UTAH STATE BULLETIN

OFFICIAL NOTICES OF UTAH STATE GOVERNMENT
Filed January 01, 2013, 12:00 a.m. through January 15, 2013, 11:59 p.m.

Number 2013-3
February 01, 2013

Nancy L. Lancaster, Editor
Kenneth A. Hansen, Director
Kimberly K. Hood, Executive Director

The *Utah State Bulletin (Bulletin)* is an official noticing publication of the executive branch of Utah State Government. The Department of Administrative Services, Division of Administrative Rules produces the *Bulletin* under authority of Section 63G-3-402.

Inquiries concerning the substance or applicability of an administrative rule that appears in the *Bulletin* should be addressed to the contact person for the rule. Questions about the *Bulletin* or the rulemaking process may be addressed to: Division of Administrative Rules, PO Box 141007, Salt Lake City, Utah 84114-1007, telephone 801-538-3764, FAX 801-537-9240. Additional rulemaking information, and electronic versions of all administrative rule publications are available at: http://www.rules.utah.gov/

The information in this *Bulletin* is summarized in the *Utah State Digest (Digest)*. The *Digest* is available by E-mail or over the Internet. Visit http://www.rules.utah.gov/publicat/digest.htm for additional information.

Division of Administrative Rules, Salt Lake City 84114

Utah state bulletin.
Semimonthly.
1. Delegated legislation--Utah--Periodicals. 2. Administrative procedure--Utah--Periodicals.
I. Utah. Office of Administrative Rules.

KFU440.A73S7
348.792'025--DDC 85-643197

TABLE OF CONTENTS

NOTICES OF
PROPOSED RULES

A state agency may file a **Proposed Rule** when it determines the need for a new rule, a substantive change to an existing rule, or a repeal of an existing rule. Filings received between January 01, 2013, 12:00 a.m., and January 15, 2013, 11:59 p.m. are included in this, the February 01, 2013 issue of the *Utah State Bulletin*.

In this publication, each **Proposed Rule** is preceded by a **Rule Analysis**. This analysis provides summary information about the **Proposed Rule** including the name of a contact person, anticipated cost impact of the rule, and legal cross-references.

Following the **Rule Analysis**, the text of the **Proposed Rule** is usually printed. New rules or additions made to existing rules are underlined (e.g., example). Deletions made to existing rules are struck out with brackets surrounding them (e.g., [~~example~~]). Rules being repealed are completely struck out. A row of dots in the text between paragraphs (**. . . . . .**) indicates that unaffected text from within a section was removed to conserve space. Unaffected sections are not printed. If a **Proposed Rule** is too long to print, the Division of Administrative Rules will include only the **Rule analysis**. A copy of each rule that is too long to print is available from the filing agency or from the Division of Administrative Rules.

The law requires that an agency accept public comment on **Proposed Rules** published in this issue of the *Utah State Bulletin* until at least March 4, 2013. The agency may accept comment beyond this date and will indicate the last day the agency will accept comment in the **Rule Analysis**. The agency may also hold public hearings. Additionally, citizens or organizations may request the agency hold a hearing on a specific **Proposed Rule**. Section 63G-3-302 requires that a hearing request be received by the agency proposing the rule "in writing not more than 15 days after the publication date of the proposed rule."

From the end of the public comment period through June 1, 2013, the agency may notify the Division of Administrative Rules that it wants to make the **Proposed Rule** effective. The agency sets the effective date. The date may be no fewer than seven calendar days after the close of the public comment period nor more than 120 days after the publication date of this issue of the *Utah State Bulletin*. Alternatively, the agency may file a **Change in Proposed Rule** in response to comments received. If the Division of Administrative Rules does not receive a **Notice of Effective Date** or a **Change in Proposed Rule**, the **Proposed Rule** lapses and the agency must start the process over.

The public, interest groups, and governmental agencies are invited to review and comment on **Proposed Rules**. *Comment may be directed to the contact person identified on the* Rule Analysis *for each rule.*

Proposed Rules are governed by Section 63G-3-301; Rule R15-2; and Sections R15-4-3, R15-4-4, R15-4-5, R15-4-9, and R15-4-10.

The Proposed Rules Begin on the Following Page

Commerce, Occupational And Professional Licensing
R156-1-102
Definitions

NOTICE OF PROPOSED RULE
(Amendment)
DAR FILE NO.: 37199
FILED: 01/14/2013

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: The Division needs to clarify the type of evidence that may not be considered as a mitigating circumstance in informal disciplinary proceedings brought on the basis of findings or sanctions issued in a prior criminal case or disciplinary action.

SUMMARY OF THE RULE OR CHANGE: In Subsection R156-1-102(16), the definition of "mitigating circumstances" is expanded to specify the arguments and evidence that may not be considered in an informal disciplinary proceeding brought on the basis of a prior criminal case or disciplinary action (a proceeding referred to as "reciprocal discipline" by the Division). Well-established case law prohibits the relitigation of the prior case. The proposed rule amendments codify this case law by specifying that procedural and evidentiary arguments regarding the fairness, appropriateness, or validity of a prior proceeding may not be considered as establishing a mitigating circumstance.

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Section 58-1-308 and Subsection 58-1-106(1)(a) and Subsection 58-1-501(4)

ANTICIPATED COST OR SAVINGS TO:
♦ THE STATE BUDGET: The Division will incur minimal costs of approximately $100 to print and distribute the rule once the proposed amendments are made effective. Any costs incurred will be absorbed in the Division's current budget. It is also anticipated that the state will experience a savings in the form of increased efficiency in adjudicating reciprocal discipline matters. The proposed amendments will focus these informal proceedings on the relevant issues, relieving the state's counsel from having to file briefs and engage in oral argument on a case-by-case basis whenever a respondent attempts to relitigate a prior proceeding.
♦ LOCAL GOVERNMENTS: Local government is not required to comply with or enforce this administrative rule. Therefore, no fiscal impact to local government is anticipated.
♦ SMALL BUSINESSES: A small business that is named as a respondent in a reciprocal discipline proceeding should experience a cost savings insofar as the rule amendments will help the business focus its defense on relevant matters, rather than going to the expense and trouble of briefing arguments that, pursuant to well-established case law, may not be considered. The Division, however, is not able to quantify an exact amount of cost savings due to varying factors.
♦ PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES: An affected person who is named as a respondent in a reciprocal discipline proceeding should experience a cost savings insofar as the rule amendments will help the person focus the person's defense on relevant matters, rather than going to the expense and trouble of briefing arguments that, pursuant to a well-established case law, may not be considered. The Division, however, is not able to quantify an exact amount of cost savings due to varying factors.

COMPLIANCE COSTS FOR AFFECTED PERSONS: To comply, affected persons must focus their arguments in a reciprocal discipline case on relevant issues. There are no costs beyond those normally associated with preparing a case for hearing.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: As stated in the rule analysis, the proposed filing codifies the existing case law that prohibits a respondent from relitigating a prior criminal case or disciplinary action before a licensing board. It is possible that affected businesses will experience reduced litigation expenses by complying with the rule and properly focusing their defense at the outset of an administrative disciplinary case.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
COMMERCE
OCCUPATIONAL AND PROFESSIONAL LICENSING
HEBER M WELLS BLDG
160 E 300 S
SALT LAKE CITY, UT 84111-2316
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ W. Ray Walker by phone at 801-530-6256, by FAX at 801-530-6511, or by Internet E-mail at raywalker@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 03/04/2013

THIS RULE MAY BECOME EFFECTIVE ON: 03/11/2013

AUTHORIZED BY: Mark Steinagel, Director

R156. Commerce, Occupational and Professional Licensing.
R156-1. General Rule of the Division of Occupational and Professional Licensing.
R156-1-102. Definitions.

In addition to the definitions in Title 58, as used in Title 58 or this rule:

(1) "Active and in good standing" means a licensure status which allows the licensee full privileges to engage in the practice of the occupation or profession subject to the scope of the licensee's license classification.

(2) "Aggravating circumstances" means any consideration or factors that may justify an increase in the severity of an action to be imposed upon an applicant or licensee. Aggravating circumstances include:

(a) prior record of disciplinary action, unlawful conduct, or unprofessional conduct;

(b) dishonest or selfish motive;

(c) pattern of misconduct;

(d) multiple offenses;

(e) obstruction of the disciplinary process by intentionally failing to comply with rules or orders of the Division;

(f) submission of false evidence, false statements or other deceptive practices during the disciplinary process including creating, destroying or altering records after an investigation has begun;

(g) refusal to acknowledge the wrongful nature of the misconduct involved, either to the client or to the Division;

(h) vulnerability of the victim;

(i) lack of good faith to make restitution or to rectify the consequences of the misconduct involved;

(j) illegal conduct, including the use of controlled substances; and

(k) intimidation or threats of withholding clients' records or other detrimental consequences if the client reports or testifies regarding the unprofessional or unlawful conduct.

(3) "Cancel" or "cancellation" means nondisciplinary action by the Division to rescind, repeal, annul, or void a license issued in error. Such action includes rescinding a license issued to an applicant whose payment of the required application fee is dishonored when presented for payment, or who has been issued a conditional license pending a criminal background check and the check cannot be completed due to the applicant's failure to resolve an outstanding warrant or to submit acceptable fingerprint cards.

(4) "Charges" means the acts or omissions alleged to constitute either unprofessional or unlawful conduct or both by a licensee, which serve as the basis to consider a licensee for inclusion in the diversion program authorized in Section 58-1-404.

(5) "Denial of licensure" means action by the Division refusing to issue a license to an applicant for initial licensure, renewal of licensure, reinstatement of licensure or relicensure.

(6)(a) "Disciplinary action" means adverse licensure action by the Division under the authority of Subsections 58-1-401(2)(a) through (2)(b).

(b) "Disciplinary action", as used in Subsection 58-1-401(5), shall not be construed to mean an adverse licensure action taken in response to an application for licensure. Rather, as used in Subsection 58-1-401(5), it shall be construed to mean an adverse action initiated by the Division.

(7) "Diversion agreement" means a formal written agreement between a licensee, the Division, and a diversion committee, outlining the terms and conditions with which a licensee must comply as a condition of entering in and remaining under the diversion program authorized in Section 58-1-404.

(8) "Diversion committees" mean diversion advisory committees authorized by Subsection 58-1-404(2)(a)(i) and created under Subsection R156-1-404a.

(9) "Duplicate license" means a license reissued to replace a license which has been lost, stolen, or mutilated.

(10) "Emergency review committees" mean emergency adjudicative proceedings review committees created by the Division under the authority of Subsection 58-1-108(2).

(11) "Expire" or "expiration" means the automatic termination of a license which occurs:

(a) at the expiration date shown upon a license if the licensee fails to renew the license before the expiration date; or

(b) prior to the expiration date shown on the license:

(i) upon the death of a licensee who is a natural person;

(ii) upon the dissolution of a licensee who is a partnership, corporation, or other business entity; or

(iii) upon the issuance of a new license which supersedes an old license, including a license which:

(A) replaces a temporary license;

(B) replaces a student or other interim license which is limited to one or more renewals or other renewal limitation; or

(C) is issued to a licensee in an upgraded classification permitting the licensee to engage in a broader scope of practice in the licensed occupation or profession.

(12) "Inactive" or "inactivation" means action by the Division to place a license on inactive status in accordance with Sections 58-1-305 and R156-1-305.

(13) "Investigative subpoena authority" means, except as otherwise specified in writing by the director, the Division regulatory and compliance officer, or if the Division regulatory and compliance officer is unable to so serve for any reason, a Department administrative law judge, or if both the Division regulatory and compliance officer and a Department administrative law judge are unable to so serve for any reason, an alternate designated by the director in writing.

(14) "License" means a right or privilege to engage in the practice of a regulated occupation or profession as a licensee.

(15) "Limit" or "limitation" means nondisciplinary action placing either terms and conditions or restrictions or both upon a license:

(a) issued to an applicant for initial licensure, renewal or reinstatement of licensure, or relicensure; or

(b) issued to a licensee in place of the licensee's current license or disciplinary status.

(16) "Mitigating circumstances" means any consideration or factors that may justify a reduction in the severity of an action to be imposed upon an applicant or licensee.

(a) Mitigating circumstances include:

(i) absence of prior record of disciplinary action, unlawful conduct or unprofessional conduct;

(ii) personal, mental or emotional problems provided such problems have not posed a risk to the health, safety or welfare of the public or clients served such as drug or alcohol abuse while engaged in work situations or similar situations where the licensee

or applicant should know that they should refrain from engaging in activities that may pose such a risk;

(iii) timely and good faith effort to make restitution or rectify the consequences of the misconduct involved;

(iv) full and free disclosure to the client or Division prior to the discovery of any misconduct;

(v) inexperience in the practice of the occupation and profession provided such inexperience is not the result of failure to obtain appropriate education or consultation that the applicant or licensee should have known they should obtain prior to beginning work on a particular matter;

(vi) imposition of other penalties or sanctions if the other penalties and sanctions have alleviated threats to the public health, safety, and welfare; and

(vii) remorse.

(b) The following factors [~~should~~]may not be considered as mitigating circumstances:

(i) forced or compelled restitution;

(ii) withdrawal of complaint by client or other affected persons;

(iii) resignation prior to disciplinary proceedings;

(iv) failure of injured client to complain;[~~and~~]

(v) complainant's recommendation as to sanction; and

(vi) in an informal disciplinary proceeding brought pursuant to Subsection 58-1-501(2)(c) or (d) or Subsections R156-1-501(1) through (5):

(A) argument that a prior proceeding was conducted unfairly, contrary to law, or in violation of due process or any other procedural safeguard;

(B) argument that a prior finding or sanction was contrary to the evidence or entered without due consideration of relevant evidence;

(C) argument that a respondent was not adequately represented by counsel in a prior proceeding; and

(D) argument or evidence that former statements of a respondent made in conjunction with a plea or settlement agreement are not, in fact, true.

(17) "Nondisciplinary action" means adverse licensure action by the Division under the authority of Subsections 58-1-401(1) or 58-1-401(2)(c) through (2)(d).

(18) "Peer committees" mean advisory peer committees to boards created by the legislature in Title 58 or by the Division under the authority of Subsection 58-1-203(1)(f).

(19) "Probation" means disciplinary action placing terms and conditions upon a license;

(a) issued to an applicant for initial licensure, renewal or reinstatement of licensure, or relicensure; or

(b) issued to a licensee in place of the licensee's current license or disciplinary status.

(20) "Public reprimand" means disciplinary action to formally reprove or censure a licensee for unprofessional or unlawful conduct, with the documentation of the action being classified as a public record.

(21) "Regulatory authority" as used in Subsection 58-1-501(2)(d) means any governmental entity who licenses, certifies, registers, or otherwise regulates persons subject to its jurisdiction, or who grants the right to practice before or otherwise do business with the governmental entity.

(22) "Reinstate" or "reinstatement" means to activate an expired license or to restore a license which is restricted, as defined in Subsection (26)(b), or is suspended, or placed on probation, to a lesser restrictive license or an active in good standing license.

(23) "Relicense" or "relicensure" means to license an applicant who has previously been revoked or has previously surrendered a license.

(24) "Remove or modify restrictions" means to remove or modify restrictions, as defined in Subsection (25)(a), placed on a license issued to an applicant for licensure.

