAR file no.:	21948
Utah Admin. Code ref. (R no.):	R313-19-30
Date filed:	04/12/1999
Time filed:	10:38
Received by:	NL

1. Department: Environmental Quality
   Agency: Radiation Control
   Room no., building: State of Utah Office Park, Bldg. 2
   Street address: 168 North 1950 West
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(Interested persons may inspect this filing at the above address or at DAR between 8:00 a.m. and 5:00 p.m. on business days.)

2. Title of rule or section (catchline):

Reciprocal Recognition of Licenses

3. Type of notice:

Proposed rules [ ] New [X] Amendment [ ] Repeal [ ] Repeal and reenact

Other rule types [ ] Change in proposed rule (changes original proposed rule file no.:)

4. Purpose of the rule or reason for the change:

To clarify that Utah does not grant reciprocity in areas of exclusive federal jurisdiction.

5. This rule or change is a response to comments by the Administrative Rules Review Committee. [ ] Yes [X] No

6. Summary of the rule or change:

This change provides clarification that reciprocity is granted by rule anywhere in the State of Utah, except in areas of exclusive Federal jurisdiction

7. Aggregate anticipated cost or savings to:

State budget:	The proposed change is of value to the Nuclear Regulatory Commission (NRC), as it lessens the possibility of reciprocity licensees in Utah using radioactivity in areas of exclusive Federal Jurisdiction without authorization. No fiscal impact on the State is expected because the NRC has jurisdiction for areas of Exclusive Federal Jurisdiction.
Local government:	As this change only embodies clarification of an existing rule, no fiscal impact is expected.
Other persons:	As this change only embodies clarification of an existing rule, no fiscal impact is expected.

8. Compliance costs for affected persons ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an agency):

As this change only embodies clarification of an existing rule, no fiscal impact is expected.

9. Comments by the department head on the fiscal impact the rule may have on businesses:

Businesses in Utah are still covered under 10 CFR 150 to do work in areas of Exclusive Federal Jurisdiction. No change in this has occurred and no fiscal impact is expected.

10. This rule or change is authorized or mandated by state law, and implements or interprets the following state and federal laws.

State code or constitution citations (required):	Sections 19-3-104 and 19-3-108
Federal citations (optional):	10 CFR 19.12

11. This rule or change adds or updates an incorporated reference (submit a copy to DAR): Yes [X] No

Reference title and date of issue or edition:

12. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the *Utah State Bulletin*. See Section 63-46a-5 and Rule R15-1 for more information.)

Comments will be accepted until 5:00 p.m. on (mm/dd/yyyy): 06/01/1999

A public hearing (optional) will be held on (mm/dd/yyyy): at (time):

at (place):

13. This rule or change may become effective on (mm/dd/yyyy): 06/11/1999

14. Indexing information - keywords (maximum of four, in lower case):

license, reciprocity, transportation, exemptions

15. Indexing information - affected industries (two-digit SIC codes):

12, 13, 16, 39, 40, 42, 45, 47, 80, 82

16. Attach a WordPerfect document containing the text of this rule or change (filename): R313-019.948

To the agency: Information requested on this form is required by Sections 63-46a-4, 5, 6, and 10. Incomplete forms may be returned to the agency for completion, possibly delaying publication in the *Utah State Bulletin*, and delaying the first possible effective date.

AGENCY AUTHORIZATION

Agency head or designee, and title:	William J. Sinclair, Executive Secretary	Date (mm/dd/yyyy):	04/12/1999

62 FR 4120 Criteria for Release...
effective date 3/20/98

R313. Environmental Quality, Radiation Control.
R313-15. Standards for Protection Against Radiation.
R313-15-1. Purpose, Authority and Scope.

(1) R313-15 establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses issued by the Executive Secretary. These rules are issued pursuant to Sections 19-3-104(3) and 19-3-104(6).

(2) The requirements of Rule R313-15 are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in Rule R313-15. However, nothing in Rule R313-15 shall be construed as limiting actions that may be necessary to protect health and safety.

(3) Except as specifically provided in other sections of these rules, Rule R313-15 applies to persons licensed or registered by the Executive Secretary to receive, possess, use, transfer, or dispose of sources of radiation. The limits in Rule R313-15 do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with Section R313-32-75, or to exposure from voluntary participation in medical research programs.

R313-15-2. Definitions.

"Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix B of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference.

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

"Constraint (dose constraint)" means a value above which specified licensee actions are required.

"Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

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

Table I, Column 3, of Appendix B of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference.

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

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

"Inhalation class", refer to "Class".

"Labeled package" means a package labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations 49 CFR 172.403 and 49 CFR 172.436 through 440, 199[3]7 ed. Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403(m) and (w) and 49 CFR 173.421 through 424, 199[2]7 ed.

"Lung class", refer to "Class".

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

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

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

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

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

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

"Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than

its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these rules, "probabilistic effect" is an equivalent term.

"Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of five Gy (500 rad) in one hour at one meter from a source of radiation or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.

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

TABLE

ORGAN DOSE WEIGHTING FACTORS

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

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

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

R313-15-3. Implementation.

(1) Any existing license or registration condition that is more restrictive than Rule R313-15 remains in force until there is an amendment or renewal of the license or registration.

(2) If a license or registration condition exempts a licensee or registrant from a provision of Rule R313-15 in effect on or before January 1, 1994, it also exempts the licensee or registrant from the corresponding provision of Rule R313-15.

(3) If a license or registration condition cites provisions of Rule R313-15 in effect prior to January 1, 1994, which do not correspond to any provisions of Rule R313-15, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes

this condition.

R313-15-101. Radiation Protection Programs.

(1) Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of Rule R313-15. See Section R313-15-1102 for recordkeeping requirements relating to these programs.

(2) The licensee or registrant shall use, to the extent [~~practicable~~]practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).

(3) The licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

(4) To implement the ALARA requirements of Subsection R313-15-101(2), and notwithstanding the requirements in Section R313-15-301, a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its daughters, shall be established by licensees or registrants such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 0.1 mSv (10 mrem) per year from these emissions. If a licensee or registrant subject to this requirement exceeds this dose constraint, the licensee or registrant shall report the exceedance as provided in Section R313-15-1203 and promptly take appropriate corrective action to ensure against recurrence.

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

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

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

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

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

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

(i) An eye dose equivalent of 0.15 Sv (15 rem), and

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

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

(3) The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure determined as follows:

(a) The deep dose equivalent, eye dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation

measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable; or

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

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

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

(4) Derived air concentration (DAC) and annual limit on intake (ALI) values are [~~presented~~]specified in Table I of Appendix B of 10 CFR 20.1001 to 20.2402, 199[~~3~~]7 ed., which is incorporated by reference, and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See Section R313-15-1107.

(5) Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to ten milligrams in a week in consideration of chemical toxicity. See footnote 3, of Appendix B of 10 CFR 20.1001 to 20-2402, 199[~~3~~]7 ed., which is incorporated by reference.

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

R313-15-202. Compliance with Requirements for Summation of External and Internal Doses.

(1) If the licensee or registrant is required to monitor pursuant to both Subsections R313-15-502(1) and R313-15-502(2), the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to Subsection R313-15-502(1) or only pursuant to Subsection R313-15-502(2), then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to Subsections R313-15-202(2), R313-15-202(3) and R313-15-202(4). The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

(2) Intake by Inhalation. If the only intake of

radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

(a) The sum of the fractions of the inhalation ALI for each radionuclide, or

(b) The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or

(c) The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, w_T, and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than ten percent of the maximum weighted value of $H_{T,50}$, that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

(3) Intake by Oral Ingestion. If the occupationally exposed individual [~~also~~]receives an intake of radionuclides by oral ingestion greater than ten percent of the applicable oral ALI, the licensee or registrant shall account for this intake and include it in demonstrating compliance with the limits.

(4) Intake through Wounds or Absorption through Skin. The licensee or registrant shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for pursuant to Subsection R313-15-202(4).

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

(1) Licensees or registrants shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, eye dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See footnotes 1 and 2 of Appendix B of 10 CFR 20.1001 to 20.2402, 199[~~3~~]7 ed., which is incorporated by reference.

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

R313-15-204. Determination of Internal Exposure.

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

(a) Concentrations of radioactive materials in air in work areas; or

(b) Quantities of radionuclides in the body; or

(c) Quantities of radionuclides excreted from the body; or

(d) Combinations of these measurements.

(2) Unless respiratory protective equipment is used, as provided in Section R313-15-703, or the assessment of intake is based on bioassays, the licensee or registrant shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

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

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

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

(c) Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See Appendix B of 10 CFR 20.1001 to 20.2402, 199[~~3~~]7 ed., which is incorporated by reference.

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

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

(a) The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix B of 10 CFR 20.1001 to 20.2402, 199[~~3~~]7 ed., which is incorporated by reference, for each radionuclide in the mixture; or

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

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

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

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

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

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

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

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

(b) For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.50 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix B of 10 CFR 20.1001 to 20.2402, 199[~~3~~]7 ed., which is incorporated by reference. The licensee or registrant may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALI, the licensee or registrant shall also demonstrate that the limit in Subsection R313-15-201(1)(a)(ii) is met.

R313-15-205. Determination of Prior Occupational Dose.

(1) For each individual [~~who may enter the licensee's or registrant's restricted or controlled area and is~~]likely to receive, in a year, an occupational dose requiring monitoring pursuant to Section R313-15-502, the licensee or registrant shall:

(a) Determine the occupational radiation dose received during the current year; and

(b) Attempt to obtain the records of [~~lifetime~~]cumulative occupational radiation dose. A licensee or registrant may accept, as the record of cumulative radiation dose, an up-to-date form DRC-05 or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant.

(2) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

(a) The internal and external doses from all previous planned special exposures; and

(b) All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual[~~; and~~].

[~~(c) All lifetime cumulative occupational radiation dose.~~]

(3) In complying with the requirements of Subsection R313-15-205(1), a licensee or registrant may:

(a) Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and

[~~(b) Accept, as the record of lifetime cumulative radiation~~

~~dose, an up-to-date form DRC-05 or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and~~]

[~~(c)~~](b) Obtain reports of the individual's dose equivalents from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, facsimile, other electronic media or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(4)[~~(a)~~] The licensee or registrant shall record the exposure history, as required by Subsection R313-15-205(1), on form DRC-05, or other clear and legible record, of all the information required on that form.

(a) The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing form DRC-05 or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on form DRC-05 or equivalent indicating the periods of time for which data are not available.

(b) For the purpose of complying with this requirement, [~~t~~]licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the rules in Rule R313-15 in effect before January 1, 1994. Further, occupational exposure histories obtained and recorded on form DRC-05 or equivalent before January 1, 1994, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

(5) If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:

(a) In establishing administrative controls under Subsection R313-15-201(6) for the current year, that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

(b) That the individual is not available for planned special exposures.

(6) The licensee or registrant shall retain the records on form DRC-05 or equivalent until the Executive Secretary terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing form DRC-05 or equivalent for three years after the record is made.

R313-15-206. Planned Special Exposures.

A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in Section R313-15-201 provided that each of the following conditions is satisfied:

(1) The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the higher exposure are unavailable or impractical.

(2) The licensee or registrant, and employer if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

(3) Before a planned special exposure, the licensee or registrant ensures that each individual involved is:

(a) Informed of the purpose of the planned operation; and

(b) Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

(c) Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

(4) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by Subsection R313-15-205(2) during the lifetime of the individual for each individual involved.

(5) Subject to Subsection R313-15-201(2), the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

(a) The numerical values of any of the dose limits in Subsection R313-15-201(1) in any year; and

(b) Five times the annual dose limits in Subsection R313-15-201(1) during the individual's lifetime.