(25) "Restrict" or "restriction" means disciplinary action qualifying or limiting the scope of a license:

(a) issued to an applicant for initial licensure, renewal or reinstatement of licensure, or relicensure in accordance with Section 58-1-304; or

(b) issued to a licensee in place of the licensee's current license or disciplinary status.

(26) "Revoke" or "revocation" means disciplinary action by the Division extinguishing a license.

(27) "Suspend" or "suspension" means disciplinary action by the Division removing the right to use a license for a period of time or indefinitely as indicated in the disciplinary order, with the possibility of subsequent reinstatement of the right to use the license.

(28) "Surrender" means voluntary action by a licensee giving back or returning to the Division in accordance with Section 58-1-306, all rights and privileges associated with a license issued to the licensee.

(29) "Temporary license" or "temporary licensure" means a license issued by the Division on a temporary basis to an applicant for initial licensure, renewal or reinstatement of licensure, or relicensure in accordance with Section 58-1-303.

(30) "Unprofessional conduct" as defined in Title 58 is further defined, in accordance with Subsection 58-1-203(1)(e), in Section R156-1-502.

(31) "Warning or final disposition letters which do not constitute disciplinary action" as used in Subsection 58-1-108(3) mean letters which do not contain findings of fact or conclusions of law and do not constitute a reprimand, but which may address any or all of the following:

(a) Division concerns;

(b) allegations upon which those concerns are based;

(c) potential for administrative or judicial action; and

(d) disposition of Division concerns.

KEY: diversion programs, licensing, [~~occupational licensing,~~] supervision, evidentiary restrictions

Date of Enactment or Last Substantive Amendment: [~~November 26, 2012~~]2013

Notice of Continuation: January 5, 2012

Authorizing, and Implemented or Interpreted Law: 58-1-106(1)(a); 58-1-308; 58-1-501(4)

Commerce, Occupational And Professional Licensing
R156-82
Electronic Prescribing Act Rule

NOTICE OF PROPOSED RULE
(New Rule)
DAR FILE NO.: 37202
FILED: 01/15/2013

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: The Division needs to establish a rule which clarifies provisions in Title 58, Chapter 82, the Electronic Prescribing Act.

SUMMARY OF THE RULE OR CHANGE: Section R156-82-101 establishes the title for the rule. Section R156-82-103 establishes the authority of the Division to enact the rule. Section R156-82-201 explains the security requirements to transmit and receive electronic prescriptions. Section R156-82-202 describes the practitioner's requirements to inform their patients of their rights, restrictions, and responsibilities. Section R156-82-203 explains that the Division may grant waivers.

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Section 58-82-101 and Subsection 58-1-106(1)(a)

MATERIALS INCORPORATED BY REFERENCE:
♦ Adds 21 CFR Part 1311, published by United States Government Printing Office, April 1, 2012

ANTICIPATED COST OR SAVINGS TO:
♦ THE STATE BUDGET: The Division will incur minimal costs of approximately $50 to print and distribute the new rule once the proposed amendments are made effective. Any costs incurred will be absorbed in the Division's current budget.
♦ LOCAL GOVERNMENTS: The proposed new rule only applies to licensees who prescribe drugs in the normal course of their employment, licensed pharmacists who fill said prescriptions, and applicants in those license classifications. As a result, the proposed new rule does not apply to local governments.
♦ SMALL BUSINESSES: The proposed new rule only applies to licensees who prescribe drugs in the normal course of their employment., licensed pharmacists who fill said prescriptions, and applicants in those license classifications. Those who are affected have the right to request a waiver for financial hardship with the Division. Any costs associated with the implementation of the governing statute, Title 58, Chapter 82, would have been addressed when the statute was initially passed by the Legislature in 2009 in HB 128.
♦ PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES: The proposed new rule only applies to licensees who prescribe drugs in the normal course of their employment., licensed pharmacists who fill said prescriptions, and applicants in those license classifications. Those who are affected have the right to request a waiver for financial hardship with the Division. Any costs associated with the implementation of the governing statute, Title 58, Chapter 82, would have been addressed when the statute was initially passed by the Legislature in 2009 in HB 128.

COMPLIANCE COSTS FOR AFFECTED PERSONS: The proposed new rule only applies to licensees who prescribe drugs in the normal course of their employment., licensed pharmacists who fill said prescriptions, and applicants in those license classifications. Those who are affected have the right to request a waiver for financial hardship with the Division. Any costs associated with the implementation of the governing statute, Title 58, Chapter 82, would have been addressed when the statute was initially passed by the Legislature in 2009 in HB 128.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: Many businesses have the software and other technology in place that is required to facilitate electronic prescribing. These businesses will not experience any fiscal impact from this rule filing. Businesses that do not have the necessary technology will incur costs if they choose to implement electronic prescribing. Those costs will vary and cannot be estimated. Any business that does not wish to incur such costs may obtain a waiver from the Division and continue to prescribe according to its current practice. Therefore, any fiscal impact will be incurred voluntarily, if at all.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
COMMERCE
OCCUPATIONAL AND PROFESSIONAL LICENSING
HEBER M WELLS BLDG
160 E 300 S
SALT LAKE CITY, UT 84111-2316
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Mark Steinagel by phone at 801-530-6292, by FAX at 801-530-6511, or by Internet E-mail at msteinagel@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 03/04/2013

INTERESTED PERSONS MAY ATTEND A PUBLIC HEARING REGARDING THIS RULE:
♦ 02/25/2013 11:00 PM, Heber Wells Bldg, 160 E 300 S, Conference Room 474, Salt Lake City, UT

THIS RULE MAY BECOME EFFECTIVE ON: 03/11/2013

AUTHORIZED BY: Mark Steinagel, Director

R156. Commerce, Occupational and Professional Licensing.
R156-1. Electronic Prescribing Act Rule.
R156-1-101. Title.
This rule is known as the "Electronic Prescribing Act Rule."

R156-1-103. Authority - Purpose.
This rule is adopted by the Division under the authority of Subsection 58-1-106(1)(a) to enable the Division to administer Title 58, Chapter 82.

R156-82-201. Security.
(1) Practitioners and pharmacies who transmit and receive controlled substance prescriptions shall comply with 21 CFR 1311, dated April 1, 2012, which is adopted and incorporated by reference.
(2) Electronic prescribing for non-controlled substances shall be conducted in a secure manner, consistent with industry standards.

R156-82-202. Informing Patients.
(1) Practitioners shall fully inform their patients of their:
(a) rights;
(b) restrictions; and
(c) obligations pertaining to electronic prescribing.

R156-82-203. Waiver.
The Division may grant an exemption from the requirements in accordance with Subsection 58-82-201(6).

KEY: licensing, electronic prescribing
Date of Enactment or Last Substantive Amendment: 2013
Authorizing, and Implemented or Interpreted Law: 58-1-106(1)(a); 58-82-101

Environmental Quality, Radiation Control
R313-12
General Provisions

NOTICE OF PROPOSED RULE
(Amendment)
DAR FILE NO.: 37189
FILED: 01/11/2013

RULE ANALYSIS
PURPOSE OF THE RULE OR REASON FOR THE CHANGE: Changes are required to conform with S.B. 21, 2012 General Session (Chapter 360, Laws of Utah 2012).

SUMMARY OF THE RULE OR CHANGE: S.B. 21 (2012) gave authority to the Director of the Division of Radiation Control to make many regulatory decisions that had previously been made either by the Radiation Control Board or by the Executive Secretary of the Radiation Control Board. This rule change implements these statutory changes by replacing occurrences of both "executive secretary" and "board" with "director." Definitions are added for "director" and "division." The definition for "executive secretary" is removed.

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Section 19-3-104 and Section 19-3-108

ANTICIPATED COST OR SAVINGS TO:
♦ THE STATE BUDGET: There are no anticipated costs or savings to the state budget as this amendment only changes who has authority to make regulatory decisions.
♦ LOCAL GOVERNMENTS: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.
♦ SMALL BUSINESSES: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.
♦ PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.

COMPLIANCE COSTS FOR AFFECTED PERSONS: There are no compliance costs for affected persons as this amendment only changes who has authority to make regulatory decisions.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: There is no anticipated fiscal impact on businesses as this amendment only changes who has authority to make regulatory decisions.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
ENVIRONMENTAL QUALITY
RADIATION CONTROLROOM THIRD FLOOR
195 N 1950 W
SALT LAKE CITY, UT 84116-3085
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Craig Jones by phone at 801-536-4264, by FAX at 801-533-4097, or by Internet E-mail at cwjones@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 03/04/2013

THIS RULE MAY BECOME EFFECTIVE ON: 03/19/2013

AUTHORIZED BY: Rusty Lundberg, Director

R313. Environmental Quality, Radiation Control.
R313-12. General Provisions.
R313-12-1. Authority.

The rules set forth herein are adopted pursuant to the provisions of Subsections 19-3-104(4) and 19-3-104(8) and Section 63J-1-504.

R313-12-2. Purpose and Scope.

It is the purpose of these rules to state such requirements as shall be applied in the use of radiation, radiation machines, and radioactive materials to ensure the maximum protection of the public health and safety to all persons at, or in the vicinity of, the place of use, storage, or disposal. These rules are intended to be consistent with the proper use of radiation machines and radioactive materials. Except as otherwise specifically provided, these rules apply to all persons who receive, possess, use, transfer, own or acquire any source of radiation, provided, however, that nothing in these rules shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission. See also Section R313-12-55.

R313-12-3. Definitions.

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

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

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

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

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

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

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

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

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

"Advanced practice registered nurse" means an individual licensed by this state to engage in the practice of advanced practice registered nursing. See Sections 58-31b-101 through 58-31b-801, Nurse Practice Act.

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

"Airborne radioactive material" means a radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

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

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

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

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

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

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

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

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

"Board" means the Radiation Control Board created under Section [~~19-1-106~~]19-1-103.

"Byproduct material" means:

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

(b) the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

(c) (i) a discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) material that

(A) has been made radioactive by use of a particle accelerator; and

(B) is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(d) a discrete source of naturally occurring radioactive material, other than source material, that

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, has determined would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

"Calibration" means the determination of:

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

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

"CFR" means Code of Federal Regulations.

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

"Chiropractor" means an individual licensed by this state to engage in the practice of chiropractic. See Sections 58-73-101 through 58-73-701, Chiropractic Physician Practice Act.

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

"Commission" means the U.S. Nuclear Regulatory Commission.

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

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

"Consortium" means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution, a Federal facility, or a medical facility.

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

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

"Curie" means a unit of measurement of activity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7 x 1010 disintegrations or transformations per second (dps or tps).

"Cyclotron means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.

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

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

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

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

"Dentist" means an individual licensed by this state to engage in the practice of dentistry. See sections 58-69-101 through 58-69-805, Dentist and Dental Hygienist Practice Act.

"Department" means the Utah State Department of Environmental Quality.

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

"Diffuse source" means a radionuclide that has been unintentionally produced or concentrated during the processing of materials for use for commercial, medical, or research activities.

"Director" means the Director of the Division of Radiation Control.

"Discrete source" means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Individual" means a human being.

"Individual monitoring" means the assessment of:

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

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

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

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

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

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

"Lens dose equivalent" (LDE) applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

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

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

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

"Licensing state" means a state which, prior to November 30, 2007, was provisionally or finally designated as such by the Conference of Radiation Control Program Directors, Inc., which reviewed state regulations to establish equivalency with the Suggested State Regulations and ascertained whether a State has an effective program for control of natural occurring or accelerator produced radioactive material.

"Limits". See "Dose limits".

"Lost or missing source of radiation" means licensed or registered sources of radiation whose location is unknown. This definition includes, but is not limited to, radioactive material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

"Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in 10 CFR 71.4.

"Member of the public" means an individual except when that individual is receiving an occupational dose.

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

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

"Natural radioactivity" means radioactivity of naturally occurring nuclides.

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

"Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties for the licensee or registrant involve exposure to sources of radiation, whether or not the sources of radiation are in the possession of the licensee, registrant, or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Rule R313-32, 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 megaelectron volt. For purposes of these rules, "accelerator" is an equivalent term.

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

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

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

"Personnel monitoring equipment," see individual monitoring devices.

"Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy. See Sections 58-17a-101 through 58-17a-801, Pharmacy Practice Act.

"Physician" means both physicians and surgeons licensed under Section 58-67-301, Utah Medical Practice Act, and osteopathic physicians and surgeons licensed under Section 58-68-301, Utah Osteopathic Medical Practice Act.

"Physician assistant" means an individual licensed by this state to engage in practice as a physician assistant. See Sections 58-70a-101 through 58-70a-504, Physician Assistant Act.

"Podiatrist" means an individual licensed by this state to engage in the practice of podiatry. See Sections 58-5a-101 through 58-5a-501, Podiatric Physician Licensing Act.

"Practitioner" means an individual licensed by this state in the practice of a healing art. For these rules, only the following are considered to be a practitioner: physician, dentist, podiatrist, chiropractor, physician assistant, and advanced practice registered nurse.

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

"Public dose" means the dose received by a member of the public from exposure to radiation or to radioactive materials released by a licensee, or to any other source of radiation under the control of a licensee or registrant. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Rule R313-32, or from voluntary participation in medical research programs.

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

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

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

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

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

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

"Radiation safety officer" means an individual who has the knowledge and responsibility to apply appropriate radiation protection rules and has been assigned such responsibility by the licensee or registrant. For a licensee authorized to use radioactive materials in accordance with the requirements of Rule R313-32,

(1) the individual named as the "Radiation Safety Officer" must meet the training requirements for a Radiation Safety Officer as stated in Rule R313-32; or

(2) the individual must be identified as a "Radiation Safety Officer" on

(a) a specific license issued by the [~~Executive Secretary~~]Director, the U.S. Nuclear Regulatory Commission, or an Agreement State that authorizes the medical use of radioactive materials; or

(b) a medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee.

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

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

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

"Radiobioassay". See "Bioassay".

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

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

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

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

"Research and development" means:

(a) theoretical analysis, exploration, or experimentation; or

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

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

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

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

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

"Shallow dose equivalent" (Hs) which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (seven mg per cm2).

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

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

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

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

"Source material" means:

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

(b) ores that contain by weight one-twentieth of one percent (0.05 percent), or more of, uranium, thorium, or any combination of uranium and thorium. Source material does not include special nuclear material.

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

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

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

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

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

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

"Special nuclear material" means:

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

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

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

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

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

"Test" means the process of verifying compliance with an applicable rule.

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

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

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

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

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

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

"Waste" means those low-level radioactive wastes containing radioactive material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs (b), (c), and (d) of the definition of byproduct material found in Section R313-12-3.

"Week" means seven consecutive days starting on Sunday.

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

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

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

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

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

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

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

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

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

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

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

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

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

TABLE 1

Quality Factors and Absorbed Dose Equivalencies

Type of Radiation	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent
X, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High energy protons	10	0.1

For the column in Table 1 labeled "Absorbed Dose Equal to a Unit Dose Equivalent", the absorbed dose in rad is equal to one rem or the absorbed dose in gray is equal to one Sv.

(4) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in Subsection R313-12-20(3), 0.01 Sv of neutron radiation of unknown energies may, for purposes of these rules, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table 2 to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

TABLE 2

Mean Quality Factors, Q, and Fluence Per Unit Dose Equivalent for Monoenergetic Neutrons

	Neutron Energy Mev	Quality Factor Q	Fluence per Unit Dose Equivalent neutrons cm^{-2} rem^{-1}	Fluence per Unit Dose Equivalent neutrons cm^{-2} Sv^{-1}
thermal	2.5×10^{-8}	2	980×10^{6}	980×10^{8}
	1×10^{-7}	2	980×10^{6}	980×10^{8}
	1×10^{-6}	2	810×10^{6}	810×10^{8}
	1×10^{-5}	2	810×10^{6}	810×10^{8}
	1×10^{-4}	2	840×10^{6}	840×10^{8}
	1×10^{-3}	2	980×10^{6}	980×10^{8}
	1×10^{-2}	2.5	1010×10^{6}	1010×10^{8}
	1×10^{-1}	7.5	170×10^{6}	170×10^{8}
	5×10^{-1}	11	39×10^{6}	39×10^{8}
	1	11	27×10^{6}	27×10^{8}
	2.5	9	29×10^{6}	29×10^{8}
	5	8	23×10^{6}	23×10^{8}
	7	7	24×10^{6}	24×10^{8}
	10	6.5	24×10^{6}	24×10^{8}
	14	7.5	17×10^{6}	17×10^{8}
	20	8	16×10^{6}	16×10^{8}
	40	7	14×10^{6}	14×10^{8}
	60	5.5	16×10^{6}	16×10^{8}
	1×10^{2}	4	20×10^{6}	20×10^{8}
	2×10^{2}	3.5	19×10^{6}	19×10^{8}
	3×10^{2}	3.5	16×10^{6}	16×10^{8}
	4×10^{2}	3.5	14×10^{6}	14×10^{8}

For the column in Table 2 labeled "Quality Factor", the values of Q are at the point where the dose equivalent is maximum in a 30 cm diameter cylinder tissue-equivalent phantom.

For the columns in Table 2 labeled "Fluence per Unit Dose Equivalent", the values are for monoenergetic neutrons incident normally on a 30 cm diameter cylinder tissue equivalent phantom.

R313-12-40. Units of Radioactivity.

For purposes of these rules, activity is expressed in the SI unit of becquerel (Bq), or in the special unit of curie (Ci), or their multiples, or disintegrations or transformations per unit of time.

(1) One becquerel (Bq) equals one disintegration or transformation per second.

(2) One curie (Ci) equals 3.7×10^{10} disintegrations or transformations per second, which equals 3.7×10^{10} becquerel, which equals 2.22×10^{12} disintegrations or transformations per minute.

R313-12-51. Records.

(1) A licensee or registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation.

(2) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, may forward the following records to the [~~Executive Secretary~~]Director:

(a) records of disposal of licensed material made under Sections R313-15-1002 (including burials authorized before January 28, 1981), R313-15-1003, R313-15-1004, and R313-15-1005; and

(b) records required by Subsection R313-15-1103(2)(d).

NOTE: 10 CFR 20.304 permitted burial of small quantities of licensed materials in soil before January 28, 1981, without specific U.S. Nuclear Regulatory Commission authorization. See 20.304 contained in the 10 CFR, parts 0 to 199, edition revised as of January 1, 1981.

(3) If licensed activities are transferred or assigned in accordance with Subsection R313-19-34(2), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(a) records of disposal of licensed material made under Sections R313-15-1002 (including burials authorized before January 28, 1981), R313-15-1003, R313-15-1004, R313-15-1005, and R313-15-1008; and

(b) records required by Subsection R313-15-1103(2)(d).

(4) Prior to license termination, each licensee may forward the records required by Subsection R313-22-35(7) to the [~~Executive Secretary~~]Director.

(5) Additional records requirements are specified elsewhere in these rules.

R313-12-52. Inspections.

(1) A licensee or registrant shall afford representatives of the [~~Executive Secretary~~]Director, at reasonable times, opportunity to inspect sources of radiation and the premises and facilities wherein those sources of radiation are used or stored.

(2) A licensee or registrant shall make available to representatives of the [~~Executive Secretary~~]Director for inspection, at any reasonable time, records maintained pursuant to these rules.

R313-12-53. Tests.

(1) A licensee or registrant shall perform upon instructions from a representative of the [~~Board or the Executive Secretary~~]Director or shall permit the representative to perform reasonable tests as the representative deems appropriate or necessary including, but not limited to, tests of:

(a) sources of radiation;

(b) facilities wherein sources of radiation are used or stored;

(c) radiation detection and monitoring instruments; and

(d) other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

R313-12-54. Additional Requirements.

The [~~Board~~]Director may, by [~~rule, or~~]order, impose upon a licensee or registrant requirements in addition to those established in these rules that [~~it~~]the Director deems appropriate or necessary to minimize any danger to public health and safety or the environment.

R313-12-55. Exemptions.

(1) The Board may, upon application or upon its own initiative, grant exemptions or exceptions from the requirements of these rules as it determines are authorized by law and will not result in undue hazard to public health and safety or the environment.

(2) U.S. Department of Energy contractors or subcontractors and U.S. Nuclear Regulatory Commission contractors or subcontractors operating within this state are exempt from these rules to the extent that the contractor or subcontractor under his contract receives, possesses, uses, transfers, or acquires sources of radiation. The following contractor categories are included:

(a) prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or controlled sites,

including the transportation of sources of radiation to or from the sites and the performance of contract services during temporary interruptions of the transportation;

(b) prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof;

(c) prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and

(d) any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the state and the U.S. Nuclear Regulatory Commission jointly determine (i) that the exemption of the prime contractor or subcontractor is authorized by law; and (ii) that under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

R313-12-70. Impounding.

Sources of radiation shall be subject to impounding pursuant to Section 19-3-111. Persons who have a source of radiation impounded are subject to fees established in accordance with the Legislative Appropriations Act for the actual cost of the management and oversight activities performed by representatives of the [~~Executive Secretary~~]Director.

R313-12-100. Prohibited Uses.

(1) A hand-held fluoroscopic screen using x-ray equipment shall not be used unless it has been listed in the Registry of Sealed Source and Devices or accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health.

(2) A shoe-fitting fluoroscopic device shall not be used.

R313-12-110. Communications.

All communications and reports concerning these rules, and applications filed thereunder, should be addressed to the Division of Radiation Control, P.O. Box 144850, 195 North 1950 West, Salt Lake City, Utah 84114-4850.

R313-12-111. Submission of Electronic Copies.

(1) All submissions to the [~~Executive Secretary~~]Director not exempt in paragraph R313-12-111(5) shall also be submitted to the [~~Executive Secretary~~]Director in electronic format. This requirement extends to all attachments to these documents.

(2) The electronic copy shall be a true, accurate, searchable and reproducible copy of the official submission, except that it need not include signatures or professional stamps.

(3) All electronic copies shall be submitted on a CD or DVD nonrewritable disc, except that documents smaller than 25 megabytes may be submitted by email.

(4) All documents shall be submitted in one of the following electronic formats, at the choice of the submitter:

(a) A searchable PDF document (a document that may be read and searched using Adobe Reader); or

(b) A Microsoft Word document.

(5) The requirements of this rule do not apply to:

(a) X-ray registration applications;

(b) Submissions shorter than 25 pages unless otherwise ordered by the [~~Executive Secretary~~]Director;

(c) Public comments received during a formal public comment period;

(d) Correspondence received from individuals or organizations that are not currently regulated by the agency, unless that correspondence is about proposing an activity or facility that would be subject to agency regulation; and

(e) Documents used to make payments to the agency.

(6) If an official submission includes information for which business confidentiality is claimed or that is security-sensitive, this requirement applies only to that portion of the submission for which no confidentiality is claimed.

(7) The [~~Executive Secretary~~]Director may waive the requirements of R313-12-111(1) for good cause.

KEY: definitions, units, inspections, exemptions
Date of Enactment or Last Substantive Amendment: [~~October 13, 2010~~]2013
Notice of Continuation: July 7, 2011
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-3-108

Environmental Quality, Radiation Control
R313-14
Violations and Escalated Enforcement

NOTICE OF PROPOSED RULE
(Amendment)
DAR FILE NO.: 37190
FILED: 01/11/2013

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: Changes are required to conform with S.B. 21, 2012 General Session (Chapter 360, Laws of Utah 2012).

SUMMARY OF THE RULE OR CHANGE: S.B. 21 (2012) gave authority to the Director of the Division of Radiation Control to make many regulatory decisions that had previously been made either by the Radiation Control Board or by the Executive Secretary of the Radiation Control Board. This rule change implements these statutory changes by replacing occurrences of both "executive secretary" and "board" with "director." Responsibilities of the "executive secretary" are removed.

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Section 19-3-109 and Section 19-3-111

ANTICIPATED COST OR SAVINGS TO:
♦ THE STATE BUDGET: There are no anticipated costs or savings to the state budget as this amendment only changes who has authority to make regulatory decisions.

♦ LOCAL GOVERNMENTS: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.
♦ SMALL BUSINESSES: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.
♦ PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.

COMPLIANCE COSTS FOR AFFECTED PERSONS: There are no compliance costs for affected persons as this amendment only changes who has authority to make regulatory decisions.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: There is no anticipated fiscal impact on businesses as this amendment only changes who has authority to make regulatory decisions.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
ENVIRONMENTAL QUALITY
RADIATION CONTROLROOM THIRD FLOOR
195 N 1950 W
SALT LAKE CITY, UT 84116-3085
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Craig Jones by phone at 801-536-4264, by FAX at 801-533-4097, or by Internet E-mail at cwjones@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 03/04/2013

THIS RULE MAY BECOME EFFECTIVE ON: 03/19/2013

AUTHORIZED BY: Rusty Lundberg, Director

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

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

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

(b) obtaining prompt correction of violations;

(c) deterring future violations; and

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

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

(3) The rules set forth herein are adopted pursuant to the provisions of Subsections 19-3-103.5(1)(d), 19-3-104(4) and 19-3-104(8), 19-3-108, 19-3-109, and 19-3-111.

[~~**R313-14-2. Responsibilities.**~~
~~(1) The Board has authorized the Executive Secretary to:~~
~~(a) enforce rules through the issuance of orders and assess penalties in accordance with Section 19-3-109; and~~
~~(b) impound radioactive material in accordance with Section 19-3-111.~~
~~(2) The Executive Secretary is authorized to issue Notices of Violations.~~

]**R313-14-3. Definitions.**

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

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

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

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

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

R313-14-10. Severity of Violations.

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

(a) electronically produced radiation operations; or

(b) radioactive materials operations.

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

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

(4) The severity of a violation shall be characterized at the level best suited to the significance of the particular violation. A severity level may be increased if the circumstances surrounding the violation involve careless disregard of requirements, deception, or other indications of willfulness. In determining the specific severity

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

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

R313-14-15. Enforcement Actions.

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

(1) Notice of Violation

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

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

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

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

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

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

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

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

(iii) it was reported, in writing, to the [~~Executive Secretary~~]Director;

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

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

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

(2) Civil Penalty.

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

(b) The level of a civil penalty is established so that a penalty does not exceed $5,000 per violation. Except as modified by provision of the next paragraphs, the base civil penalties are as follows:

TABLE

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

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

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

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

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

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

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

(D) The civil penalty may be increased as much as 50% for cases where the licensee, permittee or registrant had prior knowledge of a problem as a result of an internal audit, or specific [~~Executive~~

~~Secretary~~]Director or industry notification, and had failed to take effective preventive steps.

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

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

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

(3) Orders.

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

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

(c) Suspension Orders may be used:

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

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

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

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

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

(d) Revocation Orders may be used:

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

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

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

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

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

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

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

(4) Escalation of Enforcement Sanctions.

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

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

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

(5) Related Administrative Actions.

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

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

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

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

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

Enforcement actions and responses are publicly available for inspection. In addition, press releases are generally issued for Notices of Proposed Imposition of a Civil Penalty and Orders. In the case of orders and civil penalties related to violations at Severity Level I, II or III, press releases may be issued at the time of the Order or the Notice

of Proposed Imposition of the Civil Penalty. Press releases are not normally issued for Notices of Violation.

KEY: violations, penalties, enforcement
Date of Enactment or Last Substantive Amendment: [~~October 20, 2006~~]2013
Notice of Continuation: July 7, 2011
Authorizing, and Implemented or Interpreted Law: 19-3-109; 19-3-111

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

NOTICE OF PROPOSED RULE
(Amendment)
DAR FILE NO.: 37191
FILED: 01/11/2013

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: Changes are required to conform with S.B. 21, 2012 General Session (Chapter 360, Laws of Utah 2012).

SUMMARY OF THE RULE OR CHANGE: S.B. 21 (2012) gave authority to the Director of the Division of Radiation Control to make many regulatory decisions that had previously been made either by the Radiation Control Board or by the Executive Secretary of the Radiation Control Board. This rule change implements these statutory changes by replacing occurrences of both "executive secretary" and "board" with "director." Sections R313-15-1104 and R313-15-1401 were deleted. They were identified as unnecessary as part of Governor Herbert's "Business Regulation Review".

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Section 19-3-104 and Section 19-3-108

ANTICIPATED COST OR SAVINGS TO:
♦ THE STATE BUDGET: There are no anticipated costs or savings to the state budget as this amendment only changes who has authority to make regulatory decisions.
♦ LOCAL GOVERNMENTS: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.
♦ SMALL BUSINESSES: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.
♦ PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.

COMPLIANCE COSTS FOR AFFECTED PERSONS: There are no compliance costs for affected persons as this amendment only changes who has authority to make regulatory decisions. The requirements for leak testing sealed sources and for maintaining records of leak tests are currently required for affected persons through license conditions.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: There is no anticipated fiscal impact on businesses as this amendment only changes who has authority to make regulatory decisions and leak tests are currently required through license conditions.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
ENVIRONMENTAL QUALITY
RADIATION CONTROLROOM THIRD FLOOR
195 N 1950 W
SALT LAKE CITY, UT 84116-3085
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Craig Jones by phone at 801-536-4264, by FAX at 801-533-4097, or by Internet E-mail at cwjones@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 03/04/2013

THIS RULE MAY BECOME EFFECTIVE ON: 03/19/2013

AUTHORIZED BY: Rusty Lundberg, Director

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

(1) Rule R313-15 establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses issued by the [~~Executive Secretary~~]Director. These rules are issued pursuant to Subsections 19-3-104(4) and 19-3-104(8).

(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~~]Director 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 Rule R313-32 (incorporating 10 CFR 35.75 by

reference), 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, (2010), which is incorporated by reference.

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

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

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

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

"Constraint (dose constraint)" in accordance with 10 CFR 20.1003, (2010), means a value above which specified licensee actions are required.

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

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

"Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these rules, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of Appendix B of 10 CFR 20.1001 to 20.2402, (2010), which is incorporated by reference.

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

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

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

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

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

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

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

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

"Inhalation class", refer to "Class".

"Labeled package" means a package labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations 49 CFR 172.403 and 49 CFR 172.436 through 440, (2009). 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 and 49 CFR 173.421 through 424, (2009).

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

"Lung class", refer to "Class".

"Nationally tracked source" is a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix E of 10 CFR 20.1001 to 20.2402 (2010), which is incorporated by reference. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

TABLE

ORGAN DOSE WEIGHTING FACTORS

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

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

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

R313-15-3. Implementation.