(6) The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with Section R313-15-1106 and submits a written report in accordance with Section R313-15-1204.

(7) The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to Subsection R313-15-201(1) but shall be included in evaluations required by Subsections R313-15-206(4) and R313-15-206(5).

R313-15-207. Occupational Dose Limits for Minors.

The annual occupational dose limits for minors are ten percent of the annual occupational dose limits specified for adult workers in Section R313-15-201.

R313-15-208. Dose to an Embryo/Fetus.

(1) The licensee or registrant shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed five mSv (0.5 rem). See Section R313-15-1107 for recordkeeping

requirements.

(2) The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in Subsection R313-15-208(1).

(3) The dose to an embryo/fetus shall be taken as the sum of:

(a) The [~~deep dose equivalent to the~~]dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman; and

(b) The dose that is most representative of the dose to the embryo/fetus from external radiation, that is, in the mother's lower torso region.[~~ radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.~~]

(i) If multiple measurements have not been made, assignment of the highest deep dose equivalent for the declared pregnant woman shall be the dose to the embryo/fetus, in accordance with Subsection R313-15-205(3); or

(ii) If multiple measurements have been made, assignment of the deep dose equivalent for the declared pregnant woman from the individual monitoring device which is most representative of the dose to the embryo/fetus shall be the dose to the embryo fetus. Assignment of the highest deep dose equivalent for the declared pregnant woman to the embryo/fetus is not required unless that dose is also the most representative deep dose equivalent for the region of the embryo/fetus.

(4) If by the time the woman declares pregnancy to the licensee or registrant, the dose to the embryo/fetus has exceeded 4.5 mSv (0.45 rem) the licensee or registrant shall be deemed to be in compliance with Subsection R313-15-208(1) if the additional dose to the embryo/fetus does not exceed 0.50 mSv (0.05 rem) during the remainder of the pregnancy.

R313-15-301. Dose Limits for Individual Members of the Public.

(1) Each licensee or registrant shall conduct operations so that:

(a) [~~The~~]Except as provided in Subsection R313-15-301(1)(c), the total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed one mSv (0.1 rem) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Section R313-32-75, from voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with Section R313-15-1003[~~,~~]; and

(b) The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with Section R313-32-75, does not exceed 0.02 mSv (0.002 rem) in any one hour[~~.~~]; and

(c) The total effective dose equivalent to individual members of the public from infrequent exposure to radiation from radiation machines does not exceed 5 mSv (0.5 rem) in a year.

(2) If the licensee or registrant permits members of the

public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

(3) A licensee, registrant, or an applicant for a license or registration may apply for prior Executive Secretary authorization to operate up to an annual dose limit for an individual member of the public of five mSv (0.5 rem). This application shall include the following information:

(a) Demonstration of the need for and the expected duration of operations in excess of the limit in Subsection R313-15-301(1); and

(b) The licensee's or registrant's program to assess and control dose within the five mSv (0.5 rem) annual limit; and

(c) The procedures to be followed to maintain the dose ALARA.

(4) The Executive Secretary may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.

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

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

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

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

(b) Demonstrating that:

(i) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B of 10 CFR 20.1001 to 20.2402, 199[~~3~~]7 ed., which is incorporated by reference; and

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

(3) Upon approval from the Executive Secretary, the licensee or registrant may adjust the effluent concentration values in Appendix B, Table II of 10 CFR 20.1001 to 20.2402, 199[~~3~~]7 ed., which is incorporated by reference, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as, aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

R313-15-401. Testing for Leakage or Contamination of Sealed Sources.

(1) The licensee or registrant in possession of any sealed source shall assure that:

(a) Each sealed source, except as specified in Subsection R313-15-401(2), is tested for leakage or contamination and the test

results are received before the sealed source is put into use unless the licensee or registrant has a certificate from the transferor indicating that the sealed source was tested within six months before transfer to the licensee or registrant.

(b) Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed six months or at alternative intervals approved by the Executive Secretary, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission.

(c) Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three months or at alternative intervals approved by the Executive Secretary, an Agreement State, a Licensing State, or the Nuclear Regulatory Commission.

(d) For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee or registrant shall assure that the sealed source is tested for leakage or contamination before further use.

(e) Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of 185 Bq (0.005 uCi) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position.

(f) The test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 37 Bq (0.001 uCi) of radon-222 in a 24 hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume and time.

(g) Tests for contamination from radium daughters shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 185 Bq (0.005 uCi) of a radium daughter which has a half-life greater than four days.

(2) A licensee or registrant need not perform tests for leakage or contamination on the following sealed sources:

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

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

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

(d) Sealed sources containing only hydrogen-3;

(e) Seeds of iridium-192 encased in nylon ribbon; and

(f) Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used and identified as in storage. The licensee or registrant shall, however, test each such sealed source for leakage or contamination and receive the test

results before any use or transfer unless it has been tested for leakage or contamination within six months before the date of use or transfer.

(3) Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Executive Secretary, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such services.

(4) Test results shall be kept in units of becquerel or microcurie and maintained for inspection by representatives of the Executive Secretary. Records of test results for sealed sources shall be made pursuant to Section R313-15-1104.

(5) The following shall be considered evidence that a sealed source is leaking:

(a) The presence of 185 Bq (0.005 uCi) or more of removable contamination on any test sample.

(b) Leakage of 37 Bq (0.001 uCi) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium.

(c) The presence of removable contamination resulting from the decay of 185 Bq (0.005 uCi) or more of radium.

(6) The licensee or registrant shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with Rule R313-15.

(7) Reports of test results for leaking or contaminated sealed sources shall be made pursuant to Section R313-15-1208.

R313-15-501. Surveys and Monitoring - General.

(1) Each licensee or registrant shall make, or cause to be made, surveys that:

(a) Are necessary for the licensee or registrant to comply with Rule R313-15; and

(b) Are necessary under the circumstances to evaluate:

(i) Radiation levels; and

(ii) Concentrations or quantities of radioactive material; and

(iii) The potential radiological hazards that could be present.

(2) The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured, except when a more frequent interval is specified in another applicable part of these rules or a license condition.

(3) All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with Section R313-15-201, with other applicable provisions of these rules, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

(a) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(b) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

(4) The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

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

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

(1) Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

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

(b) Minors and declared pregnant women likely to receive, in one year from sources external to the body, a dose in excess of ten percent of any of the applicable limits in Sections R313-15-207 or R313-15-208; and

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

(d) Individuals working with medical fluoroscopic equipment.

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

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

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

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

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

(a) Adults likely to receive, in one year, an intake in excess of ten percent of the applicable ALI in Table I, Columns 1 and 2, of Appendix B of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference; and

(b) Minors and declared pregnant women likely to receive, in one year, a committed effective dose equivalent in excess of 0.50 mSv (0.05 rem).

R313-15-503. Location of Individual Monitoring Devices.

Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with Subsection R313-15-502(1) wear individual monitoring devices as follows:

(1) An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar).

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

(3) An individual monitoring device used for monitoring the eye dose equivalent, to demonstrate compliance with Subsection R313-15-201(1)(b)(i), shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye.

(4) An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with Subsection R313-15-201(1)(b)(ii), shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

R313-15-601. Control of Access to High Radiation Areas.

(1) The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

(a) A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of one mSv (0.1 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates; or

(b) A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

(c) Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

(2) In place of the controls required by Subsection R313-15-601(1) for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(3) The licensee or registrant may apply to the Executive Secretary for approval of alternative methods for controlling access to high radiation areas.

(4) The licensee or registrant shall establish the controls required by Subsections R313-15-601(1) and R313-15-601(3) in a way that does not prevent individuals from leaving a high radiation area.

(5) The licensee or registrant is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the rules of the U.S. Department of Transportation provided that:

(a) The packages do not remain in the area longer than three days; and

(b) The dose rate at one meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.

(6) The licensee or registrant is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in Rule R313-15 and to operate within the ALARA provisions of the licensee's or registrant's radiation protection program.

(7) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in Section R313-15-601 if the registrant has met all the specific requirements for access and control specified in other applicable sections of these rules, such as, Rule R313-36 for industrial radiography, Rule R313-28 for x rays in the healing arts, Rule R313-30 for therapeutic radiation machines, and Rule R313-[~~44~~]35 for [~~particle accelerators~~]industrial use of x-ray systems.

R313-15-602. Control of Access to Very High Radiation Areas.

(1) In addition to the requirements in Section R313-15-601, the licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at five Gy (500 rad) or more in one hour at one meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation, or to non-self-shielded irradiators.

(2) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in Subsection R313-15-602(1) if the registrant has met all the

specific requirements for access and control specified in other applicable sections of these rules, such as, Rule R313-36 for industrial radiography, Rule R313-28 for x rays in the healing arts, Rule R313-30 for therapeutic radiation machines, and Rule R313-[~~44~~]35 for [~~particle accelerators~~]industrial use of x-ray systems.

R313-15-603. Control of Access to Very High Radiation Areas -- Irradiators.

(1) Section R313-15-603 applies to licensees or registrants with sources of radiation in non-self-shielded irradiators. Section R313-15-603 does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create a high levels of radiation in an area that is accessible to any individual.

(2) Each area in which there may exist radiation levels in excess of five Gy (500 rad) in one hour at one meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

(a) Each entrance or access point shall be equipped with entry control devices which:

(i) Function automatically to prevent any individual from inadvertently entering a very high radiation area; and

(ii) Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of one mSv (0.1 rem) in one hour; and

(iii) Prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of one mSv (0.1 rem) in one hour.

(b) Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by Subsection R313-15-603(2)(a):

(i) The radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of one mSv (0.1 rem) in one hour; and

(ii) Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.

(c) The licensee or registrant shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:

(i) The radiation level from the source of radiation is reduced below that at which it would be possible for an individual

to receive a deep dose equivalent in excess of one mSv (0.1 rem) in one hour; and

(ii) Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or registrant or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

(d) When the shield for stored sealed sources is a liquid, the licensee or registrant shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

(e) Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of Subsections R313-15-603(2)(c) and R313-15-603(2)(d).

(f) Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, which shall be installed in the area and which can prevent the source of radiation from being put into operation.

(g) Each area shall be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

(h) Each area shall be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of one mSv (0.1 rem) in one hour.

(i) The entry control devices required in Subsection R313-15-603(2)(a) shall be tested for proper functioning. See Section R313-15-1110 for recordkeeping requirements.

(i) Testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day; and

(ii) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and

(iii) The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

(j) The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.

(k) Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to

physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and automatically to prevent loose radioactive material from being carried out of the area.

(3) Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of Subsection R313-15-603(2) which will be used in a variety of positions or in locations, such as open fields or forests, that make it [~~impracticable~~]impractical to comply with certain requirements of Subsection R313-15-603(2), such as those for the automatic control of radiation levels, may apply to the Executive Secretary for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in Subsection R313-15-603(2). At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

(4) The entry control devices required by Subsections R313-15-603(2) and R313-15-603(3) shall be established in such a way that no individual will be prevented from leaving the area.

R313-15-701. Use of Process or Other Engineering Controls.

The licensee or registrant shall use, to the extent [~~practicable~~]practical, process or other engineering controls, such as, containment or ventilation, to control the concentrations of radioactive material in air.

R313-15-702. Use of Other Controls.

When it is not [~~practicable~~]practical to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee or registrant shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

(1) Control of access; or
(2) Limitation of exposure times; or
(3) Use of respiratory protection equipment; or
(4) Other controls.