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

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

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

R313-15-101. Radiation Protection Programs.

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

(2) The licensee or registrant shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses

to members of the public that are as low as is reasonably achievable (ALARA).

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

(4) To implement the ALARA requirements of Subsection R313-15-101(2), and notwithstanding the requirements in Section R313-15-301, a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its decay products, shall be established by licensees or registrants such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 0.1 mSv (0.01 rem) per year from these emissions. If a licensee or registrant subject to this requirement exceeds this dose constraint, the licensee or registrant shall report the exceedance as provided in Section R313-15-1203 and promptly take appropriate corrective action to ensure against recurrence.

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

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

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

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

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

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

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

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

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

(3) When the external exposure is determined by measurement with an external personal monitoring device, the deep dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the [~~Executive Secretary~~]Director, U.S. Nuclear Regulatory Commission, or an Agreement State. The assigned deep dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow dose equivalent must be the dose averaged over the contiguous ten square centimeters of skin receiving the highest exposure.

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

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

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

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

(4) Derived air concentration (DAC) and annual limit on intake (ALI) values are specified in Table I of Appendix B of 10 CFR 20.1001 to 20.2402, (2010), 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, (2010), which is incorporated by reference.

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

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

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

(2) Intake by Inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

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

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

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

percent of the maximum weighted value of $H_{T,50}$, that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

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

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

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

(1) Licensees or registrants shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, lens dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See footnotes 1 and 2 of Appendix B of 10 CFR 20.1001 to 20.2402, (2010), 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~~]Director, 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, (2010), 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, (2010), 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, (2010), which is incorporated by reference. The licensee or registrant may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALI, the licensee or registrant shall also demonstrate that the limit in Subsection R313-15-201(1)(a)(ii) is met.

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

(1) For each individual likely to receive, in a year, an occupational dose requiring monitoring pursuant to Section R313-15-502, the licensee or registrant shall Determine the occupational radiation dose received during the current year; and

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

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

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

(3) In complying with the requirements of Subsections R313-15-205(1) or (2), 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;

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

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

(4) The licensee or registrant shall record the exposure history, as required by Subsection R313-15-205(1) or (2), on form DRC-05, or other clear and legible record, of all the information required on form DRC-05. 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.

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

(6) 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.

(7) The licensee or registrant shall retain the records on form DRC-05 or equivalent until the [~~Executive Secretary~~]Director 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. This includes records required under the standards for protection against radiation in effect prior to January 1, 1994.

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 dose estimated to result from the planned special exposure are unavailable or impractical.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) The dose equivalent to an embryo/fetus is the sum of:

(a) The deep dose equivalent to the declared pregnant woman; and

(b) The dose equivalent resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

(4) If the dose equivalent to the embryo/fetus is found to have exceeded five mSv (0.5 rem) or is within 0.5 mSv (0.05 rem) of this dose by the time the woman declares the pregnancy to the licensee or registrant, the licensee or registrant shall be deemed to be in compliance with Subsection R313-15-208(1) if the additional dose equivalent to the embryo/fetus does not exceed 0.50 mSv (0.05 rem) during the remainder of the pregnancy.

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

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

(a) 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 contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released, under Rule R313-32 (incorporating 10 CFR 35.75 by reference), 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 Rule R313-32 (incorporating 10 CFR 35.75 by reference), does not exceed 0.02 mSv (0.002 rem) in any one hour; and

(c) Notwithstanding Subsection R313-15-301(1)(a), a licensee may permit visitors to an individual who cannot be released, under R313-32 (incorporating 10 CFR 35.75 by reference), to receive a radiation dose greater than one mSv (0.1 rem) if:

(i) The radiation dose received does not exceed five mSv (0.5 rem); and

(ii) The authorized user, as defined in R313-32, has determined before the visit that it is appropriate.; and

(d) 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~~]Director 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) In addition to the requirements of R313-15, a licensee subject to the provisions of the United States Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards.

(5) The [~~Executive Secretary~~]Director 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, (2010), which is incorporated by reference; and

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

(3) Upon approval from the [~~Executive Secretary~~]Director, the licensee or registrant may adjust the effluent concentration values in Appendix B, Table II of 10 CFR 20.1001 to 20.2402, (2010), which is incorporated by reference, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as, aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

R313-15-401. Radiological Criteria for License Termination - General Provisions.

(1) The criteria in Sections R313-15-401 through R313-15-406 apply to the decommissioning of facilities licensed under Rules R313-22 and R313-25, as well as other facilities subject to the[~~Board's jurisdiction under the~~] Act. For low-level waste disposal facilities (Rule R313-25), the criteria apply only to ancillary surface facilities that support radioactive waste disposal activities.

(2) The criteria in Sections R313-15-401 through R313-15-406 do not apply to sites which:

(a) Have been decommissioned prior to the effective date of the rule in accordance with criteria approved by the [~~Executive Secretary~~]Director;

(b) Have previously submitted and received [~~Executive Secretary~~]Director approval on a license termination plan or decommissioning plan; or

(c) Submit a sufficient license termination plan or decommissioning plan before the effective date of the rule with criteria approved by the [~~Executive Secretary~~]Director.

(3) After a site has been decommissioned and the license terminated in accordance with the criteria in Sections R313-15-401 through R313-15-406, the [~~Executive Secretary~~]Director will require additional cleanup only if, based on new information, the [~~Executive Secretary~~]Director determines that the criteria in Sections R313-15-401 through R313-15-406 was not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

(4) When calculating the total effective dose equivalent to the average member of the critical group, the licensee shall determine the peak annual total effective dose equivalent dose expected within the first 1000 years after decommissioning.

R313-15-402. Radiological Criteria for Unrestricted Use.

A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a total effective dose equivalent to an average member of the critical group that does not exceed 0.25 mSv (0.025 rem) per year, including no greater than 0.04 mSv (0.004 rem) committed effective dose equivalent or total effective dose equivalent to an average member of the critical group from groundwater sources, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

R313-15-403. Criteria for License Termination Under Restricted Conditions.

A site will be considered acceptable for license termination under restricted conditions if:

(1) The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of Section R313-15-402 would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal; and

(2) The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the total effective dose equivalent from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 0.25 mSv (0.025 rem)per year; and

(3) The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

(a) Funds placed into an account segregated from the licensee's assets outside the licensee's administrative control as described in Subsection R313-22-35(6)(a);

(b) Surety method, insurance, or other guarantee method as described in Subsection R313-22-35(6)(b);

(c) A statement of intent in the case of Federal, State, or local Government licensees, as described in Subsection R313-22-35(6)(d); or

(d) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity; and

(4) The licensee has submitted a decommissioning plan or license termination plan to the [~~Executive Secretary~~]Director indicating the licensee's intent to decommission in accordance with Subsection R313-22-36(4) and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the license termination plan or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice;

(a) Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:

(i) Whether provisions for institutional controls proposed by the licensee;

(A) Will provide reasonable assurance that the total effective dose equivalent from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 0.25 mSv (0.025 rem) total effective dose equivalent per year;

(B) Will be enforceable; and

(C) Will not impose undue burdens on the local community or other affected parties; and

(ii) Whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site; and

(b) In seeking advice on the issues identified in Subsection R313-15-403(4)(a), the licensee shall provide for:

(i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

(5) Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the total effective dose equivalent from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either:

(a) one mSv (0.1 rem) per year; or

(b) five mSv (0.5 rem) per year provided the licensee:

(i) Demonstrates that further reductions in residual radioactivity necessary to comply with the one mSv (0.1 rem) per year value of Subsection R313-15-403(5)(a) are not technically achievable,

would be prohibitively expensive, or would result in net public or environmental harm;

(ii) Makes provisions for durable institutional controls; and

(iii) Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every five years to assure that the institutional controls remain in place as necessary to meet the criteria of Subsection R313-15-403(2) and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in Subsection R313-15-403(3).

R313-15-404. Alternate Criteria for License Termination.

(1) The [~~Executive Secretary~~]Director may terminate a license using alternative criteria greater than the dose criterion of Section R313-15-402, and Subsections R313-15-403(2) and R313-15-403(4)(a)(i)(A), if the licensee:

(a) Provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the one mSv (0.1 rem) per year limit of Subsection R313-15-301(1)(a), by submitting an analysis of possible sources of exposure; and

(b) Has employed, to the extent practical, restrictions on site use according to the provisions of Section R313-15-403 in minimizing exposures at the site; and

(c) Reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal; and

(d) Has submitted a decommissioning plan or license termination plan to the [~~Executive Secretary~~]Director indicating the licensee's intent to decommission in accordance with Subsection R313-22-36(4), and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or license termination plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:

(i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning; and

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.

(2) The use of alternate criteria to terminate a license requires the approval of the [~~Executive Secretary~~]Director after consideration of recommendations from the Division's staff, comments provided by federal, state and local governments, and any public comments submitted pursuant to Section R313-15-405.

R313-15-405. Public Notification and Public Participation.

Upon the receipt of a license termination plan or decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to Sections R313-15-403 or R313-15-404, or whenever the [~~Executive Secretary~~]Director deems such notice to be in the public interest, the [~~Executive Secretary~~]Director shall:

(1) Notify and solicit comments from:

(a) Local and State governments in the vicinity of the site and any Indian Nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and

(b) Federal, state and local governments for cases where the licensee proposes to release a site pursuant to Section R313-15-404.

(2) Publish a notice in a forum, such as local newspapers, letters to State or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

R313-15-406. Minimization of Contamination.

Applicants for licenses, other than renewals, shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of waste.

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

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

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

(b) Are necessary under the circumstances to evaluate:

(i) The magnitude and the extent of radiation levels; and

(ii) Concentrations or quantities of radioactive material; and

(iii) The potential radiological hazards.

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

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

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

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

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

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

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

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

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

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

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

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

(e) Individuals working with medical fluoroscopic equipment.

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

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

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

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

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

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

(a) Adults likely to receive, in one year, an intake in excess of ten percent of the applicable ALI(s) in Table I, Columns 1 and 2, of Appendix B of 10 CFR 20.1001 to 20.2402, (2010), which is incorporated by reference; and

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

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

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

R313-15-503. 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 lens dose equivalent, to demonstrate compliance with Subsection R313-15-201(1)(b)(i), shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in Subsection R313-15-602(1) if the registrant has met all the specific requirements for access and control specified in other applicable sections of these rules, such as, Rule R313-36 for industrial radiography, Rule R313-28 for x rays in the healing arts, Rule R313-30 for therapeutic radiation machines, and Rule R313-35 for industrial use of x-ray systems.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(k) Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and automatically to prevent loose radioactive material from being carried out of the area.

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

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

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

The licensee or registrant shall use, to the extent practical, process or other engineering controls, such as, containment, decontamination, or ventilation, to control the concentration of radioactive material in air.

R313-15-702. Use of Other Controls.

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

(a) Control of access; or

(b) Limitation of exposure times; or

(c) Use of respiratory protection equipment; or

(d) Other controls.

(2) If the licensee or registrant performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee or registrant should also consider the impact of respirator use on workers' industrial health and safety.

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

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

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

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

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

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

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

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

(d) Written procedures regarding

(i) Monitoring, including air sampling and bioassays;

(ii) Supervision and training of respirator users;

(iii) Fit testing;

(iv) Respirator selection;

(v) Breathing air quality;

(vi) Inventory and control;

(vii) Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;

(viii) Recordkeeping; and

(ix) Limitations on periods of respirator use and relief from respirator use; and

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

(f) Fit testing, with fit factor greater than or equal to ten times the APF for negative pressure devices, and a fit factor greater

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

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

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

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

(7) Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997 ed. and included in 29 CFR 1910.134(i)(1)(ii)(A) through (E), (2010). Grade D quality air criteria include:

(a) Oxygen content (v/v) of 19.5 to 23.5%;

(b) Hydrocarbon (condensed) content of five milligrams per cubic meter of air or less;

(c) Carbon monoxide (CO) content of ten ppm or less;

(d) Carbon dioxide content of 1,000 ppm or less; and

(e) Lack of noticeable odor.

(8) The licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face and facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

(9) In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

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

The [~~Executive Secretary~~]Director may impose restrictions in addition to the provisions of Section R313-15-702, Section R313-15-703, and Appendix A of 10 CFR 20.1001 to 20.2402, (2010), which is incorporated by reference to:

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

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

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

The licensee or registrant shall obtain authorization from the [~~Executive Secretary~~]Director before using assigned protection factors in excess of those specified in Appendix A of 10 CFR 20.1001 to 20.2402, (2010), which is incorporated by reference. The [~~Executive Secretary~~]Director may authorize a licensee or registrant to use higher assigned protection factors on receipt of an application that:

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

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

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

(1) The licensee or registrant shall secure licensed or registered radioactive material from unauthorized removal or access.

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

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

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

R313-15-901. Caution Signs.

(1) Standard Radiation Symbol. Unless otherwise authorized by the [~~Executive Secretary~~]Director, the symbol prescribed by 10 CFR 20.1901, (2010), which is incorporated by reference, shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

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

(b) The background is to be yellow.

(2) Exception to Color Requirements for Standard Radiation Symbol. Notwithstanding the requirements of 10 CFR 20.1901(a), (2010), 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, (2010), which is incorporated by reference, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL."

R313-15-903. Exceptions to Posting Requirements.

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

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

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

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

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

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

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

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

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

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

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

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

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

R313-15-905. Exemptions to Labeling Requirements.

A licensee or registrant is not required to label:

(1) Containers holding licensed or registered material in quantities less than the quantities listed in Appendix C of 10 CFR 20.1001 to 20.2402, (2010), 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, (2010), which is incorporated by reference; or

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

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

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

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

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

(1) Each licensee or registrant who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as used in Section R313-19-100, which incorporates 10 CFR 71.4 by reference, shall make arrangements to receive:

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

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

(2) Each licensee or registrant shall:

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

(b) Monitor the external surfaces of a labeled package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as used in Section R313-19-100, which incorporates 10 CFR 71.4 by reference; and

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

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

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

(a) Removable radioactive surface contamination exceeds the limits of Section R313-19-100 which incorporates 10 CFR 71.87(i) by reference; or

(b) External radiation levels exceed the limits of Section R313-19-100 which incorporates 10 CFR 71.47 by reference.

(5) Each licensee or registrant shall:

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

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

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

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

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

(a) By transfer to an authorized recipient as provided in Section R313-15-1006 or in Rules R313-21, R313-22, R313-24, 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, R313-15-1005, or R313-15-1008.

(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~~]Director 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, (2010), 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, (2010), 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, (2010), which is incorporated by reference; and

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

(d) The total quantity of licensed or registered radioactive material that the licensee or registrant releases into the sanitary sewerage system in a year does not exceed 185 GBq (five Ci) of

hydrogen-3, 37 GBq (one Ci) of carbon-14, and 37 GBq (one Ci) of all other radioactive materials combined.

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

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

A licensee or registrant may treat or dispose of licensed or registered material by incineration only in the form and concentration specified in Section R313-15-1005 or as specifically approved by the [~~Executive Secretary~~]Director 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 requirements of Section R313-15-1006 and Appendix G of 10 CFR 20.1001 to 20.2402, (2010), which are incorporated into these rules by reference, are designed to:

(a) control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in Appendix G in 10 CFR 20.1001 to 20.2402, (2010), who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility as defined in Section R313-25-2;

(b) establish a manifest tracking system; and

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

(2) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G to 10 CFR 20.1001 to 20.2402, (2010), which is incorporated into these rules by reference.

(3) Each shipment manifest shall include a certification by the waste generator as specified in Section II of Appendix G to 10 CFR 20.1001 to 20.2402, (2010), which is incorporated by reference.

(4) Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix G to 10 CFR 20.1001 to 20.2402, (2010), which is incorporated by reference.

(5) A licensee shipping byproduct material as defined in paragraphs (c) and (d) of the Section R313-12-3 definition of byproduct material intended for ultimate disposal at a land disposal facility licensed under Rule R313-25 must document the information required on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer the recorded manifest information to the intended consignee in accordance with Appendix G to 10 CFR Part 20 (2010 edition).

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. Disposal of Section R313-12-3 Byproduct Material Definition Paragraphs (c) and (d).

(1) Licensed material defined in Section R313-12-3, byproduct material definition, paragraphs (c) and (d), may be disposed in accordance with Rule R313-25, even though it is not defined as low-level radioactive waste. Therefore, licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under Rule R313-25, must meet the requirements of Section R313-15-1006.

(2) A licensee may dispose of licensed material defined in Section R313-12-3, byproduct material definition, paragraphs (c) and (d), at a disposal facility authorized to dispose of such material in accordance with Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

R313-15-1009. 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 R313-15-1009(2)(a). If Class A waste also meets the stability requirements set forth in Subsection R313-15-1009(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 R313-15-1009(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 R313-15-1009(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 R313-15-1009(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 R313-15-1009(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 R313-15-1009(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 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 R313-15-1009(2)(a)(viii).

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

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

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

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

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

(ii) Notwithstanding the provisions in Subsections R313-15-1009(2)(a)(iii) and R313-15-1009(2)(a)(iv), liquid wastes, or wastes containing liquid, shall be converted into a form that contains as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed one percent of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5 percent of the volume of the waste for waste processed to a stable form.

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

(3) Labeling. Each package of waste shall be clearly labeled to identify whether it is Class A, Class B, or Class C waste, in accordance with Subsection R313-15-1009(1).

R313-15-1101. Records - General Provisions.

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

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

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

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

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

(a) The provisions of the program; and

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

(2) The licensee or registrant shall retain the records required by Subsection R313-15-1102(1)(a) until the [~~Executive Secretary~~]Director 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~~]Director 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(3)(a) and R313-15-703(3)(b); and

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

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

~~Records of tests for leakage or contamination of sealed sources required by Section R313-15-1401 shall be kept in units of becquerel or microcurie and maintained for inspection by the Executive Secretary for five years after the records are made.~~

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

For each individual who is likely to receive in a year an occupational dose requiring monitoring pursuant to Section R313-15-502, the licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in Section R313-15-205 on form DRC-05 or equivalent until the [~~Executive Secretary~~]Director 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~~]Director 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, lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and

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

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

(d) The specific information used to calculate the committed effective dose equivalent pursuant to Subsections R313-15-204(1) and R313-15-204(3) and when required by Section R313-15-502; and

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

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

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

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

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

(5) The licensee or registrant shall retain each required form or record until the [~~Executive Secretary~~]Director 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~~]Director 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~~]Director 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~~]Director by telephone as follows:

(a) Immediately after its occurrence becomes known to the licensee or registrant, stolen, lost, or missing licensed or registered radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C of 10 CFR 20.1001 to 20.2402, (2010), 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, (2010), 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~~]Director 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~~]Director pursuant to Section R313-15-1201 so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

R313-15-1202. Notification of Incidents.

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

(a) An individual to receive:

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

(ii) A lens dose equivalent of 0.75 Sv (75 rem) or more; or

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

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

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

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

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

(ii) A lens dose equivalent exceeding 0.15 Sv (15 rem); or

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

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

(3) The licensee or registrant shall prepare each report filed with the [~~Executive Secretary~~]Director 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~~]Director by telephone, telegram, mailgram, or facsimile.

(5) The provisions of Section R313-15-1202 do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to Section R313-15-1204.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) Contents of Reports.

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

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

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

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

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

(b) Each report filed pursuant to Subsection R313-15-1203(1) shall include for each occupationally overexposed individual: the name, Social Security account number, and date of birth. With respect to the limit for the embryo/fetus in Section R313-15-208, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

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

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

The licensee or registrant shall submit a written report to the [~~Executive Secretary~~]Director within 30 days following any planned special exposure conducted in accordance with Section R313-15-206, informing the [~~Executive Secretary~~]Director 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~~]Director 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 the individual a written report on the exposure data included in the report to the [~~Executive Secretary~~]Director. This report shall be transmitted at a time no later than the transmittal to the [~~Executive Secretary~~]Director.

R313-15-1206. Reports of Transactions Involving Nationally Tracked Sources.

Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in paragraphs (1) through (5) of this section for each type of transaction.

(1) Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The manufacturer, model, and serial number of the source;

(d) The radioactive material in the source;

(e) The initial source strength in becquerels (curies) at the time of manufacture; and

(f) The manufacture date of the source.

(2) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The name and license number of the recipient facility and the shipping address;

(d) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(e) The radioactive material in the source;

(f) The initial or current source strength in becquerels (curies);

(g) The date for which the source strength is reported;

(h) The shipping date;

(i) The estimated arrival date; and

(j) For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source.

(3) Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The name, address, and license number of the person that provided the source;

(d) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(e) The radioactive material in the source;

(f) The initial or current source strength in becquerels (curies);

(g) The date for which the source strength is reported;

(h) The date of receipt; and

(i) For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

(4) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(d) The radioactive material in the source;

(e) The initial or current source strength in becquerels (curies);

(f) The date for which the source strength is reported; and

(g) The disassemble date of the source.

(5) Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The waste manifest number;

(d) The container identification with the nationally tracked source.

(e) The date of disposal; and

(f) The method of disposal.

(6) The reports discussed in paragraphs (1) through (5) of this section must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

(a) The on-line National Source Tracking System;

(b) Electronically using a computer-readable format;

(c) By facsimile;

(d) By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

(e) By telephone with followup by facsimile or mail.

(7) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by paragraphs (1) through (5) of this section. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

(8) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by November 15, 2007. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by November 30, 2007. The information may be submitted by using any of the methods identified by paragraph (6)(a) through (6)(d) of this section. The initial inventory report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;

(d) The radioactive material in the sealed source;

(e) The initial or current source strength in becquerels (curies); and

(f) The date for which the source strength is reported.

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~~]Director 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~~]Director, and shall comply with the provisions of Rule R313-18.

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

If the test for leakage or contamination required pursuant to Section R313-15-1401 indicates a sealed source is leaking or contaminated, a report of the test shall be filed within five days with the [~~Executive Secretary~~]Director 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~~]Director in writing of intent to vacate. When deemed necessary by the [~~Executive Secretary~~]Director, the licensee shall decontaminate the premises in such a manner that the annual total effective dose equivalent to any individual after the site is released for unrestricted use should not exceed 0.1 mSv (0.01 rem)above background and that the annual total effective dose equivalent from any specific environmental source during decommissioning activities should not exceed 0.1 mSv (0.01 rem)above background.

~~**[R313-15-1401. Testing for Leakage or Contamination of Sealed Sources.**~~

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

~~(a) Each sealed source, except as specified in Subsection R313-15-1401(2), is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee or registrant has a certificate from the transferor indicating that the sealed source was tested within six months before transfer to the licensee or registrant.~~

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

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

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

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

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

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

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

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

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

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

~~(d) Sealed sources containing only hydrogen-3;~~

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

~~(f) Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used and identified as in storage. The licensee or registrant shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within six months before the date of use or transfer.~~

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

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

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

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

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

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

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

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

]KEY: radioactive material, contamination, waste disposal, safety
Date of Enactment or Last Substantive Amendment: [~~October 13, 2010~~]2013
Notice of Continuation: December 3, 2007
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-3-108

Environmental Quality, Radiation Control
R313-17
Administrative Procedures

NOTICE OF PROPOSED RULE
(Amendment)
DAR FILE NO.: 37192
FILED: 01/11/2013

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: Changes are required to conform with S.B. 21, 2012 General Session (Chapter 360, Laws of Utah 2012).

SUMMARY OF THE RULE OR CHANGE: S.B. 21 (2012) gave authority to the Director of the Division of Radiation Control to make many regulatory decisions that had previously been made either by the Radiation Control Board or by the Executive Secretary of the Radiation Control Board. This rule change implements these statutory changes by replacing occurrences of both "executive secretary" and

"board" with "director." Some citations to Title 63G, Chapter 4, were deleted and the correct citations were added.

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Section 19-1-301 and Section 19-1-301.5 and Subection 19-3-104(4)

ANTICIPATED COST OR SAVINGS TO:
♦ THE STATE BUDGET: There are no anticipated costs or savings to the state budget as this amendment only changes who has authority to make regulatory decisions.
♦ LOCAL GOVERNMENTS: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.
♦ SMALL BUSINESSES: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.
♦ PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.

COMPLIANCE COSTS FOR AFFECTED PERSONS: There are no compliance costs for affected persons as this amendment only changes who has authority to make regulatory decisions.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: There is no anticipated fiscal impact on businesses as this amendment only changes who has authority to make regulatory decisions.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
ENVIRONMENTAL QUALITY
RADIATION CONTROLROOM THIRD FLOOR
195 N 1950 W
SALT LAKE CITY, UT 84116-3085
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Craig Jones by phone at 801-536-4264, by FAX at 801-533-4097, or by Internet E-mail at cwjones@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 03/04/2013

THIS RULE MAY BECOME EFFECTIVE ON: 03/19/2013

AUTHORIZED BY: Rusty Lundberg, Director

R313. Environmental Quality, Radiation.
R313-17. Administrative Procedures.
R313-17-1. Authority.

The rules set forth herein are adopted pursuant to the provision of Subsection 19-3-104(4) and Sections [~~63G-4-102 and Sections 63G-4-201 through 63G-4-205~~]19-1-301 and 19-1-301.5.

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

(1) The [~~Executive Secretary~~]Director shall give public notice of and provide an opportunity to comment on the following:

(a) A proposed major licensing action for license categories 2b and c, 4a, b, c, d and 6 identified in Section R313-70-7.

(i) Major licensing actions include:

(A) Pending issuance of a new license,

(B) Pending issuance of a license renewal,

(C) Pending approval of a license termination,

(D) An increase in process, storage, or disposal capacity,

(E) A geographic expansion,

(F) A change in engineering design, construction, or process controls that will more than likely cause an individual to receive a higher total effective dose equivalent or increase the annual quantity of radioactive effluents released to the environment,

(G) A decrease in environmental monitoring or sampling frequency,

(H) Pending approval of reclamation, decontamination or decommissioning plans,

(I) Pending approval of corrective actions to control or remediate existing radioactive material contamination, not already authorized by a license,

(J) A licensing issue the [~~Executive Secretary~~]Director deems is of significant public interest.

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

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

(2) The [~~Executive Secretary~~]Director may elect to give public notice of and provide an opportunity to comment on licensing actions that do not include the actions in Subsection R313-17-2(1)(a)(i), for all license categories identified in Section R313-70-7.

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

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

(5) Public notice shall be given by one or more of the following methods:

(a) Publication in a newspaper of general circulation in the area affected by the proposed action,

(b) Publication on the Division of Radiation Control website, or

(c) Distribution by an electronic mail server.

R313-17-3. Administrative Procedures.

Administrative proceedings under the Radiation Control Act are governed by Rule [~~R305-6~~]R305-7.

KEY: administrative procedures, comment, hearings, adjudicative proceedings
Date of Enactment or Last Substantive Amendment: [~~March 19, 2012~~]2013
Notice of Continuation: July 7, 2011
Authorizing, and Implemented or Interpreted Law: 19-3-104(4); [~~63G-4-102; 63G-4-201 through 63G-4-205~~]19-1-301 and 19-1-301.5.

Environmental Quality, Radiation Control
R313-18
Notices, Instructions and Reports to Workers by Licensees or Registrants--Inspections

NOTICE OF PROPOSED RULE
(Amendment)
DAR FILE NO.: 37193
FILED: 01/11/2013

RULE ANALYSIS
PURPOSE OF THE RULE OR REASON FOR THE CHANGE: Changes are required to conform with S.B. 21, 2012 General Session (Chapter 360, Laws of Utah 2012).

SUMMARY OF THE RULE OR CHANGE: S.B. 21 (2012) gave authority to the Director of the Division of Radiation Control to make many regulatory decisions that had previously been made either by the Radiation Control Board or by the Executive Secretary of the Radiation Control Board. This rule change implements these statutory changes by replacing occurrences of both "executive secretary" and "board" with "director."

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Section 19-3-104 and Section 19-3-108

ANTICIPATED COST OR SAVINGS TO:
♦ THE STATE BUDGET: There are no anticipated costs or savings to the state budget as this amendment only changes who has authority to make regulatory decisions.
♦ LOCAL GOVERNMENTS: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.
♦ SMALL BUSINESSES: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.
♦ PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.

COMPLIANCE COSTS FOR AFFECTED PERSONS: There are no compliance costs for affected persons as this amendment only changes who has authority to make regulatory decisions.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: There is no anticipated fiscal impact on businesses as this amendment only changes who has authority to make regulatory decisions.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
ENVIRONMENTAL QUALITY
RADIATION CONTROLROOM THIRD FLOOR
195 N 1950 W
SALT LAKE CITY, UT 84116-3085
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Craig Jones by phone at 801-536-4264, by FAX at 801-533-4097, or by Internet E-mail at cwjones@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 03/04/2013

THIS RULE MAY BECOME EFFECTIVE ON: 03/19/2013

AUTHORIZED BY: Rusty Lundberg, Director

R313. Environmental Quality, Radiation Control.
R313-18. Notices, Instructions and Reports to Workers by Licensees or Registrants--Inspections.
R313-18-1. Purpose and Authority.

(1) The purpose of this rule is to establish requirements for notices, instructions and reports by licensees or registrants to individuals engaged in work under a license or registration and options available to such individuals in connection with inspections of licensees or registrants.

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

R313-18-2. General.

The rules of R313-18 shall apply to all persons who receive, possess, use, own or transfer a source of radiation licensed by or registered with the Department pursuant to the rules in R313-16, R313-19 or R313-22.

R313-18-11. Posting of Notices to Workers.

(1) Licensees or registrants shall post current copies of the following documents:

(a) the rules in R313-15 and R313-18;

(b) the license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;

(c) the operating procedures applicable to work under the license or registration; and

(d) a notice of violation involving radiological working conditions, proposed imposition of civil penalty, order issued pursuant to R313-14, or any response from the licensee or registrant.

(2) If posting of a document specified in R313-18-11(1)(a), (b), or (c) is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

(3) DRC-04 "Notice to Employees," shall be posted by licensees or registrants wherever individuals work in or frequent a portion of a restricted area.