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

(1) If the licensee or registrant uses respiratory protection equipment to limit intakes pursuant to Section R313-15-702:

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

(b) [~~If t~~]The licensee or registrant [~~wishes to~~]may use equipment that has not been tested or certified by the National

Institute for Occupational Safety and Health and the Mine Safety and Health Administration, has not had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, or for which there is no schedule for testing or certification, provided the licensee or registrant [~~shall submit~~]has submitted to the Executive Secretary and the Executive Secretary has approved an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of [~~reliable~~]test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

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

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

(ii) Surveys and bioassays, as appropriate, to evaluate actual intakes; and

(iii) Testing of respirators for operability immediately prior to each use; and

(iv) Written procedures regarding selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and recordkeeping; and

(v) Determination by a physician prior to initial fitting of respirators, and [~~at least~~]either every 12 months thereafter or periodically at a frequency determined by a physician, that the individual user is [~~physically~~]medically [~~able~~]fit to use the respiratory protection equipment.

(d) The licensee or registrant shall issue a written policy statement on respirator usage covering:

(i) The use of process or other engineering controls, instead of respirators; and

(ii) The routine, nonroutine, and emergency use of respirators; and

(iii) The length of periods of respirator use and relief from respirator use.

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

(f) The licensee or registrant shall use respiratory protection equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities, such as adequate skin protection, when needed.

(2) When estimating exposure of individuals to airborne radioactive materials, the licensee or registrant may make allowance for respiratory protection equipment used to limit intakes pursuant to Section R313-15-702, provided that the following conditions, in addition to those in Subsection R313-15-

703(1), are satisfied:

(a) The licensee or registrant selects respiratory protection equipment that provides a protection factor, specified in Appendix A of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B, Table I, Column 3 of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference. However, if the selection of respiratory protection equipment with a protection factor greater than the [~~peak concentration~~]multiple defined in the preceding sentence is inconsistent with the goal specified in Section R313-15-702 of keeping the total effective dose equivalent ALARA, the licensee or registrant may select respiratory protection equipment with a lower protection factor provided that such a selection would result in a total effective dose equivalent that is ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used.

(b) The licensee or registrant shall obtain authorization from the Executive Secretary before assigning respiratory protection factors in excess of those specified in Appendix A of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference. The Executive Secretary may authorize a licensee or registrant to use higher protection factors on receipt of an application that:

(i) Describes the situation for which a need exists for higher protection factors, and

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

(c) In an emergency, the licensee or registrant shall use as emergency equipment only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

(d) The licensee or registrant shall notify the Executive Secretary in writing at least 30 days before the date that respiratory protection equipment is first used pursuant to either Subsections R313-15-703(1) or R313-15-703(2).

R313-15-801. Security and Control of Licensed or Registered[Stored] Sources of Radiation.

~~[The licensee or registrant shall secure from unauthorized removal or access licensed or registered sources of radiation that are stored in controlled or unrestricted areas.~~

~~**R313-15-802. Control of Sources of Radiation not in Storage.**~~

~~(1) The licensee or registrant shall control and maintain constant surveillance of licensed or registered radioactive~~

~~material that is in a controlled or unrestricted area and that is not in storage or in a patient.~~

~~(2) The registrant shall maintain control of radiation machines that are in a controlled or unrestricted area and that are not in storage.~~] (1) The licensee or registrant shall secure licensed or registered radioactive material from unauthorized removal or access.

(2) The licensee or registrant shall maintain constant surveillance, and use devices or administrative procedures to prevent unauthorized use of licensed or registered radioactive material that is in an unrestricted area and that is not in storage.

(3) The registrant shall secure registered radiation machines from unauthorized removal.

(4) The registrant shall use devices or administrative procedures to prevent unauthorized use of registered radiation machines.

R313-15-901. Caution Signs.

(1) Standard Radiation Symbol. Unless otherwise authorized by the Executive Secretary, the symbol prescribed by 10 CFR 20.1901, 199[~~3~~]7 ed., which is incorporated by reference, shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

(a) Cross-hatched area is to be magenta, or purple, or black, and

(b) The background is to be yellow.

(2) Exception to Color Requirements for Standard Radiation Symbol. Notwithstanding the requirements of 10 CFR 20.1901a, 199[~~3~~]7 ed., which is incorporated by reference, licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

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

R313-15-902. Posting Requirements.

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

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

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

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

(5) Posting of Areas or Rooms in which Licensed or Registered Material is Used or Stored. The licensee or registrant shall post each area or room in which there is used or stored an amount of licensed or registered material exceeding ten times the quantity of such material specified in Appendix C of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL."

R313-15-903. Exceptions to Posting Requirements.

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

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

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

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

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

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

R313-15-904. Labeling Containers and Radiation Machines.

(1) The licensee or registrant shall ensure that each container of licensed or registered material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

(2) Each licensee or registrant shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

(3) Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

R313-15-905. Exemptions to Labeling Requirements.

A licensee or registrant is not required to label:

(1) Containers holding licensed or registered material in quantities less than the quantities listed in Appendix C of 10 CFR 20.1001 to 20.2402, 199[~~3~~]7 ed., which is incorporated by reference; or

(2) Containers holding licensed or registered material in concentrations less than those specified in Table III of Appendix B of 10 CFR 20.1001 to 20.2402, 199[~~3~~]7 ed., which is incorporated by reference; or

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

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

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

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

R313-15-906. Procedures for Receiving and Opening Packages.

(1) Each licensee or registrant who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in Section R313-19-4 and Subsection R313-19-100(19), shall make arrangements to receive:

(a) The package when the carrier offers it for delivery; or

(b) The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

(2) Each licensee or registrant shall:

(a) Monitor the external surfaces of a labeled package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in Section R313-12-3; and

(b) Monitor the external surfaces of a labeled package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in Section R313-19-4 and Subsection R313-19-100(19); and

(c) Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

(3) The licensee or registrant shall perform the monitoring required by Subsection R313-15-906(2) as soon as [~~practicable~~]practical after receipt of the package, but not later than three hours after the package is received at the licensee's or registrant's facility if it is received during the licensee's or registrant's normal working hours[~~, or not later than three hours from the beginning of the next working day if it is received after working hours.~~] or if there is evidence of degradation of package integrity, such as a package that is crushed, wet, or damaged. If a package is received after working hours, and has no evidence of degradation of package integrity, the package shall be monitored no later than three hours from the beginning of the next working day.

(4) The licensee or registrant shall immediately notify the final delivery carrier and, by telephone and telegram, mailgram, or facsimile, the Executive Secretary when:

(a) Removable radioactive surface contamination exceeds the limits of Subsection R313-19-100(13)(h); or

(b) External radiation levels exceed the limits of Subsections R313-19-100(13)(i) and R313-19-100(13)(j).

(5) Each licensee or registrant shall:

(a) Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

(b) Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

(6) Licensees or registrants transferring special form sources in vehicles owned or operated by the licensee or registrant to and from a work site are exempt from the contamination monitoring requirements of Subsection R313-15-906(2), but are not exempt from the monitoring requirement in Subsection R313-15-906(2) for measuring radiation levels that ensures that the source is still properly lodged in its shield.

R313-15-1001. Waste Disposal - General Requirements.

(1) A licensee or registrant shall dispose of licensed or registered material only:

(a) By transfer to an authorized recipient as provided in Section R313-15-1006 or in Rules R313-21, R313-22, or R313-25, or to the U.S. Department of Energy; or

(b) By decay in storage; or

(c) By release in effluents within the limits in Section R313-15-301; or

(d) As authorized pursuant to Sections R313-15-1002, R313-15-1003, R313-15-1004, or R313-15-1005.

(2) A person shall be specifically licensed or registered to receive waste containing licensed or registered material from other persons for:

(a) Treatment prior to disposal; or

(b) Treatment or disposal by incineration; or

(c) Decay in storage; or

(d) Disposal at a land disposal facility licensed pursuant to Rule R313-25; or

(e) Storage until transferred to a storage or disposal

facility authorized to receive the waste.

R313-15-1002. Method for Obtaining Approval of Proposed Disposal Procedures.

A licensee or registrant or applicant for a license or registration may apply to the Executive Secretary for approval of proposed procedures, not otherwise authorized in these rules, to dispose of licensed or registered material generated in the licensee's or registrant's operations. Each application shall include:

(1) A description of the waste containing licensed or registered material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal; and

(2) An analysis and evaluation of pertinent information on the nature of the environment; and

(3) The nature and location of other potentially affected facilities; and

(4) Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in Rule R313-15.

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

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

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

(b) The quantity of licensed or registered radioactive material that the licensee or registrant releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee or registrant does not exceed the concentration listed in Table III of Appendix B of 10 CFR 20.1001 to 20.2402,199[3]7 ed., which is incorporated by reference; and

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

(i) The licensee or registrant shall determine the fraction of the limit in Table III of Appendix B of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference, represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee or registrant into the sewer by the concentration of that radionuclide listed in Table III of Appendix B of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference; and

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

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

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

R313-15-1004. Treatment or Disposal by Incineration.

A licensee or registrant may treat or dispose of licensed or registered material by incineration only in the [~~amounts and forms~~]form and concentration specified in Section R313-15-1005 or as specifically approved by the Executive Secretary pursuant to Section R313-15-1002.

R313-15-1005. Disposal of Specific Wastes.

(1) A licensee or registrant may dispose of the following licensed or registered material as if it were not radioactive:

(a) 1.85 kBq (0.05 uCi), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

(b) 1.85 kBq (0.05 uCi) or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

(2) A licensee or registrant shall not dispose of tissue pursuant to Subsection R313-15-1005(1)(b) in a manner that would permit its use either as food for humans or as animal feed.

(3) The licensee or registrant shall maintain records in accordance with Section R313-15-1109.

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

(1) [~~The r~~]Requirements of Section R313-15-1006 and Appendix F and G of 10 CFR 20.1001 to 20.2402, 199[~~3~~]7 ed.[~~, which is incorporated by reference,~~]

(a) The requirements of Section R313-15-1006 and Appendix F and G of 10 CFR 20.1001 to 20.2402, 1997 ed., which are incorporated into these rules by reference, are designed to:

(i) control transfers of low-level radioactive waste[~~intended for disposal at a licensed low-level radioactive waste disposal facility, establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes.~~] by any waste generator, waste collector, or waste processor licensee, as defined in Appendix F or G in 10 CFR 20.1001 to 20.2402, 1997 ed., who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility as defined in Section R313-25-2;

(ii) establish a manifest tracking system; and

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

(b) Beginning March 1, 1998, all affected licensees must use Appendix G of 10 CFR 20.1001 to 20.2402, 1997 ed., which is incorporated into these rules by reference. Prior to March 1, 1998, a low-level waste disposal facility operator or its regulatory authority may require the shipper to use Appendix F or Appendix G of 10 CFR 20.1001 to 20.2402, 1997 ed. Licensees using Appendix F shall comply with Subsection R313-15-1006(2)(a). Licensees using Appendix G shall comply with Subsection R313-15-1006(2)(b).

(2) Shipment of Radioactive Waste.

(a) Each shipment of radioactive waste designated for disposal at a licensed low-level radioactive waste disposal facility shall be accompanied by a shipment manifest as specified

in Section I of Appendix F of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference.

(b) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded information to the intended consignee in accordance with Appendix G to 10 CFR 20.1001 to 20.2402, 1997 ed., which is incorporated into these rules by reference.

(3) Each shipment manifest shall include a certification by the waste generator as specified in Section II of Appendix F or G, as appropriate, of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference. See Subsection R313-15-1006(1)(b) to determine the appropriate Appendix.

(4) Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix F or G, as appropriate, of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference. See Subsection R313-15-1006(1)(b) to determine the appropriate Appendix.

R313-15-1007. Compliance with Environmental and Health Protection Rules.