(4) Documents from the [~~Executive Secretary~~]Director which are posted pursuant to R313-18-11(1)(d) shall be posted within five working days after receipt of the documents from the [~~Executive Secretary~~]Director; the licensee's or registrant's response, if there is one, shall be posted for a minimum of five working days after dispatch from the licensee or registrant. The documents shall remain posted for a minimum of five working days or until action correcting the violation has been competed, whichever is later.

(5) Documents, notices or forms posted pursuant to R313-18-11 shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

R313-18-12. Instructions to Workers.

(1) All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 1.0 mSv (100 mrem):

(a) shall be kept informed of the storage, transfer, or use of sources of radiation in the licensee's or registrant's workplace;

(b) shall be instructed in the health protection considerations associated with exposure to radiation or radioactive material to the individual and potential offspring, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

(c) shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of these rules and licenses for the protection of personnel from exposure to radiation or radioactive material;

(d) shall be instructed as to their responsibility to report promptly to the licensee or registrant a condition which may constitute, lead to, or cause a violation of the Act, these rules, or a condition of the licensee's license or unnecessary exposure to radiation or radioactive material;

(e) shall be instructed in the appropriate response to warnings made in the event of an unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and

(f) shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to R313-18-13.

(2) In determining those individuals subject to the requirements of R313-18-12(1), licensees must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation or radioactive material which can reasonably be expected to occur during the life of a licensed facility. The extent of these instructions shall be commensurate with potential radiological health protection considerations for the workplace.

R313-18-13. Notifications and Reports to Individuals.

(1) Radiation exposure data for an individual and the results of measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in R313-18-13. The information reported shall include data and results obtained pursuant to these rules, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to R313-15-1107. Notifications and reports shall:

(a) be in writing;

(b) include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number, preferably social security number;

(c) include the individual's exposure information; and

(d) contain the following statement:

"This report is furnished to you under the provisions of the Utah Administrative Code Section R313-18-13. You should preserve this report for further reference."

(2) Licensees or registrants shall make dose information available to workers as shown in records maintained by the licensee or registrant pursuant to R313-15-1107. The licensee shall provide an annual report to each individual monitored under R313-15-502 of the dose received in that monitoring year if:

(a) The individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue; or

(b) The individual requests his or her annual dose report.

(3) Licensees or registrants shall furnish a written report of the worker's exposure to sources of radiation at the request of a worker formerly engaged in activities controlled by the licensee or registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to R313-15-502. The report shall be furnished within 30 days from the date of the request, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

(4) When a licensee or registrant is required pursuant to R313-15-1202, R313-15-1203, or R313-15-1204 to report to the [~~Executive Secretary~~]Director an exposure of an individual to sources of radiation, the licensee or registrant shall also provide the individual a written report on the exposure data included in the report to the [~~Executive Secretary~~]Director. This report shall be transmitted at a time no later than the transmittal to the [~~Executive Secretary~~]Director.

(5) At the request of a worker who is terminating employment with the licensee or registrant in work involving exposure to radiation or radioactive material, during the current year, the licensee or registrant shall provide at termination to the worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written

estimate of the dose shall be provided together with a clear indication that this is an estimate.

R313-18-14. Presence of Representatives of Licensees or Registrants and Workers During Inspection.

(1) Licensees or registrants shall afford representatives of the [~~Board or the Executive Secretary~~]Director, at reasonable times, the opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these rules.

(2) During an inspection, representatives of the [~~Board or the Executive Secretary~~]Director may consult privately with workers as specified in R313-18-15. The licensee or registrant may accompany representatives during other phases of an inspection.

(3) If, at the time of inspection, an individual has been authorized by the workers to represent them during Department inspections, the licensee or registrant shall notify the representatives of the [~~Board or the Executive Secretary~~]Director of the authorization and shall give the workers' representative an opportunity to accompany the representatives during the inspection of physical working conditions.

(4) The workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in R313-18-12.

(5) Different representatives of licensees or registrants and workers may accompany the representatives of the [~~Board or the Executive Secretary~~]Director during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the representatives of the [~~Board or the Executive Secretary~~]Director.

(6) With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany representatives of the [~~Board or the Executive Secretary~~]Director during the inspection of physical working conditions.

(7) Notwithstanding the other provisions of R313-18-14, representatives of the [~~Board or the Executive Secretary~~]Director are authorized to refuse to permit accompaniment by an individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an Agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to areas containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

R313-18-15. Consultation with Workers During Inspections.

(1) Representatives of the [~~Board or the Executive Secretary~~]Director may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of these rules and licenses to the extent the representatives deem necessary for the conduct of an effective and thorough inspection.

(2) During the course of an inspection, workers may bring privately to the attention of the representatives of the [~~Board or the Executive Secretary~~]Director, either orally or in writing, a past or present condition which the worker has reason to believe may have contributed to or caused a violation of the Act, these rules, or license condition, or an unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. A notice in writing shall comply with the requirements of R313-18-16(1).

(3) The provisions of R313-18-15(2) shall not be interpreted as authorization to disregard instructions pursuant to R313-18-12.

R313-18-16. Request by Workers for Inspections.

(1) A worker or representative of workers believing that a violation of the Act, these rules, or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the [~~Executive Secretary~~]Director. The notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by representatives of the [~~Board or the Executive Secretary~~]Director no later than at the time of inspection except that, upon the request of the worker giving the notice, his name and the name of individuals referred to therein shall not appear in a copy or on a record published, released, or made available by the Department except for good cause shown.

(2) If, upon receipt of the notice, representatives of the [~~Board or the Executive Secretary,~~]Director determine that the complaint meets the requirements set forth in R313-18-16(1), and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if the alleged violation exists or has occurred. Inspections pursuant to R313-18-16 need not be limited to matters referred to in the complaint.

(3) A licensee, registrant or contractor or subcontractor of a licensee or registrant shall not discharge or discriminate against a worker because that worker has filed a complaint or instituted or caused to be instituted a proceeding under these rules or has testified or is about to testify in a proceeding or because of the exercise by the worker on behalf of the worker or others of an option afforded by R313-18.

R313-18-17. Inspections Not Warranted -- Informal Review.

(1)(a) If the [~~representatives of the Board or the Executive Secretary~~]Director determines, with respect to a complaint under Section R313-18-16, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the [~~Executive Secretary~~]Director shall notify the complainant in writing of that determination. The complainant may obtain review of the determination by submitting a written statement of position with the [~~Executive Secretary~~]Director. The [~~Executive Secretary~~]Director will provide the licensee or registrant with a copy of the statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the [~~Executive Secretary~~]Director. The [~~Executive Secretary~~]Director will provide the complainant with a copy of the statement by certified mail.

(b) Upon the request of the complainant, the [~~Board~~]Director may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the

complainant. After considering written and oral views presented, the [~~Board~~]Director shall affirm, modify, or reverse the determination of the representatives of the [~~Board or the Executive Secretary~~]Director and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefor.

(2) If the [~~Executive Secretary~~]Director determines that an inspection is not warranted because the requirements of R313-18-16(1) have not been met, the complainant shall be notified in writing of the determination. The determination shall be without prejudice to the filing of a new complaint meeting the requirements of R313-18-16(1).

KEY: radioactive materials, inspections, radiation safety, licensing
Date of Enactment or Last Substantive Amendment: [~~October 13, 2010~~]2013
Notice of Continuation: July 7, 2011
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-3-108

Environmental Quality, Radiation Control
R313-19
Requirements of General Applicability to Licensing of Radioactive Material

NOTICE OF PROPOSED RULE
(Amendment)
DAR FILE NO.: 37194
FILED: 01/11/2013

RULE ANALYSIS
PURPOSE OF THE RULE OR REASON FOR THE CHANGE: Changes are required to conform with S.B. 21, 2012 General Session (Chapter 360, Laws of Utah 2012).

SUMMARY OF THE RULE OR CHANGE: S.B. 21 (2012) gave authority to the Director of the Division of Radiation Control to make many regulatory decisions that had previously been made either by the Radiation Control Board or by the Executive Secretary of the Radiation Control Board. This rule change implements these statutory changes by replacing occurrences of both "executive secretary" and "board" with "director."

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Section 19-3-104 and Section 19-3-108

ANTICIPATED COST OR SAVINGS TO:
♦ THE STATE BUDGET: There are no anticipated costs or savings to the state budget as this amendment only changes who has authority to make regulatory decisions.
♦ LOCAL GOVERNMENTS: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.
♦ SMALL BUSINESSES: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.
♦ PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.

COMPLIANCE COSTS FOR AFFECTED PERSONS: There are no compliance costs for affected persons as this amendment only changes who has authority to make regulatory decisions.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: There is no anticipated fiscal impact on businesses as this amendment only changes who has authority to make regulatory decisions.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
ENVIRONMENTAL QUALITY
RADIATION CONTROLROOM THIRD FLOOR
195 N 1950 W
SALT LAKE CITY, UT 84116-3085
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Craig Jones by phone at 801-536-4264, by FAX at 801-533-4097, or by Internet E-mail at cwjones@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 03/04/2013

THIS RULE MAY BECOME EFFECTIVE ON: 03/19/2013

AUTHORIZED BY: Rusty Lundberg, Director

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~~]Director enforcement action for violation of Section R313-19-5.

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

R313-19-2. General.

(1) A person shall not manufacture, produce, 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. Licensees engaged in source material milling operations, authorized to possess byproduct material, as defined in Section R313-12-3 (see definition (b)) from source material milling operations, authorized to possess and maintain a source material milling facility in standby mode, authorized to receive byproduct material from other persons for disposal, or authorized to possess and dispose of byproduct material generated by source material milling operations are subject to the requirements of Rule R313-24.

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~~]Director; or

(b) Deliberately submit to the [~~Executive Secretary~~]Director, 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~~]Director.

(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~~]Director; 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)(iii) 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) diffuse sources of natural occurring radioactive materials containing less than 15 picocuries per gram radium-226.

(ii) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in Rules R313-19, R313-21 and R313-22 and Rules R313-32, R313-34, R313-36, and R313-38 to the extent that the person transfers:

(A) radioactive material contained in a product or material in concentrations not in excess of those specified in R313-19-70; and

(B) introduced into the product or material by a licensee holding a specific license issued by the U.S. Nuclear Regulatory Commission authorizing the introduction.

(C) The exemption in R313-19-13-2(a)(ii)(A) and R313-19-13-2(a)(ii)(B) does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(iii) 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).

(b) Exempt quantities.

(i) Except as provided in Subsections R313-19-13(2)(b)(ii) through (iv) 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 CFR Part 32 or by the [~~Executive Secretary~~]Director 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 CFR Part 31.4 or equivalent regulations of a State 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 radioactive material. This exemption does not apply for diffuse sources of radium-226.

(v) No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in R313-19-71, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise provided by these rules.

(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 November 30, 2007.

(B) 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 manufactured before June 9, 2010.

(C) 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 manufactured before June 9, 2010.

(D) Ionization chamber smoke detectors containing not more than 1 microcurie (37 kBq) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

(E) 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.

(F) 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)(F), 0.05 microcurie (1.85 kBq) of americium-241 is considered an exempt quantity under Section R313-19-71.

(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 CFR 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, produce, or initially transfer for sale or distribution 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, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 32.26, or manufactured or distributed before November 30, 2007 in accordance with a specific license issued by an Agreement State or Licensing State under comparable provisions to 10 CFR 32.26 (2010) authorizing distribution to persons who are exempt from regulatory requirements.

(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 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) 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~~]Director or the issuance of licensing documents to the particular persons, although the filing of a registration certificate with the [~~Executive Secretary~~]Director 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~~]Director and the issuance of a licensing document by the [~~Executive Secretary~~]Director. 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~~]Director 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~~]Director.

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~~]Director 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~~]Director, obtain permission to proceed sooner. The [~~Executive Secretary~~]Director 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~~]Director 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 specifically licensed by the [~~Executive Secretary~~]Director or by the U.S. Nuclear Regulatory Commission, a Licensing State, or an Agreement State to receive the material.

(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~~]Director 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~~]Director 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 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~~]Director.

(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~~]Director 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~~]Director, and shall give his consent in writing.

(3) Persons licensed by the [~~Executive Secretary~~]Director 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~~]Director 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~~]Director 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 USC 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 USC 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~~]Director. The licensee may change the approved plan without the [~~Executive Secretary's~~]Director's approval only if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the [~~Executive Secretary~~]Director 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~~]Director.

(8) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with Rule R313-32 (incorporating 10 CFR 35.204 by reference). The licensee shall record the results of each test and retain each record for three years after the record is made.

(9) Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(10) (a) Authorization under Subsection R313-22-32(9) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(b) A licensee authorized under Subsection R313-22-32(9) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(i) Satisfy the labeling requirements in Subsection R313-22-75(9)(a)(iv) for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(ii) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in Subsection R313-22-75(9)(c).

(c) A licensee that is a pharmacy authorized under Subsection R313-22-32(9) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(i) an authorized nuclear pharmacist that meets the requirements in Subsection R313-22-75(9)(b)(ii); or

(ii) an individual under the supervision of an authorized nuclear pharmacist as specified in Rule R313-32 (incorporating 10 CFR 35.27 by reference).

(d) A pharmacy authorized under Subsection R313-22-32(9) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of Subsection R313-22-75(9)(b)(v).

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~~]Director, if prior approval from the [~~Executive Secretary~~]Director 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~~]Director, 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~~]Director, an Agreement State or a Licensing State; or

(e) as otherwise authorized by the [~~Executive Secretary~~]Director in writing.

(3) Before transferring radioactive material to a specific licensee of the [~~Executive Secretary~~]Director, 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~~]Director, 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~~]Director, 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~~]Director, 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~~]Director 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~~]Director 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 through 20.2402 (2010), 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 through 20.2402 (2010), 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) For radioactive materials, other than special nuclear material, licensees shall make reports required by Subsections R313-19-50(1) and (2) by telephone to the [~~Executive Secretary~~]Director. 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) For special nuclear materials, licensees shall make reports required by Subsections R313-19-50(1) and (2) by telephone to the [~~Executive Secretary~~]Director. 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, position title, and call-back telephone number;

(ii) the date, time, and exact location of the event; and

(iii) a description of the event, including:

(A) radiological or chemical hazards involved, including isotopes, quantities, and chemical and physical form of any material released; and

(B) actual or potential health and safety consequences to the workers, the public, and the environment, including relevant chemical and radiation data for actual personnel exposures to radiation or radioactive materials or hazardous chemicals produced from radioactive materials (e.g., level of radiation exposure, concentration of chemicals, and duration of exposure).

(c) Written report for materials other than special nuclear materials. 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~~]Director. 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.

(d) Written report for special nuclear material. 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~~]Director. The report shall include the following:

(i) the complete applicable information required by Subsection R313-19-50(3)(b);

(ii) the probable cause of the event, including all factors that contributed to the event and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned; and

(iii) corrective actions taken or planned to prevent occurrence of similar or identical events in the future and the results of any evaluations or assessments.

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~~]Director.

(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~~]Director 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~~]Director.

(3) Administrative reviews, modifications, revocations or terminations of licenses will be in accordance with Title 19, Chapter 3.

(4) The [~~Executive Secretary~~]Director may terminate a specific license upon written request submitted by the licensee to the [~~Executive Secretary~~]Director.

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 (Columbium) (41)	Nb-95		1 E-3
	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 (Cl-36)	10
Chlorine-38 (Cl-38)	10
Chromium-51 (Cr-51)	1,000
Cobalt-57 (Co-57)	100
Cobalt-58m (Co-58m)	10
Cobalt-58 (Co-58)	10
Cobalt-60 (Co-60)	1
Copper-64 (Cu-64)	100
Dysprosium-165 (Dy-165)	10
Dysprosium-166 (Dy-166)	100
Erbium-169 (Er-169)	100
Erbium-171 (Er-171)	100
Europium-152 (Eu-152) 9.2h	100
Europium-152 (Eu-152) 13 yr	1
Europium-154 (Eu-154)	1
Europium-155 (Eu-155)	10
Fluorine-18 (F-18)	1,000

Gadolinium-153 (Gd-153)	10
Gadolinium-159 (Gd-159)	100
Gallium-67 (Ga-67)	100
Gallium-72 (Ga-72)	10
Germanium-68 (Ge-68)	10
Germanium-71 (Ge-71)	100
Gold-195 (Au 195)	10
Gold-198 (Au-198)	100
Gold-199 (Au-199)	100
Hafnium-181 (Hf-181)	10
Holmium-166 (Ho-166)	100
Hydrogen-3 (H-3)	1,000
Indium-111 (In-111)	100
Indium-113m (In-113m)	100
Indium-114m (In-114m)	10
Indium-115m (In-115m)	100
Indium-115 (In-115)	10
Iodine-123 (I-123)	100
Iodine-125 (I-125)	1
Iodine-126 (I-126)	1
Iodine-129 (I-129)	0.1
Iodine-131 (I-131)	1
Iodine-132 (I-132)	10
Iodine-133 (I-133)	1
Iodine-134 (I-134)	10
Iodine-135 (I-135)	10
Iridium-192 (Ir-192)	10
Iridium-194 (Ir-194)	100
Iron-52 (Fe-52)	10
Iron-55 (Fe-55)	100
Iron-59 (Fe-59)	10
Krypton-85 (Kr-85)	100
Krypton-87 (Kr-87)	10
Lanthanum-140 (La-140)	10
Lutetium-177 (Lu-177)	100
Manganese-52 (Mn-52)	10
Manganese-54 (Mn-54)	10
Manganese-56 (Mn-56)	10
Mercury-197m (Hg-197m)	100
Mercury-197 (Hg-197)	100
Mercury-203 (Hg-203)	10
Molybdenum-99 (Mo-99)	100
Neodymium-147 (Nd-147)	100
Neodymium-149 (Nd-149)	100
Nickel-59 (Ni-59)	100
Nickel-63 (Ni-63)	10
Nickel-65 (Ni-65)	100
Niobium-93m (Nb-93m)	10
Niobium-95 (Nb-95)	10
Niobium-97 (Nb-97)	10
Osmium-185 (Os-185)	10
Osmium-191m (Os-191m)	100
Osmium-191 (Os-191)	100
Osmium-193 (Os-193)	100
Palladium-103 (Pd-103)	100
Palladium-109 (Pd-109)	100
Phosphorus-32 (P-32)	10
Platinum-191 (Pt-191)	100
Platinum-193m (Pt-193m)	100
Platinum-193 (Pt-193)	100
Platinum-197m (Pt-197m)	100
Platinum-197 (Pt-197)	100
Polonium-210 (Po-210)	0.1
Potassium-42 (K-42)	10
Potassium-43 (K-43)	10
Praseodymium-142 (Pr-142)	100
Praseodymium-143 (Pr-143)	100
Promethium-147 (Pm-147)	10
Promethium-149 (Pm-149)	10
Rhenium-186 (Re-186)	100
Rhenium-188 (Re-188)	100
Rhodium-103m (Rh-103m)	100
Rhodium-105 (Rh-105)	100
Rubidium-81 (Rb-81)	10
Rubidium-86 (Rb-86)	10
Rubidium-87 (Rb-87)	10
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 71.0(c), 71.1(a), 71.3, 71.4, 71.13, 71.14(a), 71.15, 71.17, 71.19(a), 71.19(b), 71.19(c), 71.20 through 71.23, 71.47, 71.83 through 71.89, 71.97, 71.101(a), 71.101(b), 71.101(c)(1), 71.101(g), 71.105, 71.127 through 71.137, and Appendix A to Part 71 (2010) are incorporated by reference with the following clarifications or exceptions:

(1) The exclusion of the following:

(a) In 10 CFR 71.4 the following definitions:

(i) "close reflection by water";

(ii) "licensed material";

(iii) "optimum interspersed hydrogenous moderation";

(iv) "spent nuclear fuel or spent fuel"; and

(v) "state."

(2) The substitution of the following date reference:

(a) "October 1, 2011" for "October 1, 2008".

(3) The substitution of the following rule references:

(a) "R313-36 (incorporating 10 CFR 34.31(b) by reference)" for "Sec. 34.31(b) of this chapter" as found in 10 CFR 71.101(g);

(b) "R313-15-502" for reference to "10 CFR 20.1502";

(c) "R313-14" for reference to "10 CFR Part 2 Subpart B";

(d) "Rule R313-32, 10 CFR Part 35," for reference to "10 CFR part 35";

(e) "R313-15-906(5)" for reference to "10 CFR 20.1906(e)";

(f) "R313-19-100(5)" for "Sec.71.5";

(g) "10 CFR 71.101(a), 71.101(b), 71.101(c)(1), 71.101(g), 71.105, and 71.127 through 71.137" for "subpart H of this part" or for "subpart H" except in 10 CFR 71.17(b), 71.20(b), 71.21(b), 71.22(b), 71.23(b);

(h) "10 CFR 71.0(c), 71.1(a), 71.3, 71.4, 71.17(c)(2), 71.20(c)(2), 71.21(d)(2), 71.83 through 71.89, 71.97, 71.101(a), 71.101(b), 71.101(c)(1), 71.101(g), 71.105, and 71.127 through 71.137" for "subparts A, G, and H of this part";

(i) "10 CFR 71.47" for "subparts E and F of this part"; and

(j) "10 CFR 71.101(a), 71.101(b), 71.101(c)(1), 71.101(g), 71.105, and 71.127 through 71.137" for "Sec. Sec. 71.101 through 71.137."

(4) The substitution of the following terms:

(a) "[~~Executive Secretary~~]Director" for:

(i) "Commission" in 10 CFR 71.0(c), 71.17(a), 71.20(a), 71.21(a), 71.22(a), 71.23(a), and 71.101(c)(1);

(ii) "Director, Division of Nuclear Safety, Office of Nuclear Security and Incident Response" in 10 CFR 71.97(c)(1), and 71.97(f)(1);

(iii) "Director, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001" in 10 CFR 71.97(c)(3)(iii);

(iv) "NRC" in 10 CFR 71.101(f);

(b) "[~~Executive Secretary~~]Director, the U.S. Nuclear Regulatory Commission, or an Agreement State" for "Commission" in 10 CFR 71.3;

(c) "The Governor of Utah" for:

(i) "the governor of a State" in 71.97(a);

(ii) "each appropriate governor" in 10 CFR 71.97(c)(1);

(iii) "the governor" in 10 CFR 71.97(c)(3);

(iv) "the governor of the state" in 10 CFR 71.97(e);

(v) "the governor of each state" in 10 CFR 71.97(f)(1);

(vi) "a governor" in 10 CFR 71.97(e);

(d) "State of Utah" for "State" in 71.97(a), 71.97(b)(2), and 71.97(d)(4);

(e) "the Governor of Utah's" for:

(i) "the governor's" in 10 CFR 71.97(a), 71.97(c)(3), 71.97(c)(3)(iii), 71.97(e), and 71.97(f)(1);

(ii) "governor's" in 10 CFR 71.97(c)(1), and 71.97(e);

(f) "Specific or general" for "NRC" in 10 CFR 71.0(c);

(g) "The [~~Executive Secretary~~]Director at the address specified in R313-12-110" for reference to "ATTN: Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards" in 10 CFR 71.101(c)(1);

(h) "Each" for "Using an appropriate method listed in Sec. 71.1(a), each" in 10 CFR 71.101(c)(1);

(i) "The material must be contained in a Type A package meeting the requirements of 49 CFR 173.417(a)." for "The fissile material need not be contained in a package which meets the standards of subparts E and F of this part; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a)." as found in 10 CFR 71.22(a) and 71.23(a);

(j) "Licensee" for "licensee, certificate holder, and applicant for a COC"; and

(k) "Licensee is" for reference to "licensee, certificate holder, and applicant for a COC are."

(5) Transportation of licensed material

(a) Each licensee who transports licensed material outside the site of usage, as specified in the license issued by the [~~Executive Secretary~~]Director, the U.S. Nuclear Regulatory Commission or an Agreement State, 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 regulations in 49 CFR parts 107, 171 through 180, and 390 through 397 (2009), appropriate to the mode of transport.

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

(A) Packaging--49 CFR part 173: subparts A (49 CFR 173.1 through 49 CFR 173.13), B (49 CFR 173.21 through 49 CFR 173.40), and I (49 CFR 173.401 through 49 CFR 173.477).

(B) Marking and labeling--49 CFR part 172: subpart D (49 CFR 172.300 through 49 CFR 172.338); and 49 CFR 172.400 through 49 CFR 172.407 and 49 CFR 172.436 through 49 CFR 172.441 of subpart E.

(C) Placarding--49 CFR part 172: subpart F (49 CFR 172.500 through 49 CFR 172.560), especially 49 CFR 172.500 through 49 CFR 172.519 and 49 CFR 172.556; and appendices B and C.

(D) Accident reporting--49 CFR part 171: 49 CFR 171.15 and 171.16.

(E) Shipping papers and emergency information--49 CFR part 172: subparts C (49 CFR 172.200 through 49 CFR 172.205) and G (49 CFR 172.600 through 49 CFR 172.606).

(F) Hazardous material employee training--49 CFR part 172: subpart H (49 CFR 172.700 through 49 CFR 172.704).

(G) Security plans--49 CFR part 172: subpart I (49 CFR 172.800 through 49 CFR 172.804).

(H) Hazardous material shipper/carrier registration--49 CFR part 107: subpart G (49 CFR 107.600 through 49 CFR 107.606).

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

(A) Rail--49 CFR part 174: subparts A through D (49 CFR 174.1 through 49 CFR 174.86) and K (49 CFR 174.700 through 49 CFR 174.750).

(B) Air--49 CFR part 175.

(C) Vessel--49 CFR part 176: subparts A through F (49 CFR 176.1 through 49 CFR 176.99) and M (49 CFR 176.700 through 49 CFR 107.720).

(D) Public Highway--49 CFR part 177 and parts 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, waiver, or exemption from those requirements, and any notification referred to in those requirements, must be filed with, or made to, the [~~Executive Secretary~~]Director, P.O. Box 144850, Salt Lake City, Utah 84114-4850.

KEY: license, reciprocity, transportation, exemptions
Date of Enactment or Last Substantive Amendment: [~~October 13, 2010~~]2013
Notice of Continuation: September 23, 2011
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-3-108

Environmental Quality, Radiation Control
R313-22
Specific Licenses

NOTICE OF PROPOSED RULE
(Amendment)
DAR FILE NO.: 37195
FILED: 01/11/2013

RULE ANALYSIS
PURPOSE OF THE RULE OR REASON FOR THE CHANGE: Changes are required to conform with S.B. 21, 2012 General Session (Chapter 360, Laws of Utah 2012).

SUMMARY OF THE RULE OR CHANGE: S.B. 21 (2012) gave authority to the Director of the Division of Radiation Control to make many regulatory decisions that had previously been made either by the Radiation Control Board or by the Executive Secretary of the Radiation Control Board. This rule change implements these statutory changes by replacing occurrences of both "executive secretary" and "board" with "director."

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Section 19-3-104 and Section 19-3-108

ANTICIPATED COST OR SAVINGS TO:
♦ THE STATE BUDGET: There are no anticipated costs or savings to the state budget as this amendment only changes who has authority to make regulatory decisions.
♦ LOCAL GOVERNMENTS: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.
♦ SMALL BUSINESSES: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.
♦ PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.

COMPLIANCE COSTS FOR AFFECTED PERSONS: There are no compliance costs for affected persons as this amendment only changes who has authority to make regulatory decisions.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: There is no anticipated fiscal impact on businesses as this amendment only changes who has authority to make regulatory decisions.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
ENVIRONMENTAL QUALITY
RADIATION CONTROLROOM THIRD FLOOR
195 N 1950 W
SALT LAKE CITY, UT 84116-3085
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Craig Jones by phone at 801-536-4264, by FAX at 801-533-4097, or by Internet E-mail at cwjones@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 03/04/2013

THIS RULE MAY BECOME EFFECTIVE ON: 03/19/2013

AUTHORIZED BY: Rusty Lundberg, Director

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

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

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

R313-22-2. General.

The provisions and requirements of Rule R313-22 are in addition to, and not in substitution for, other requirements of these

rules. In particular the provisions of Rule R313-19 apply to applications and licenses subject to Rule R313-22.

R313-22-4. Definitions.

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

"Nationally tracked source" is a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix E of 10 CFR 20.1001 to 20.2402 (2010), which is incorporated by reference. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

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

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

R313-22-30. Specific License by Rule.

A license by rule is issued in the following circumstances, without the necessity of filing an application for a specific license as required by Subsection R313-22-32(1), and the licensee shall be subject to the applicable provisions of Sections R313-22-33, R313-22-34, R313-22-35, R313-22-36 and R313-22-37:

(1) When a site must be timely remediated of contamination by radioactive materials that are subject to licensing under these rules but are unlicensed;

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

R313-22-32. Filing Application for Specific Licenses.

(1) Applications for specific licenses shall be filed on a form prescribed by the [~~Executive Secretary~~]Director.

(2) The [~~Executive Secretary~~]Director may, after the filing of the original application, and before the expiration of the license, require further statements in order to enable the [~~Executive Secretary~~]Director to determine whether the application should be granted or denied or whether a license should be modified or revoked.

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

(4) An application for a license may include a request for a license authorizing one or more activities.

(5) In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the [~~Executive Secretary~~]Director, provided the references are clear and specific.

(6) An application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source shall identify the source or device by manufacturer and model number as registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 (2010),the equivalent regulations of an Agreement State, or with a State under provisions comparable to 10 CFR 32.210.

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

(8)(a) Applications to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in Section R313-22-90, "Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release", shall contain either:

(i) An evaluation showing that the maximum dose to a individual off-site due to a release of radioactive materials would not exceed one rem effective dose equivalent or five rems to the thyroid; or

(ii) An emergency plan for responding to a release of radioactive material.

(b) One or more of the following factors may be used to support an evaluation submitted under Subsection R313-22-32(8)(a)(i):

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

(ii) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(iii) The release fraction in the respirable size range would be lower than the release fraction shown in Section R313-22-90 due to the chemical or physical form of the material;

(iv) The solubility of the radioactive material would reduce the dose received;

(v) Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Section R313-22-90;

(vi) Operating restrictions or procedures would prevent a release fraction as large as that shown in Section R313-22-90; or

(vii) Other factors appropriate for the specific facility.

(c) An emergency plan for responding to a release of radioactive material submitted under Subsection R313-22-32(8)(a)(ii) shall include the following information:

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

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

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

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

(v) Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of

accident, including those provided to protect workers on-site, and a description of the program for maintaining equipment.