Nothing in Sections R313-15-1001, R313-15-1002, R313-15-1003, R313-15-1004, R313-15-1005, or R313-15-1006 relieves the licensee or registrant from complying with other applicable Federal, State and local rules governing any other toxic or hazardous properties of materials that may be disposed of pursuant to Sections R313-15-1001, R313-15-1002, R313-15-1003, R313-15-1004, R313-15-1005, or R313-15-1006.

R313-15-1008. Classification and Characteristics of Low-Level Radioactive Waste.

(1) Classification of Radioactive Waste for Land Disposal

(a) Considerations. Determination of the classification of radioactive waste involves two considerations. First, consideration shall be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration shall be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.

(b) Classes of waste.

(i) Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste shall meet the minimum requirements set forth in Subsection R313-15-1008(2)(a). If Class

A waste also meets the stability requirements set forth in Subsection R313-15-1008(2)(b), it is not necessary to segregate the waste for disposal.

(ii) Class B waste is waste that shall meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste shall meet both the minimum and stability requirements set forth in Subsection R313-15-1008(2).

(iii) Class C waste is waste that not only shall meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste shall meet both the minimum and stability requirements set forth in Subsection R313-15-1008(2).

(c) Classification determined by long-lived radionuclides. If the radioactive waste contains only radionuclides listed in Table I, classification shall be determined as follows:

(i) If the concentration does not exceed 0.1 times the value in Table I, the waste is Class A.

(ii) If the concentration exceeds 0.1 times the value in Table I, but does not exceed the value in Table I, the waste is Class C.

(iii) If the concentration exceeds the value in Table I, the waste is not generally acceptable for land disposal.

(iv) For wastes containing mixtures of radionuclides listed in Table I, the total concentration shall be determined by the sum of fractions rule described in Subsection R313-15-1008(1)(g).

TABLE I

Radionuclide	Concentration curie/cubic meter(1)	Concentration nanocurie/gram(2)
C-14	8	
C-14 in activated metal	80	
Ni-59 in activated metal	220	
Nb-94 in activated metal	0.2	
Tc-99	3	
I-129	0.08	
Alpha emitting transuranic radionuclides with half-life greater than five years		100
Pu-241		3,500
Cm-242		20,000
Ra-226		100

NOTE: (1) To convert the Ci/m^3 values to gigabecquerel (GBq)/cubic meter, multiply the Ci/m^3 value by 37.
(2) To convert the nCi/g values to becquerel (Bq)/gram, multiply the nCi/g value by 37.

(d) Classification determined by short-lived radionuclides.

If the waste does not contain any of the radionuclides listed in Table I, classification shall be determined based on the concentrations shown in Table II. However, as specified in Subsection R313-15-1008(1)(f), if radioactive waste does not contain any nuclides listed in either Table I or II, it is Class A.

(i) If the concentration does not exceed the value in Column 1, the waste is Class A.

(ii) If the concentration exceeds the value in Column 1 but does not exceed the value in Column 2, the waste is Class B.

(iii) If the concentration exceeds the value in Column 2 but does not exceed the value in Column 3, the waste is Class C.

(iv) If the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.

(v) For wastes containing mixtures of the radionuclides listed in Table II, the total concentration shall be determined by the sum of fractions rule described in Subsection R313-15-1008(1)(g).

TABLE II

Radionuclide	Concentration, curie/cubic meter(1)		
	Column 1	Column 2	Column 3
Total of all radionuclides with less than 5-year half-life	700	(2)	(2)
H-3	40	(2)	(2)
Co-60	700	(2)	(2)
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7000
Sr-90	0.04	150	7000
Cs-137	1	44	4600

NOTE: (1) To convert the Ci/m^3 value to gigabecquerel (GBq)/cubic meter, multiply the Ci/m^3 value by 37.

(2) There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other radionuclides in Table II determine the waste to be Class C independent of these radionuclides.

(e) Classification determined by both long- and short-lived radionuclides. If the radioactive waste contains a mixture of radionuclides, some of which are listed in Table I and some of which are listed in Table II, classification shall be determined as follows:

(i) If the concentration of a radionuclide listed in Table I is less than 0.1 times the value listed in Table I, the class shall be that determined by the concentration of radionuclides listed in

Table II.

(ii) If the concentration of a radionuclide listed in Table I exceeds 0.1 times the value listed in Table I, but does not exceed the value in Table I, the waste shall be Class C, provided the concentration of radionuclides listed in Table II does not exceed the value shown in Column 3 of Table II.

(f) Classification of wastes with radionuclides other than those listed in Tables I and II. If the waste does not contain any radionuclides listed in either Table I or II, it is Class A.

(g) The sum of the fractions rule for mixtures of radionuclides. For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits shall all be taken from the same column of the same table. The sum of the fractions for the column shall be less than 1.0 if the waste class is to be determined by that column. Example: A waste contains Sr-90 in a concentration of 1.85 TBq/m^3 (50 Ci/m^3) and Cs-137 in a concentration of 814 GBq/m^3 (22 Ci/m^3). Since the concentrations both exceed the values in Column 1, Table II, they shall be compared to Column 2 values. For Sr-90 fraction, 50/150 = 0.33., for Cs-137 fraction, 22/44 = 0.5; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.

(h) Determination of concentrations in wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as becquerel (nanocurie) per gram.

(2) Radioactive Waste Characteristics

(a) The following are minimum requirements for all classes of waste and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site.

(i) Wastes shall be packaged in conformance with the conditions of the license issued to the site operator to which the waste will be shipped. Where the conditions of the site license are more restrictive than the provisions of [~~Part D~~]Rule R313-15, the site license conditions shall govern.

(ii) Wastes shall not be packaged for disposal in cardboard or fiberboard boxes.

(iii) Liquid waste shall be packaged in sufficient absorbent material to absorb twice the volume of the liquid.

(iv) Solid waste containing liquid shall contain as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed one percent of the volume.

(v) Waste shall not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

(vi) Waste shall not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons

transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with Subsection R313-15-1008(2)(a)(viii).

(vii) Waste shall not be pyrophoric. Pyrophoric materials contained in wastes shall be treated, prepared, and packaged to be nonflammable.

(viii) Wastes in a gaseous form shall be packaged at an absolute pressure that does not exceed 1.5 atmospheres at 20 degrees celsius. Total activity shall not exceed 3.7 TBq (100 Ci) per container.

(ix) Wastes containing hazardous, biological, pathogenic, or infectious material shall be treated to reduce to the maximum extent [~~practicable~~]practical the potential hazard from the non-radiological materials.

(b) The following requirements are intended to provide stability of the waste. Stability is intended to ensure that the waste does not degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

(i) Waste shall have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.

(ii) Notwithstanding the provisions in Subsections R313-15-1008(2)(a)(iii) and R313-15-1008(2)(a)(iv), liquid wastes, or wastes containing liquid, shall be converted into a form that contains as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed one percent of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5 percent of the volume of the waste for waste processed to a stable form.

(iii) Void spaces within the waste and between the waste and its package shall be reduced to the extent [~~practicable~~]practical.

(3) Labeling. Each package of waste shall be clearly labeled to identify whether it is Class A, Class B, or Class C waste, in accordance with Subsection R313-15-1008(1).

R313-15-1101. Records - General Provisions.

(1) Each licensee or registrant shall use the SI units becquerel, gray, sievert and coulomb per kilogram, or the special units, curie, rad, rem, and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by Rule R313-15.

(2) Notwithstanding the requirements of Subsection R313-15-1101(1), when recording information on shipment manifests, as required in Subsection R313-15-1006(2), information must be recorded in SI units or in SI units and the special units specified

in Subsection R313-15-1101(1).

[~~(2)~~](3) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by Rule R313-15, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, eye dose equivalent, deep dose equivalent, or committed effective dose equivalent.

R313-15-1102. Records of Radiation Protection Programs.

(1) Each licensee or registrant shall maintain records of the radiation protection program, including:

(a) The provisions of the program; and

(b) Audits and other reviews of program content and implementation.

(2) The licensee or registrant shall retain the records required by Subsection R313-15-1102(1)(a) until the Executive Secretary terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by Subsection R313-15-1102(1)(b) for three years after the record is made.

R313-15-1103. Records of Surveys.

(1) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by Section R313-15-501 and Subsection R313-15-906(2). The licensee or registrant shall retain these records for three years after the record is made.

(2) The licensee or registrant shall retain each of the following records until the Executive Secretary terminates each pertinent license or registration requiring the record:

(a) Records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and

(b) Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

(c) Records showing the results of air sampling, surveys, and bioassays required pursuant to Subsections R313-15-703(1)(c)(i) and R313-15-703(1)(c)(ii); and

(d) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

R313-15-1104. Records of Tests for Leakage or Contamination of Sealed Sources.

Records of tests for leakage or contamination of sealed sources required by Section R313-15-401 shall be kept in units of becquerel or microcurie and maintained for inspection by the Executive Secretary for five years after the records are made.

R313-15-1105. Records of Prior Occupational Dose.

For each individual who is likely to receive in a year an occupational dose requiring monitoring pursuant to Section R313-15-502, [~~T~~]the licensee or registrant shall retain the records of

prior occupational dose and exposure history as specified in Section R313-15-205 on form DRC-05 or equivalent until the Executive Secretary terminates each pertinent license requiring this record. The licensee or registrant shall retain records used in preparing form DRC-05 or equivalent for three years after the record is made.

R313-15-1106. Records of Planned Special Exposures.

(1) For each use of the provisions of Section R313-15-206 for planned special exposures, the licensee or registrant shall maintain records that describe:

(a) The exceptional circumstances requiring the use of a planned special exposure; and

(b) The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and

(c) What actions were necessary; and

(d) Why the actions were necessary; and

(e) What precautions were taken to assure that doses were maintained ALARA; and

(f) What individual and collective doses were expected to result; and

(g) The doses actually received in the planned special exposure.

(2) The licensee or registrant shall retain the records until the Executive Secretary terminates each pertinent license or registration requiring these records.

R313-15-1107. Records of Individual Monitoring Results.

(1) Recordkeeping Requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to Section R313-15-502, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before January 1, 1994, need not be changed. These records shall include, when applicable:

(a) The deep dose equivalent to the whole body, eye dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and

(b) The estimated intake of radionuclides, see Section R313-15-202; and

(c) The committed effective dose equivalent assigned to the intake of radionuclides; and

(d) The specific information used to calculate the committed effective dose equivalent pursuant to Subsection R313-15-204(3); and

(e) The total effective dose equivalent when required by Section R313-15-202; and

(f) The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

(2) Recordkeeping Frequency. The licensee or registrant shall make entries of the records specified in Subsection R313-15-1107(1) at intervals not to exceed one year.

(3) Recordkeeping Format. The licensee or registrant shall maintain the records specified in Subsection R313-15-1107(1) on form DRC-06, in accordance with the instructions for form DRC-06, or in clear and legible records containing all the information required by form DRC-06.

(4) The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

(5) The licensee or registrant shall retain each required form or record until the Executive Secretary terminates each pertinent license or registration requiring the record.

R313-15-1108. Records of Dose to Individual Members of the Public.

(1) Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See Section R313-15-301.

(2) The licensee or registrant shall retain the records required by Subsection R313-15-1108(1) until the Executive Secretary terminates each pertinent license or registration requiring the record. Requirements for disposition of these records, prior to license termination, are located in Section R313-12-51 for activities licensed under these rules.

R313-15-1109. Records of Waste Disposal.

(1) Each licensee or registrant shall maintain records of the disposal of licensed or registered materials made pursuant to Sections R313-15-1002, R313-15-1003, R313-15-1004, R313-15-1005, Rule R313-25, and disposal by burial in soil, including burials authorized before January 28, 1981.

(2) The licensee or registrant shall retain the records required by Subsection R313-15-1109(1) until the Executive Secretary terminates each pertinent license or registration requiring the record.

R313-15-1110. Records of Testing Entry Control Devices for Very High Radiation Areas.

(1) Each licensee or registrant shall maintain records of tests made pursuant to Subsection R313-15-603(2)(i) on entry control devices for very high radiation areas. These records shall include the date, time, and results of each such test of function.

(2) The licensee or registrant shall retain the records required by Subsection R313-15-1110(1) for three years after the record is made.

R313-15-1111. Form of Records.

Each record required by Rule R313-15 shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period or the record may also be stored in electronic media with the capability for producing legible,

accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

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

(1) Telephone Reports. Each licensee or registrant shall report to the Executive Secretary by telephone each stolen, lost, or missing source of radiation immediately after its absence becomes known to the licensee or registrant. This requirement does not apply to sources of radiation that are not required to be licensed or registered. [~~as follows:~~]

[~~(a) Immediately after its occurrence becomes known to the licensee or registrant, stolen, lost, or missing licensed or registered radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C of 10 CFR 20.1001 to 20.2402, 1993 ed., which is incorporated by reference, under such circumstances that it appears to the licensee or registrant that an exposure could result to individuals in unrestricted areas;~~

~~(b) Within 30 days after its occurrence becomes known to the licensee or registrant, lost, stolen, or missing licensed or registered radioactive material in an aggregate quantity greater than ten times the quantity specified in Appendix C of 10 CFR 20.1001 to 20.2402, 1993 ed., which is incorporated by reference, that is still missing.~~

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

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

(a) A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;

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

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

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

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

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

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

learns of such information.

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

R313-15-1202. Notification of Incidents.

(1) Immediate Notification. Notwithstanding other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

(a) An individual to receive:

(i) A total effective dose equivalent of 0.25 Sv (25 rem) or more; or

(ii) An eye dose equivalent of 0.75 Sv (75 rem) or more; or

(iii) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 2.5 Gy (250 rad) or more; or

(b) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(2) Twenty-Four Hour Notification. Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Executive Secretary each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

(a) An individual to receive, in a period of 24 hours:

(i) A total effective dose equivalent exceeding 0.05 Sv (five rem); or

(ii) An eye dose equivalent exceeding 0.15 Sv (15 rem); or

(iii) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 Sv (50 rem); or

(b) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(3) The licensee or registrant shall prepare each report filed with the Executive Secretary pursuant to Section R313-15-1202 so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

(4) Licensees or registrants shall make the reports required by Subsections R313-15-1202(1) and R313-15-1202(2) to the Executive Secretary by telephone, telegram, mailgram, or facsimile to the Executive Secretary.

(5) The provisions of Section R313-15-1202 do not apply to doses that result from planned special exposures, provided such

doses are within the limits for planned special exposures and are reported pursuant to Section R313-15-1204.

R313-15-1203. Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits.

(1) Reportable Events. In addition to the notification required by Section R313-15-1202, each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:

(a) Incidents for which notification is required by Section R313-15-1202; or

(b) Doses in excess of any of the following:

(i) The occupational dose limits for adults in Section R313-15-201; or

(ii) The occupational dose limits for a minor in Section R313-15-207; or

(iii) The limits for an embryo/fetus of a declared pregnant woman in Section R313-15-208; or

(iv) The limits for an individual member of the public in Section R313-15-301; or

(v) Any applicable limit in the license or registration; or

(vi) The ALARA constraints for air emissions established under Subsection R313-15-101(4); or

(c) Levels of radiation or concentrations of radioactive material in:

(i) A restricted area in excess of applicable limits in the license or registration; or

(ii) An unrestricted area in excess of ten times the applicable limit set forth in Rule R313-15 or in the license or registration, whether or not involving exposure of any individual in excess of the limits in Section R313-15-301; or

(d) For licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

(2) Contents of Reports.

(a) Each report required by Subsection R313-15-1203(1) shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(i) Estimates of each individual's dose; and

(ii) The levels of radiation and concentrations of radioactive material involved; and

(iii) The cause of the elevated exposures, dose rates, or concentrations; and

(iv) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license or registration conditions.

(b) Each report filed pursuant to Subsection R313-15-1203(1) shall include for each occupationally overexposed individual[~~exposed~~]: the name, Social Security account number, and date of

birth. With respect to the limit for the embryo/fetus in Section R313-15-208, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

(3) All licensees or registrants who make reports pursuant to Subsection R313-15-1203(1) shall submit the report in writing to the Executive Secretary.

R313-15-1204. Reports of Planned Special Exposures.

The licensee or registrant shall submit a written report to the Executive Secretary within 30 days following any planned special exposure conducted in accordance with Section R313-15-206, informing the Executive Secretary that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by Section R313-15-1106.

R313-15-1205. Reports to Individuals of Exceeding Dose Limits.

When a licensee or registrant is required, pursuant to the provisions of Sections R313-15-1203 or R313-15-1204, to report to the Executive Secretary any exposure of an identified occupationally exposed individual, or an identified member of the public, to sources of radiation, the licensee or registrant shall also provide a copy of the report submitted to the Executive Secretary to the individual. This report shall be transmitted at a time no later than the transmittal to the Executive Secretary.

R313-15-1207. Notifications and Reports to Individuals.

(1) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in Rule R313-18.

(2) When a licensee or registrant is required pursuant to Section R313-15-1203 to report to the Executive Secretary any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the Executive Secretary, and shall comply with the provisions of Rule R313-18.

R313-15-1208. Reports of Leaking or Contaminated Sealed Sources.

If the test for leakage or contamination required pursuant to Section R313-15-401 indicates a sealed source is leaking or contaminated, a report of the test shall be filed within five days with the Executive Secretary describing the equipment involved, the test results and the corrective action taken.

R313-15-1301. Vacating Premises.

Each specific licensee or registrant shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of his activities, notify the Executive Secretary in writing of intent to vacate. When deemed necessary by the Executive Secretary, the licensee shall decontaminate the premises in such a manner as the Executive Secretary may specify.

KEY: radioactive material, contamination, waste disposal, safety
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19-3-104
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Release of Individuals ...
62 FR 4120

R313. Environmental Quality, Radiation Control.
R313-15. Standards for Protection Against Radiation.

R313-15-1. Purpose, Authority and Scope.

(1) R313-15 establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses issued by the Executive Secretary. These rules are issued pursuant to UCA 19-3-104(3) and 19-3-104(6).

(2) The requirements of R313-15 are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in R313-15. However, nothing in R313-15 shall be construed as limiting actions that may be necessary to protect health and safety.

(3) Except as specifically provided in other sections of these rules, R313-15 applies to persons licensed or registered by the Executive Secretary to receive, possess, use, transfer, or dispose of sources of radiation. The limits in R313-15 do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with R313-32-75, or to exposure from voluntary participation in medical research programs.

R313-15-2 Definitions.

"Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix B of 10 CFR 20.1001 to 20.2402, 1993 ed., which is incorporated by reference.

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

"Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

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

"Member of the public" means an individual except when that individual is receiving an occupational dose.[~~in a controlled or unrestricted area. However, an individual is not a member of the public during a period in which the individual receives an occupational dose.~~]

"Minor" means an individual less than 18 years of age.

"Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these rules, radiation monitoring and radiation protection monitoring are equivalent terms.

"NARM" means a naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source or special nuclear material.

"NORM" means a naturally occurring radioactive material.

"Natural radioactivity" means radioactivity of naturally occurring nuclides.

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

"Nuclear Regulatory Commission" (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

"Occupational dose" means the dose received by an individual[~~in a restricted area or~~] in the course of employment in which the individual's assigned duties for the licensee or registrant involve exposure to sources of radiation, whether or not the sources of radiation are in the possession of the licensee, registrant, or other person. Occupational dose does not include doses received[~~:~~] from background radiation, [~~as a patient from medical practices,~~] from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with R313-32-75, from voluntary participation in medical research programs, or as a member of the public.

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

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

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

"Personnel monitoring equipment" see individual monitoring devices.

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

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

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

"Public dose" means the dose received by a member of the public from [~~exposure to sources of radiation either within a licensee's or registrant's controlled area or in unrestricted areas~~]sources of radiation from licensed or registered operations. [~~It~~]Public dose does not include occupational dose[~~,~~]or doses received from background radiation, [~~dose received as a patient from medical practices,~~]from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with R313-32-75, or [~~dose~~]from voluntary participation in medical research programs.

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

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

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

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

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

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

R313-15-301. Dose Limits for Individual Members of the Public.

(1) Each licensee or registrant shall conduct operations so that:

(a) The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed one mSv (0.1 rem) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with R313-32-75, from voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with R313-15-1003, and

NOTE: Retrofit shall not be required for locations within facilities where only radiation machines existed prior to January 1, 1994, and met the previous requirements of 5 mSv (0.5 rem) in a year.

(b) The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with R313-32-75, does not exceed 0.02 mSv (0.002 rem) in any one hour.

(2) If the licensee or registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

(3) A licensee, registrant, or an applicant for a license or registration may apply for prior Executive Secretary authorization to operate up to an annual dose limit for an individual member of the public of five mSv (0.5 rem). This application shall include the following information:

(a) Demonstration of the need for and the expected duration of operations in excess of the limit in R313-15-301(1); and

(b) The licensee's or registrant's program to assess and control dose within the five mSv (0.5 rem) annual limit; and

(c) The procedures to be followed to maintain the dose ALARA.

(4) The Executive Secretary may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.

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

(1) The licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to

R313-15-902. Posting Requirements.

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

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

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

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

(5) Posting of Areas or Rooms in which Licensed or Registered Material is Used or Stored. The licensee or registrant shall post each area or room in which there is used or stored an amount of licensed or registered material exceeding ten times the quantity of such material specified in Appendix C of 10 CFR 20.1001 to 20.2402, 1993 ed., which is incorporated by reference, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL."

R313-15-903. Exceptions to Posting Requirements.

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

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

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

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

62AR4120 Criteria for Release of Individuals Administered RAM effective date 11/23/98

R313. Environmental Quality, Radiation Control.
R313-32. Medical Use of Radioactive Material.
R313-32-1. Purpose and Authority.

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

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

R313-32-2. Definitions.

"Authorized nuclear pharmacist" means a pharmacist who is:

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

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

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

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

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

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

(c) identified as an authorized user on a permit issued by a Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorize[~~s~~]d 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 [~~beings~~]research subjects [~~in the practice of medicine in accordance with a license issued by this State~~]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 [~~patient~~]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 administrated 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 [~~patient~~]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 [~~patient~~]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 [~~patient~~]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 [~~is 30 percent greater than~~]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 [~~patient~~]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 [~~patient~~]individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

(ii) when the dose to the [~~patient~~]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 [~~is 15 percent greater than~~] 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 [~~for brachytherapy~~] 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 another 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 [~~, except a visiting authorized user described in R313-32-27~~] 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.

[~~A licensee shall notify the Executive Secretary by letter within 30 days when an authorized user, Radiation Safety Officer, or Teletherapy Physicist permanently discontinues performance of duties under the license or has a name change, or when the licensee's mailing address changes.~~] (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 R313-32-12(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 or 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-[~~972~~]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.

([~~2~~]3) A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

~~[R313-32-27. Visiting Authorized User.~~

~~(1) A licensee may permit visiting authorized users to use licensed material for medical use under the terms of the licensee's license for sixty days each year if:~~

~~(a) the visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee;~~

~~(b) the licensee has a copy of a license issued by the Executive Secretary, Nuclear Regulatory Commission, or Agreement State, or a permit issued by the Executive Secretary, Nuclear Regulatory Commission or Agreement State broad licensee that is authorized to permit medical use, that identifies the visiting authorized user by name as an authorized user for medical use; and~~

~~(c) only those procedures for which the visiting authorized user is specifically authorized by the license or permit are performed by that individual.~~

~~(2) A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in R313-32-27(1).~~

~~(3) A licensee shall retain the records specified in R313-32-27 for two years after the visiting authorized user's last use of licensed material, but may discard the records if the visiting authorized user has been listed as an authorized user on the licensee's license.~~

~~]~~

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 <u>each</u> administration, the patient's <u>or human research subject's</u> 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) <u>a</u> representative sample[~~s~~] of patient <u>and human research subject</u> administrations,

(ii) <u>all</u> 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) [~~When~~]For a misadministration:[~~ occurs,~~]

(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) [~~T~~]the licensee shall [~~also~~]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 [~~agrees to inform the patient or believes~~], based on medical judgment, [~~that~~]telling the individual [~~patient or the patient's responsible relative (or guardian)~~] would be harmful. [~~to one or the other, respectively. These notifications shall be made within 24 hours after the licensee discovers the misadministration.~~] The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician [~~, patient, or the patient's responsible relative or guardian~~] or the individual receiving the misadministration cannot be reached within 24 hours, the licensee shall notify the [~~m~~] individual as soon as [~~practicable~~]possible thereafter. The licensee [~~is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee shall~~]may not delay any appropriate medical care for the [~~patient~~]individual, including any necessary remedial care as a result of the misadministration, because of [~~this~~]any delay in notification.

([~~2~~]d) if the individual was notified, the licensee shall also furnish, [~~W~~]within 15 days after discovery of the misadministration, [~~the licensee shall submit~~]a written report [~~,~~] to the [~~Executive Secretary and to the referring physician, and furnish a copy of the report to the patient or the patient's responsible relative or guardian if either were notified by the licensee. 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 patient; actions taken to prevent recurrence; whether the licensee informed the patient or the patient's responsible relative or guardian, and if not, why not; and if the patient was notified, what information was provided to the patient. The report shall not include the patient's name or other information that could lead to identification of the patient.~~]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.

([~~3~~]2) The licensee shall retain a record of each misadministration for five years. The record shall contain the names of all individuals involved [~~in the event~~](including the prescribing physician, allied health personnel, the [~~patient~~]individual who received the misadministration, and th[~~e~~]at [~~patient~~]individual's referring physician, if applicable), the [~~patient~~]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 [~~patient~~]individual, [~~and what~~]improvements [~~are~~] needed to prevent recurrence [~~,~~], and the actions taken to prevent recurrence.

([~~4~~]3) Aside from the notification requirement, nothing in R313-32-3[~~9~~]3 affects any rights or duties of licensees and physicians in relation to each other, [~~patients~~]to individuals receiving misadministrations, or to that individual's responsible relative[~~s~~] [~~(~~]or guardian[~~s)~~].

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

A licensee may use for medical use only:

(1) [~~Radioactive material~~]Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to the rules in R313-22[~~-33~~] and R313-22-75(10) [~~through R313-22-75(12)~~]or the equivalent [~~regulations~~]requirements of the Nuclear Regulatory Commission or an Agreement State [~~.~~]; or[

~~(2) Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval by the Executive Secretary pursuant to R313-22-39, or equivalent regulations of the Nuclear Regulatory Commission or~~

~~an Agreement State for the preparation of radiopharmaceuticals for medical use~~]

([~~3~~]2) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to R313-22[~~-33~~] or the equivalent [~~regulations~~]requirements of the Nuclear Regulatory Commission or an Agreement State.

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

(1) A [~~medical use~~]licensee [~~authorized to administer radiopharmaceuticals~~]shall [~~have in its~~]possess[~~ion~~] and use a dose calibrator [~~and use it~~]to measure the [~~amount of~~]activity of dosages of photon-emitting radionuclides prior to administrat[~~ed~~]ion 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 [~~the~~]a range [~~of its use between~~]from the highest dosage that will be administered to a patient or human research subject [~~and 370 kBq~~]to 1.1 MBq ([~~ten~~]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, [~~and~~]the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the [~~signature of the Radiation Safety Officer~~]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 [~~signature of the Radiation Safety Officer~~]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 [~~signature of the Radiation Safety Officer~~]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 [~~Radiopharmaceutical~~]Dosages of Unsealed Radioactive Material for Medical Use.

A licensee shall:

(1) measure the activity of each [~~radiopharmaceutical~~] dosage [~~that contains more than 370 kBq (ten uCi)~~]of a photon-emitting radionuclide [~~before~~]prior to medical use;

(2) measure, by direct measurement or by combination of measurements and calculations, the activity of each [~~radiopharmaceutical~~]dosage [~~with a desired activity of 370 kBq (ten uCi) or less of a photon~~]of an alpha- or beta-emitting radionuclide [~~before~~]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[~~to verify that the dosage does not exceed 370 kBq (ten uCi)~~]; 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 [~~370 kBq~~]1.1 MBq ([~~ten~~]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([~~12~~]10) or equivalent Nuclear Regulatory Commission or Agreement State regulations and that do not exceed 555 MBq (15 mCi) each;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

R313-32-60. Syringe Shields and Labels.

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

(2) To identify its contents, a licensee shall conspicuously label each syringe[~~,~~] or syringe radiation shield that contains a syringe with a radiopharmaceutical. The label shall show the radiopharmaceutical name or its

abbreviation, the clinical procedure to be performed, or the patient's or the human research subject's name.

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

R313-32-61. Vial Shields and Labels.

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

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

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

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

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

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

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

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

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

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

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

R313-32-75. Release of [~~Patients~~]Individuals Containing Radiopharmaceuticals or Permanent Implants.

(1) [~~A~~]The licensee [~~shall not~~]may authorize the release from [~~confinement for medical care a patient~~]its control of any individual who has been administered [~~a~~]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). [~~until either:~~

~~(a) the measured dose rate from the patient is less than 50 uSv (five mrem) per hour at a distance of one meter; or~~
~~(b) the activity in the patient is less than 1.11 GBq (30 mCi).~~]

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) [~~A~~]The licensee shall [~~not authorize release from confinement for medical care of a patient administered a permanent implant until the measured dose rate from the patient is less than 50 uSv (five mrem) per hour at a distance of one meter.~~]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 Radio[~~pharmaceuticals~~]active Material for Uptake, Dilution, and Excretion Studies.

A licensee may use for uptake, dilution, or excretion studies any unsealed radioactive material [~~in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution, or excretion for which the Food and Drug Administration (FDA) has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).~~]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 Radio[~~pharmaceuticals, Generators, and Reagent Kits~~]active Material for Imaging and Localization Studies.

[~~(1) ~~]A licensee may use radioactive material in a diagnostic radiopharmaceutical or generator or reagent kit for preparation and diagnostic

~~use of a radiopharmaceutical containing radioactive material for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), approved a "New Drug Application" (NDA) or approved a "Product Licensing Agreement (PLA)".~~

~~(2) A licensee shall elute generators and prepare reagent kits in accordance with the manufacturer's instructions.~~

~~(3) A licensee may depart from the manufacturer's instructions for eluting generators and preparing reagent kits for which the Food and Drug Administration (FDA) has approved a "New Drug Application" (NDA) by following the directions of an authorized user physician.~~

~~(4) R313-32-200 does not relieve a licensee from complying with applicable state, FDA or other federal regulations.~~]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 [~~Radiopharmaceuticals~~]Unsealed Radioactive Material for Therap[~~y~~]eutic Administration.

[~~(1) A licensee may use any radioactive material in a radiopharmaceutical and for a therapeutic use for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA). The licensee shall comply with the package insert instructions regarding indications and method of administration.~~

~~(2) A licensee may depart from the package insert instructions regarding indications or methods of administration for a radiopharmaceutical for which the Food and Drug Administration (FDA) has approved a "New Drug Application" (NDA), provided that the authorized user physician has prepared a written directive as required by R313-32-32(1).~~

~~(3) R313-32-300 does not relieve the licensee from complying with applicable state, FDA and other federal regulations.~~]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 [~~comply with the following~~]:

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

(b) post the patient's or the human research subject's door with a "[~~Caution --~~]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 [~~patient by patient~~]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) [~~provide the patient with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient;~~

~~(g)~~]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 [~~220~~]200 disintegrations per minute [~~(.0001 uCi or 3.7 Bq)~~]per 100 square centimeters; and

([~~h~~]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[~~s~~] 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 [~~patient~~]individual who is not receiving radiation therapy[~~ unless the licensee can demonstrate compliance with the requirements of R313-15-301(a) at a distance of one meter from the implant~~];

(b) post the patient's or human research subject's door with a "[~~Caution ~~]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 [~~patient by patient~~]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 [~~patient~~]individual if the [~~patient~~]individual was administered a permanent implant.

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

R313-32-420. Possession of Survey Instrument.

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

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

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

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

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

R313-32-520. Availability of Survey Instrument.

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

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

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

R313-32-605. Maintenance and Repair Restrictions.

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

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

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

R313-32-606. License Amendments.

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

(1) making any change in the treatment room shielding;

(2) making any change in the location of the teletherapy unit within the treatment room;

(3) using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

(4) relocating the teletherapy unit; or

(5) allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

R313-32-610. Safety Instruction.

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

(a) the procedure to be followed to ensure that only the patient <u>or the human research subject</u> 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 uSv (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 uSv (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 [~~C~~]comprehensive [~~H~~]health [~~P~~]physics;

(b) American Board of Radiology;

(c) American Board of Nuclear Medicine;

(d) American Board of Science in [~~N~~]nuclear [~~M~~]medicine;

(e) Board of Pharmaceutical Specialties in [~~N~~]nuclear [~~P~~]pharmacy; [~~or~~]

(f) American Board of Medical Physics in radiation oncology physics;

(g) [~~Canadian~~]Royal College of Physicians and Surgeons of Canada in [~~N~~]nuclear [~~M~~]medicine; [~~or~~]

(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; [~~or~~]

(d) nuclear medicine by the [~~Canadian~~]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 [~~b~~]Board of Radiology; [~~or~~]

(d) nuclear medicine by the [~~Canadian~~]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

Radio [~~pharmaceuticals~~] active 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) [~~T~~]the American Board of Nuclear Medicine;

(b) [~~T~~]the American Board of Radiology in radiology, [~~or~~] therapeutic radiology, or radiation oncology; [~~or~~]

(c) nuclear medicine by [~~T~~]the [~~Canadian~~] 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, ~~[or]~~ 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, [~~or~~]therapeutic radiology, or radiation oncology by the American Board of Radiology;

(b) nuclear medicine by the American Board of Nuclear Medicine;[~~or~~]

(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, [~~or~~]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[~~-or American Board of Medical Physics~~] in:

(a) therapeutic radiological physics[~~-or radiation oncology 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

([~~2~~]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 R313-32-9[~~72~~]00 through R313-32-981 shall have been obtained within the [~~five~~]seven years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

R313-32-980. Training for an Authorized Nuclear Pharmacist.

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(1) has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties, or

(2)(a) has completed 700 hours in a structured educational program consisting of both:

(i) didactic training in the following areas:

(A) radiation physics and instrumentation;

(B) radiation protection;

(C) mathematics pertaining to the use and measurement of radioactivity;

(D) chemistry of radioactive material for medical use; and

(E) radiation biology; and

(ii) supervised experience in a nuclear pharmacy involving the following:

(A) shipping, receiving, and performing related radiation surveys;

(B) using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) using administrative controls to avoid mistakes in the administration of radioactive material;

(E) using procedures to prevent or minimize contamination and using proper decontamination procedures; and

(b) has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

R313-32-981. Training for Experienced Nuclear Pharmacists.

A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in R313-32-980(2)(a) before January 1, 1998 and who is working in a nuclear pharmacy would

qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement (See R313-32-980(2)(b)) and recentness of training (See R313-32-972) to qualify as an authorized nuclear pharmacist.

R313-32-999. Resolution of Conflicting Requirements During Transition Period.

If the rules in R313-32 conflict with the licensee's radiation safety program as identified in its license, and if that license was approved by the Bureau of Radiation Control, Department of Health, before January 1, 1989, and has not been renewed since January 1, 1989, then the requirements in the license will apply. However, if the licensee exercises its privilege to make minor changes in its radiation safety procedures that are not potentially important to safety under R313-32-31, the portion changed shall comply with the requirements of R313-32. At the time of license renewal and thereafter, these amendments to R313-32 shall apply.

KEY: radioactive material, radiopharmaceutical, brachytherapy, nuclear medicine
[~~March 10, 1995~~]1998 **19-3-104**
19-3-108

Deliberate misconduct by unlicensed persons
63 FR 1890
63 FR 13773
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R313. Environmental Quality, Radiation Control.
R313-19. Requirements of General Applicability to Licensing of Radioactive Material.
R313-19-1. Purpose and Authority.

(1) The purpose of this rule is to prescribe requirements governing the licensing of radioactive material. This rule also gives notice to all persons who knowingly provide to any licensee, applicant, certificate of registration holder, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's, applicant's or certificate of registration holder's activities subject to these rules, that they may be individually subject to Executive Secretary enforcement action for violation of Section R313-19-5.

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

R313-19-2. General.

(1) A person shall not receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license issued pursuant to Rules R313-21 or R313-22 or as otherwise provided in Rule R313-19.

(2) In addition to the requirements of Rules R313-19, R313-21 or R313-22, all licensees are subject to the requirements of Rules R313-12, R313-15, and R313-18. Licensees authorized to use sealed sources containing radioactive materials in panoramic irradiators with dry or wet storage of radioactive sealed sources, underwater irradiators, or irradiators with high dose rates from radioactive sealed sources are subject to the requirements of Rule R313-34, licensees engaged in industrial radiographic operations are subject to the requirements of Rule R313-36, licensees using radionuclides in the healing arts are subject to the requirements of Rule R313-32, licensees engaged in land disposal of radioactive material are subject to the requirements of Rule R313-25, and licensees engaged in wireline and subsurface 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, employee of a licensee, certificate of registration holder or applicant; or any contractor, including a supplier or consultant, subcontractor, employee of a contractor or subcontractor of any licensee or certificate of registration holder or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, certificate holder, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's or applicant's activities in these rules, may not:

(a) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate of registration holder, or applicant to be in violation of any rule or order; or

any term, condition, or limitation of any license issued by the Executive Secretary; or

(b) Deliberately submit to the Executive Secretary, a licensee, certificate of registration holder, an applicant, or a licensee's, certificate holder's or applicant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or 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 in accordance with Rule R313-14.

(3) For the purposes of Subsection R313-19-5(1)(a), deliberate misconduct by a person means an intentional act or omission that the person knows:

(a) Would cause a licensee, certificate of registration holder or applicant to be in violation of any rule or order; or any 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 policy of a 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 receives, possesses, uses, owns, or transfers source material in a chemical mixture, compound, solution or alloy in which the source material is by weight less than 1/20 of 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 receives, possesses, uses or transfers unrefined and unprocessed ore containing source material; provided, that, except as authorized in a specific license, such person shall 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 receives, possesses, uses or 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 50 milligrams of thorium,

(E) germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than two grams of thorium,

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

(G) personnel neutron dosimeters provided that each dosimeter does not contain more than 50 milligrams of thorium;

(ii) source material contained in the following products:

(A) glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight 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 commercially manufactured glass brick, 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 alloys, provided that the thorium content of the alloy does not exceed four percent by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of the product or part;

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

(A) the counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission 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 or other covering: "DEPLETED URANIUM",

(C) each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "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 prior to December 31, 1969, provided that such counterweights are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - 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 the chemical, physical, or metallurgical treatment or processing of counterweights other than repair or restoration of any plating or other covering;

(vi) natural or depleted uranium metal used as shielding constituting part of a shipping container which is conspicuously and legibly impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM" and the uranium metal is encased in mild steel or 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 30 percent by weight 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 such lens into optical systems and devices without alteration of the lens, or

(B) the receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments;

(viii) uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 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), and

(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 products described.

(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, R313-21 and R313-22 to the extent that 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 R313-19-70, or

(B) natural occurring radioactive materials containing less than 15 picocuries per gram radium-226.

(ii) A person may not introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under Subsection R313-19-13(2)(a)(i) or equivalent regulations of a Licensing State, the U.S. Nuclear Regulatory Commission or an Agreement State, except in accordance with a specific license issued pursuant to Subsection R313-22-75(1) or the 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 to the extent that the person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities which do not exceed the applicable 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 purposes of 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 individual quantities set forth in Section R313-19-71, knowing or having

reason to believe that the quantities of radioactive material will be transferred to persons exempt under Subsection R313-19-13(2) (b) or equivalent regulations of a Licensing State, the U.S. Nuclear Regulatory Commission or an Agreement State, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, pursuant to 10 C.F.R. Part 32 or by the Executive Secretary pursuant to Subsection R313-22-75(2), which license states that the radioactive material may be transferred by the licensee to persons exempt under Subsection R313-19-13(2)(b) or the equivalent regulations of a Licensing State, the U.S. Nuclear Regulatory Commission or an Agreement State.

(iv) A person who possesses radioactive material received or acquired prior to September 25, 1971, under the general license formerly provided in 10 C.F.R. Part 31.5 is exempt from the requirements for a license set forth in Rule R313-19 to the extent that the person possesses, uses, transfers or owns the radioactive material. This exemption does not apply for radium-226.

(c) Exempt items.

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

(A) Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the 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 the dial;

(IV) 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of promethium-147 per any other timepiece;

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

(VI) 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) of promethium-147 per other timepiece 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, when measured through 50 milligrams per 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 the effective date of these rules.

(B) Lock illuminators containing not more than 15 millicuries (555.0 MBq) of tritium or not more than two millicuries (74.0 MBq) of promethium-147 installed in automobile locks. The levels of radiation from each lock illuminator containing promethium-147 will not exceed one millirad (10 uGy) per hour at one centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.

(C) Precision balances containing not more than one millicurie (37.0 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) 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 other marine navigational instruments 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 per thermostat.

(G) Electron tubes, including spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and other completely sealed tubes that are designed to conduct or control electrical currents; provided that each tube does not contain more than one of the following specified quantities of radioactive material:

(I) 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or ten millicuries (370.0 MBq) of tritium per any other electron 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 will not exceed one millirad (10.0 uGy) per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber.

(H) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources 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, an instrument's source(s) may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of exempt quantities in Section R313-19-71, provided that the sum of the fractions shall not exceed

unity;

(III) for purposes of Subsection R313-19-13(2)(c)(i)(H), 0.05 microcurie (1.85 kBq) of americium-241 is considered an exempt quantity under Section R313-19-71.

(I) Spark gap irradiators containing not more than one microcurie (37.0 kBq) of cobalt-60 per spark gap irradiator for use in electrically 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 receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 C.F.R. Part 32.22, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in Subsection R313-19-13(2)(c)(ii) does not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.

(B) Radium-226. A person is exempt from these rules, to the extent that such person receives, possesses, uses, transfers, or owns articles 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 containing radioactive material, a person is exempt from these rules to the extent that the person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, provided that detectors containing radioactive material shall have been manufactured, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 C.F.R. Part 32.26, or a Licensing State pursuant to Subsection R313-22-75(3) or equivalent requirements, which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

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

(C) Gas and aerosol detectors containing naturally occurring and accelerator-produced radioactive material (NARM) previously manufactured and distributed in accordance with a specific license

issued by a Licensing State shall be considered exempt under Subsection R313-19-13(2)(c)(iii)(A), provided that the device is labeled in accordance with the specific license authorizing distribution, and 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 [~~regulations~~]requirements in Rules R313-19 and R313-32 provided that the person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1 uCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

(B) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to Rule R313-32.

(C) Nothing in Subsection R313-19-13(2)(c)(iv) relieves persons from complying with applicable United States Food and Drug Administration, other Federal, and State requirements governing receipt, administration, and use of drugs.

(v) Resins containing scandium-46 and designed for sand consolidation in oil wells. A person is exempt from these rules to the extent that the person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells. The resins shall have been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the Executive Secretary or an Agreement State to the manufacturer of resins pursuant to licensing requirements equivalent to those in 10 C.F.R. Part 32.16 and 32.17. This exemption does not authorize the manufacture of any resins containing scandium-46.

(vi) With respect to Subsections R313-19-13(2)(b)(iii), R313-19-13(2)(c)(i), (iii) and (iv), the authority to transfer possession or control by the manufacturer, processor, or producer of equipment, devices, commodities, or other products containing byproduct material whose subsequent possession, use, transfer, and disposal by other persons is exempted from regulatory requirements may be obtained only 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 the Executive Secretary or the issuance of licensing documents to the particular persons, although the filing of a registration certificate with the Executive Secretary may be required by the particular general

license. The general licensee is subject to the other applicable portions of these rules and limitations of the general license.

(2) Specific licenses require the submission of an application to the Executive Secretary and the issuance of a licensing document by the Executive Secretary. The licensee is subject to applicable portions of these rules as well as limitations specified in the licensing document.

R313-19-25. Prelicensing Inspection.

The Executive Secretary may verify information contained in applications and secure additional information deemed necessary to make a reasonable determination as to whether to issue a license and whether special conditions should be attached thereto by visiting the facility or location where radioactive materials would be possessed or used, and by discussing details of the proposed possession or use of the radioactive materials with the applicant or representatives designated by the applicant. Such visits may be made by representatives of 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, an Agreement State, or Licensing State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in the licensing document within this state, except in areas of exclusive federal jurisdiction, for a period not in excess of 180 days in a calendar year provided that:

(a) the licensing document does not limit the activity authorized by the document to specified installations or locations;

(b) the out-of-state licensee notifies the Executive Secretary in writing at least three days prior to engaging in such activity. Notifications shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Executive Secretary, obtain permission to proceed sooner. The Executive Secretary may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification 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 provided 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, or an Agreement 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 issued by the U.S. Nuclear Regulatory Commission, a Licensing State, or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in Subsection R313-21-22(4) within the areas subject to the jurisdiction of the licensing body is hereby 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 quarter in which a device is transferred to or installed in this state. Reports shall identify each general licensee to whom a device is transferred by name and address, 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 applicable provisions of the specific license issued to the person by the Nuclear Regulatory Commission, a Licensing State, or an Agreement State;

(c) the person shall assure that any labels required to be affixed to the device under rules of the authority which licensed manufacture of 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 transferred or on whose premises a device is installed a copy of the general license contained in Subsection R313-21-22(4) or in equivalent rules of the agency having jurisdiction over the manufacture and distribution of the device.

(3) The Executive Secretary may withdraw, limit, or qualify his acceptance of a specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission, a Licensing State or an Agreement State, or a product distributed pursuant to the licensing document, upon determining that the action is necessary in order to prevent undue hazard to public health and safety or [~~property~~]the environment.

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 hereafter in effect, and to all rules, and orders of the Executive Secretary.

(2) Licenses issued or granted under Rules R313-21 and R313-22 and rights to possess or utilize radioactive material granted by

a license issued pursuant to Rules R313-21 and R313-22 shall not be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of a license to a person unless the Executive Secretary shall, after securing full information find that the transfer is in accordance with the provisions of the Act now or hereafter in effect, and to all rules, and orders of 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 confine use and possession of the material 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 when the licensee decides to terminate activities involving materials authorized under the license.

(5) Licensees shall notify the Executive Secretary in writing immediately following the filing of a voluntary or involuntary petition for 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 license or licensee as property of the estate; 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 follow the emergency plan approved by the Executive Secretary. The licensee may change the approved plan without the Executive Secretary's approval only if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the Executive Secretary and to affected off-site response organizations within six months after the change is made. Proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by 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) and (4), licensees may 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, or a specific license or equivalent licensing document, issued by the Executive Secretary, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, or to a person otherwise authorized to receive the material by the federal government or an agency thereof, the Executive Secretary, 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 Executive Secretary, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive 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 by license or registration certificate 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 by license or registration certificate 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 in writing within ten days;

(d) the transferor may obtain other information compiled by a reporting service from official records of the Executive Secretary, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State regarding the identity of licensees and the scope 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 or when a transferor desires to verify that information received by one of the methods is correct or up-to-date, the transferor may obtain and record confirmation from the Executive Secretary, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State that the transferee is licensed to receive the radioactive material.

(5) Shipment and transport of radioactive material shall be in accordance with the provisions of Section R313-19-100.

R313-19-50. Reporting Requirements.

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

(2) The following events involving licensed material require notification of the Executive Secretary by the licensee within 24 hours:

(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 by imposing additional 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 in Appendix B of 10 CFR 20.1001 [~~to~~]through 20.2402[~~,~~] [~~1993~~](2000)[~~ed.~~], 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 of less than 24 hours to decay prior to decontamination; 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, to prevent exposures to radiation and 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 spreadable radioactive contamination on the individual's clothing or body; or

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

(i) the quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of 10 CFR 20.1001 [~~to~~]through 20.2402[~~,~~] [~~1993~~](2000)[~~ed.~~], 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 Section R313-19-50 must be made as follows:

(a) licensees shall make reports required by Subsections R313-19-50(1) and (2) by telephone to the Executive Secretary. To the extent that the information is available at the time of notification, the information provided in these reports must 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; and

(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 follow-up report within 30 days of the initial report. Written reports prepared pursuant to other rules may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports shall be sent 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, if applicable, of 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 of individuals by name.

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 or the license may be suspended or 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 in the application or any statement of fact required under provisions of the Act, or because of conditions revealed by the application or statement of fact or any report, record, or inspection or other means which would warrant the Executive Secretary to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rule, or order of the Executive Secretary.

(3) Administrative reviews, modifications, revocations or terminations of licenses will be in accordance with Title 19, Chapter 3.

(4) The Executive Secretary may terminate a specific license upon written request submitted by the licensee to the Executive

Secretary.

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 As Gas (uCi/ml)	Column II Concentration 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 (T = 9.2 h)		6 E-4
	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 (Wolfram) (74)	W-181		4 E-3
	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 is that of the parent radionuclide and takes into account the radioactive decay products, because many radionuclides disintegrate into radionuclides which are also radioactive.

(2) For purposes of Subsection R313-19-13(2)(a) where there is involved a combination of radionuclides, the limit for the combination should be derived as follows: Determine for each radionuclide in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in Section R313-19-70 for the specific radionuclide when not in combination. The sum of the ratios may not exceed one or unity.

(3) To convert microcuries (uCi) to SI units of kilobecquerels (kBq), multiply the above values 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 (C[±]l-36)		10
Chlorine-38 (C[±]l-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
Ruthenium-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 the above values by 37.

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 71.16, 71.47, 71.81, 71.85 through 71.89, 71.97 (1998), and Appendix A to part 71 are incorporated by reference with the following clarifications or exceptions:

(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 71.4;

(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 license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the U.S. Department of Transportation (DOT) regulations in 49 CFR 170 through 189 (1998) appropriate to the mode of transport.

(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 173.476;

(B) Marking and labeling--49 CFR 172.300 through 172.338, 172.400 through 172.407, 172.436 through 172.440, and 172.400 through 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 through 172.606;

(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 transportation:

(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 conform to the standards and requirements of the DOT specified in paragraph (a) of this section to the same extent as if the shipment or transportation were subject to DOT regulations. A request for modification, wavier, or exemption from those requirements, and any notification referred to in those requirements, must be filed with, or made to, the Executive Secretary.

KEY: license, reciprocity, transportation, exemptions

[~~June 11, 1999~~]2000 **19-3—104**

Notice of Continuation May 1, 1997 **19-3—108**

State of Utah

NOTICE OF EFFECTIVE DATE

Submission of this form, by the agency identified below in box 1, establishes the effective date of the indicated rule filing (pursuant to Utah Code Section 63-46a-4).

State of Utah Division of Administrative Rules (DAR) 4120 State Office Building; 450 North Main PO Box 141007 Salt Lake City, UT 84114-1007 Phone: (801) 538-3218, FAX: (801) 538-1773 State E-mail: *asdomain.asitmain.rules*	DAR file no.: 23312 Utah Admin. Code ref. ® no.): R313-19 Date filed: Time filed: Received by:

1. Department: Environmental Quality
   Agency: Radiation Control
   Room no., building: State of Utah Office Park, Bldg. 2
   Street address: 168 North 1950 West
   Mailing address: PO Box 144850
   City, state ZIP: Salt Lake City, UT 84114-4850
   Contact person: Craig Jones
   Telephone: (801) 536-4250
   FAX: (801) 533-4097
   Internet E-mail: cjones@deq.state.ut.us

2. Title of rule or section (catchline):
   Requirements of General Applicability to Licensing of Radioactive Material

3. The rule or change made effective by this notice was submitted as a:
   [ ] New rule [X] Amendment [ ] Repeal
   [ ] Repeal and reenact [ ] Change in proposed rule (DAR file no.:)

4. Indexing information - keywords (maximum of four, in lower case):
   license, reciprocity, transportation, exemptions

5. Indexing information - affected industries (two-digit SIC codes):
   12, 13, 16, 39, 40, 42, 45, 47, 80, 82

6. Effective date (after close of comment period, but not more than 120 days after publication in the *Utah State Bulletin*):
   The rule or change described on this form is effective and enforceable on (mm/dd/yyyy): 01/26/2001

To the agency: This form must be received by the Division of Administrative Rules on or before the date indicated in box 6 (pursuant to Utah Code Section 63-46a-4). **Please do not submit rule text with this form.**

AGENCY AUTHORIZATION

Agency head or designee, and title:	William J. Sinclair, Executive Secretary	Date (mm/dd/yyyy):	01/22/2001

For DAR use only

Rule publication information:

63FR 37059
Licenses for Industrial Radiography ...
effective date 5/11/01

R313. Environmental Quality, Radiation Control.
R313-36. Special Requirements for Industrial Radiographic Operations.
R313-36-1. Purpose and Authority.

(1) The rules in R313-36 prescribe requirements for the issuance of licenses and establish radiation safety requirements for persons utilizing sources of radiation for industrial radiography.

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

(3) The requirements of R313-36 are in addition to, and not in substitution for, the other requirements of these rules.

R313-36-2. Scope.

(1) The requirements of R313-36 shall apply to licensees using radioactive materials to perform industrial radiography.

(2) The requirements of R313-36 shall not apply to persons using electronic sources of radiation to conduct industrial radiography.

R313-36-3. Clarifications or Exceptions.

For purposes of R313-36, 10 CFR 34 ([~~1998~~]2001), is incorporated by reference with the following clarifications or exceptions:

(1) The exclusion of the following 10 CFR sections: "34.1", "34.5", "34.8", "34.11", "34.121", and "34.123";

(2) The exclusion of "10 CFR 34.45(a)(9)";

(3) The exclusion of the following 10 CFR references within 10 CFR 34: "21", "30.7", "30.9", and "30.10";

(4) The exclusion of "offshore" in 10 CFR 34.3 definition for "offshore platform radiography";

(5) The substitution of the following wording:

(a) "Utah Radiation Control Rules" for the reference to:

(i) "Commission's regulations", except as stated in R313-36-3(5)(f);

(ii) "Federal regulations"; and

(iii) "NRC regulations";

(b) "Executive Secretary" for the reference to "Commission", except as stated in 10 CFR 34.20 and R313-36-3(5)(c)(iv);

(c) "Executive Secretary, U.S. Nuclear Regulatory Commission, or an Agreement State" for references to:

(i) "NRC or an Agreement State";

(ii) "Commission or by an Agreement State";

(iii) "Commission or an Agreement State"; and

(iv) "Commission" in 10 CFR 34.43(a)(2);

(d) "License" for reference to "NRC license(s)";

(e) In 10 CFR 34.27(d), "reports of test results for leaking or contaminated sealed sources shall be made pursuant to R313-15-1208.", for reference to the following statements:

(i) "A report must be filed with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, within 5 days of any test with results that exceed the threshold in this subsection, describing the

equipment involved, the test results, and the corrective action taken."; and

(ii) "A copy of the report must be sent to the Administrator of the appropriate Nuclear Regulatory Commission's Regional Office listed in appendix D of 10 CFR part 20 of this chapter "Standards for Protection Against Radiation.";

(f) In 10 CFR 34.27(d), "R313-15-401(6)" for the reference to "Commission regulations";

(g) In 10 CFR 34.89, "[-]a U.S. Nuclear Regulatory Commission or an Agreement State" for the reference to "the Agreement State";

(h) In 10 CFR 34.101(a), "Executive Secretary" for the following wording:

(i) "U.S. Nuclear Regulatory Commission, Division of Industrial and Medical Nuclear Safety, Washington, D.C. 20555-0001, with a copy to the Director, Office for Analysis and Evaluation of Operational Data, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001";

(i) In 10 CFR 34.101(c), "Executive Secretary" for the reference to "appropriate NRC regional office listed in 10 CFR 30.6(a)(2) of this chapter";

(j) In Item 12, Section I of Appendix A to 10 CFR 34, "Executive Secretary, the U.S. Nuclear Regulatory Commission and other independent certifying organizations and/or Agreements States" for the reference to "Commission and other independent certifying organizations and/or Agreement States";

(k) In Item 1, Section II of Appendix A to 10 CFR 34, "equivalent U.S. Nuclear Regulatory Commission or Agreement State regulations" for the reference to "equivalent Agreement State regulations"; and

(l) In Item 2(c), Section II of Appendix A to 10 CFR, "a Utah, U.S. Nuclear Regulatory Commission, or an Agreement State licensee" for the reference to "an Agreement State or a NRC licensee"; and

(6) The substitution of the following R313 references for specific 10 CFR references:

(a) "R313-12-55(1)" for reference to "10 CFR 34.111";

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

(c) "R313-15-601(1)(a)" for the reference to "10 CFR 20.1601(a)(1)";

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

(e) "R313-15-903" for the reference to "10 CFR 20.1903";

(f) "R313-15-1203" for the reference to "10 CFR 20.2203";

(g) "R313-18" for the reference to "10 CFR 19";

(h) "R313-19-30" for the reference to "10 CFR 150.20";

(i) "R313-19-50" for the reference to "10 CFR 30.50";

(j) "R313-19-100" for the reference to "10 CFR 71", "10 CFR 71.5", and "49 CFR 171 to 173";

(k) "R313-22-33" for the reference to "10 CFR 30.33"; and

(l) "R313-36" for the reference to "10 CFR 34." [~~; and~~

~~(7) The substitution of the following dates:~~

~~(a) In 10 CFR 34.42(d) and 10 CFR34.43(a)(2), "June 27, 1999" for the date "May 28, 1999."~~

~~(b) In 10 CFR 34.43(h), "June 27, 1998" for the date "May 28,~~

~~1998."~~]

KEY: industry, radioactive material, licensing, surveys
[~~December 12, 1997~~]2001 19-3-104
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