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

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

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

NOTE: These reporting requirements do not supersede or release licensees of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499 or other state or federal reporting requirements, including 40 CFR 302, 2010.

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

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

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

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

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

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

(9) An application from a medical facility, educational institution, or Federal facility to produce Positron Emmission Tomography (PET) radioactive drugs for non-commercial transfer to licensees in its consortium authorized for medical use under Rule R313-32 shall include:

(a) A request for authorization for the production of PET radionuclides or evidence of an existing license issued pursuant to 10 CFR Part 30 or equivalent Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(b) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in Subsection R313-22-75(9)(a)(ii).

(c) Identification of the individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in Rule R313-32.

(d) Information identified in Subsection R313-22-75(9)(a)(iii) on the PET drugs to be noncommercially transferred to members of its consortium.

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

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

(a) the applicant and all personnel who will be handling the radioactive material are qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these rules in a manner as to minimize danger to public health and safety or the environment;

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

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

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

(e) the applicant satisfies applicable special requirements in Sections R313-22-50 and R313-22-75, and Rules R313-24, R313-25, R313-32, R313-34, R313-36, or R313-38; and

(f) in the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, or for the conduct of other activities which the [~~Executive Secretary~~]Director determines will significantly affect the quality of the environment, the [~~Executive Secretary~~]Director, before commencement of construction of the plant or facility in which the activity will be conducted, has concluded, after weighing the

environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. The [~~Executive Secretary~~]Director shall respond to the application within 60 days. Commencement of construction prior to a response and conclusion shall be grounds for denial of a license to receive and possess radioactive material in the plant or facility. As used in this paragraph the term "commencement of construction" means clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

R313-22-34. Issuance of Specific Licenses.

(1) Upon a determination that an application meets the requirements of the Act and the rules of the Board, the [~~Executive Secretary~~]Director will issue a specific license authorizing the proposed activity in a form and containing conditions and limitations as the [~~Executive Secretary~~]Director deems appropriate or necessary.

(2) The [~~Executive Secretary~~]Director may incorporate in licenses at the time of issuance, additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to Rule R313-22 as he deems appropriate or necessary in order to:

(a) minimize danger to public health and safety or the environment;

(b) require reports and the keeping of records, and to provide for inspections of activities under the license as may be appropriate or necessary; and

(c) prevent loss or theft of material subject to Rule R313-22.

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

(1)(a) Applicants for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in Appendix B of 10 CFR 30.1 through 30.72, 2010, which is incorporated by reference, shall submit a decommissioning funding plan as described in Subsection R313-22-35(5). The decommissioning funding plan shall also be submitted when a combination of radionuclides is involved if R divided by 10^5 is greater than one, where R is defined here as the sum of the ratios of the quantity of each radionuclide to the applicable value in Appendix B of 10 CFR 30.1 through 30.72, 2010, which is incorporated by reference.

(b) Holders of, or applicants for, a specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding 10^{12} times the applicable quantities set forth in Appendix B of 10 CFR 30.1 through 30.72, 2010, which is incorporated by reference, or when a combination of isotopes is involved if R, as defined in Subsection R313-22-35(1)(a), divided by 10^{12} is greater than one, shall submit a decommissioning funding plan as described in Subsection R313-22-35(5).

(c) Applicants for a specific license authorizing the possession and use of more than 100 mCi of source material in a readily dispersible form shall submit a decommissioning funding plan as described in Subsection R313-22-35(5).

(2) Applicants for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in Subsection R313-22-35(4), or authorizing the possession and use of source material greater than 10 mCi but less than or equal to 100 mCi in a readily dispersible form shall either:

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

(b) submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by Subsection R313-22-35(4) using one of the methods described in Subsection R313-22-35(6). Applicants for a specific license authorizing the possession and use of source material in a readily dispersible form shall submit a certification that financial assurance for decommissioning has been provided in the amount of $225,000 by October 20, 2007. For an applicant subject to this subsection, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but before the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of Subsection R313-22-35(6) shall be submitted to the [~~Executive Secretary~~]Director before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the [~~Executive Secretary~~]Director, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements in Subsection R313-22-35(6).

(3)(a) Holders of a specific license issued on or after October 20, 2006, which is of a type described in Subsections R313-22-35(1) or (2), shall provide financial assurance for decommissioning in accordance with the criteria set forth in Section R313-22-35.

(b) Holders of a specific license issued before October 20, 2006, and of a type described in Subsection R313-22-35(1), shall submit by October 20, 2007, a decommissioning funding plan as described in Subsection R313-22-35(5) or a certification of financial assurance for decommissioning in an amount at least equal to $1,125,000 in accordance with the criteria set forth in Section R313-22-35. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan, the licensee shall include a decommissioning funding plan in any application for license renewal.

(c) Holders of a specific license issued before October 20, 2006, and of a type described in Subsection R313-22-35(2), shall submit by October 20, 2007, a decommissioning funding plan as described in Subsection R313-22-35(5) or a certification of financial assurance for decommissioning in accordance with the criteria set forth in Section R313-22-35.

(d) A licensee who has submitted an application before October 20, 2006, for renewal of license in accordance with Section R313-22-37, shall provide financial assurance for decommissioning in accordance with Subsections R313-22-35(1) and (2).

(e) Waste collectors and waste processors, as defined in Appendix G of 10 CFR 20.1001 to 20.2402, 2010, which is incorporated by reference, shall provide financial assurance in an amount based on a decommissioning funding plan as described in Subsection R313-22-35(5). The decommissioning funding plan shall include the cost of disposal of the maximum amount (curies) of radioactive material permitted by the license, and the cost of disposal

of the maximum quantity, by volume, of radioactive material which could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of Rule R313-15.

(f) Holders of a specific license issued prior to October 20, 2006, which is of a type described in Subsections R313-22-35(1), (2), or (3)(g), shall submit a decommissioning funding plan to the [~~Executive Secretary~~]Director on or before October 20, 2007. Holders of a specific license issued on or after October 20, 2006, which is of a type described in Subsections R313-22-35(1), (2), or (3)(g), shall submit a decommissioning funding plan to the [~~Executive Secretary~~]Director as a part of the license application.

(g) Applicants for a specific license authorizing the possession and use of radioactive materials in sufficient quantities that require financial assurance and recordkeeping for decommissioning under Section R313-22-35 shall assure that all documents submitted to the [~~Executive Secretary~~]Director for the purpose of demonstrating compliance with financial assurance and recordkeeping requirements meet the applicable criteria contained in the Nuclear Regulatory Commission's document NUREG-1757, Volume 3, "Consolidated NMSS Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness" (9/2003).

(h) Documents provided to the [~~Executive Secretary~~]Director under Subsection R313-22-35(3)(g) shall provide that legal remedies be sought in a court of appropriate jurisdiction within Utah.

(4) Table of required amounts of financial assurance for decommissioning by quantity of material. Licensees required to submit an amount of financial assurance listed in this table must do so during a license application or as part of an amendment to an existing license. Licensees having possession limits exceeding the upper bounds of this table must base financial assurance on a decommissioning funding plan.

TABLE

Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of radioactive material, as defined in Appendix B of 10 CFR 30.1 through 30.72 (2010) which is incorporated by reference, in unsealed form. For a combination of radionuclides, if R, as defined in Subsection R313-22-35(1)(a) divided by 10^4 is greater than one but R divided by 10^5 is less than or equal to one:	$1,125,000
Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of radioactive material, as defined in Appendix B of 10 CFR 30.1 through 30.72 (2010) which is incorporated by reference, in unsealed form. For a combination of radionuclides, if R, as defined in Subsection R313-22-35(1)(a) divided by 10^3 is greater than one but R divided by 10^4 is less than or equal to one:	$225,000
Greater than 10^{10} but less than or equal to 10^{12} times the applicable quantities of radioactive material, as defined in Appendix B of 10 CFR 30.1 through 30.72 (2010) which is incorporated by reference, in sealed sources or plated foils. For combination of radionuclides, if R, as defined in R313-22-35(1)(a), divided by 10^{10} is greater than one, but R divided by 10^{12} is less than or equal to one:	$113,000

(5) A decommissioning funding plan shall contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from Subsection R313-22-35(6), including means for adjusting cost estimates and associated funding levels periodically over the life of the facility. Cost estimates shall be adjusted at intervals not to exceed 3 years. The decommissioning funding plan shall also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of Subsection R313-22-35(6).

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

(a) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets so that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities;

(b) A surety method, insurance, or other guarantee method. These methods shall guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Subsection R313-22-35(8). A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of Section R313-22-35. A guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Subsection R313-22-35(9). A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of Section R313-22-35 or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. A surety method or insurance used to provide financial assurance for decommissioning shall contain the following conditions:

(i) the surety method or insurance shall be open-ended or, if written for a specified term, such as five years, shall be renewed automatically unless 90 days or more prior to the renewal date the issuer notifies the [~~Executive Secretary~~]Director, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance shall also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the [~~Executive Secretary~~]Director within 30 days after receipt of notification of cancellation,

(ii) the surety method or insurance shall be payable to a trust established for decommissioning costs. The trustee and trust shall be acceptable to the [~~Executive Secretary~~]Director. An acceptable trustee includes an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency, and

(iii) the surety method or insurance shall remain in effect until the [~~Executive Secretary~~]Director has terminated the license;

(c) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions shall be as stated in Subsection R313-22-35(6)(b);

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

(e) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(7) Persons licensed under Rule R313-22 shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with Subsection R313-19-34(2), licensees shall transfer all records described in Subsections R313-22-35(7)(a) through (d) to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the [~~Executive Secretary~~]Director considers important to decommissioning consists of the following:

(a) records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records shall include any known information on identification of involved nuclides, quantities, forms, and concentrations;

(b) as-built drawings and modification of structures and equipment in restricted areas where radioactive materials are used or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations;

(c) except for areas containing only sealed sources, provided the sources have not leaked or no contamination remains after a leak, or radioactive materials having only half-lives of less than 65 days, a list contained in a single document and updated every two years, including all of the following:

(i) all areas designated and formerly designated as restricted areas as defined under Section R313-12-3;

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

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

(iv) all areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in Sections R313-15-401 through R313-15-406, or apply for approval for disposal under Section R313-15-1002; and

(d) records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

(8) Criteria relating to use of financial tests and parent company guarantees for providing reasonable assurance of funds for decommissioning.

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

(i) The parent company shall have all of the following:

(A) Two of the following three ratios: a ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5;

(B) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates, or prescribed amount if a certification is used;

(C) Tangible net worth of at least $10 million; and

(D) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates, or prescribed amount if a certification is used; or

(ii) The parent company shall have all of the following:

(A) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or Aaa, Aa, A or Baa as issued by Moody's;

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

(C) Tangible net worth of at least $10 million; and

(D) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates, or prescribed amount if certification is used.

(b) The parent company's independent certified public accountant shall have compared the data used by the parent company in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform the [~~Executive Secretary~~]Director within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(c)(i) After the initial financial test, the parent company shall repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

(ii) If the parent company no longer meets the requirements of Subsection R313-22-35(8)(a) the licensee shall send notice to the [~~Executive Secretary~~]Director of intent to establish alternative

financial assurance as specified in Section R313-22-35. The notice shall be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee shall provide alternate financial assurance within 120 days after the end of such fiscal year.

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

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

(ii) If the licensee fails to provide alternate financial assurance as specified in Section R313-22-35 within 90 days after receipt by the licensee and [~~Executive Secretary~~]Director of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

(iii) The parent company guarantee and financial test provisions shall remain in effect until the [~~Executive Secretary~~]Director has terminated the license.

(iv) If a trust is established for decommissioning costs, the trustee and trust shall be acceptable to the [~~Executive Secretary~~]Director. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(9) Criteria relating to use of financial tests and self guarantees for providing reasonable assurance of funds for decommissioning.

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

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

(ii) Assets located in the United States amounting to at least 90 percent of total assets or at least ten times the total current decommissioning cost estimate, or the current amount required if certification is used, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor; and

(iii) A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poor's, or Aaa, Aa, or A as issued by Moody's.

(b) To pass the financial test, a company shall meet all of the following additional requirements:

(i) The company shall have at least one class of equity securities registered under the Securities Exchange Act of 1934;

(ii) The company's independent certified public accountant shall have compared the data used by the company in the financial test which is derived from the independently audited, yearend financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the [~~Executive Secretary~~]Director within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test; and

(iii) After the initial financial test, the company shall repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(c) If the licensee no longer meets the requirements of Subsection R313-22-35(9)(a), the licensee shall send immediate notice to the [~~Executive Secretary~~]Director of its intent to establish alternate financial assurance as specified in Section R313-22-35 within 120 days of such notice.

(d) The terms of a self-guarantee which an applicant or licensee furnishes shall provide that:

(i) The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the [~~Executive Secretary~~]Director. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the [~~Executive Secretary~~]Director, as evidenced by the return receipt.

(ii) The licensee shall provide alternative financial assurance as specified in Section R313-22-35 within 90 days following receipt by the [~~Executive Secretary~~]Director of a notice of a cancellation of the guarantee.

(iii) The guarantee and financial test provisions shall remain in effect until the [~~Executive Secretary~~]Director has terminated the license or until another financial assurance method acceptable to the [~~Executive Secretary~~]Director has been put in effect by the licensee.

(iv) The licensee shall promptly forward to the [~~Executive Secretary~~]Director and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

(v) If, at any time, the licensee's most recent bond issuance ceases to be rated in a category of "A" or above by either Standard and Poor's or Moody's, the licensee shall provide notice in writing of such fact to the [~~Executive Secretary~~]Director within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poor's and Moody's, the licensee no longer meets the requirements of Subsection R313-22-35(9)(a).

(vi) The applicant or licensee shall provide to the [~~Executive Secretary~~]Director a written guarantee, a written commitment by a corporate officer, which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the [~~Board~~]Director, the licensee shall set up and fund a trust in the amount of the current cost estimates for decommissioning.

R313-22-36. Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas.

(1) A specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under Section R313-22-37 no less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days prior to the expiration date stated in the existing license, the existing license expires at the end of the day on which the [~~Executive Secretary~~]Director makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(2) A specific license revoked by the [~~Executive Secretary~~]Director expires at the end of the day on the date of the [~~Executive Secretary's~~]Director's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by an Order issued by the [~~Executive Secretary~~]Director.

(3) A specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the [~~Executive Secretary~~]Director notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

(a) limit actions involving radioactive material to those related to decommissioning; and

(b) continue to control entry to restricted areas until they are suitable for release so that there is not an undue hazard to public health and safety or the environment.

(4) Within 60 days of the occurrence of any of the following, a licensee shall provide notification to the [~~Executive Secretary~~]Director in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release so that there is not an undue hazard to public health and safety or the environment, or submit within 12 months of notification a decommissioning plan, if required by Subsection R313-22-36(7), and begin decommissioning upon approval of that plan if:

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

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

(c) no principal activities under the license have been conducted for a period of 24 months; or

(d) no principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release because of an undue hazard to public health and safety or the environment.

(5) Coincident with the notification required by Subsection R313-22-36(4), the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to Section R313-22-35 in conjunction with a license issuance or renewal or as required by Section R313-22-36. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to Subsection R313-22-36(7)(d)(v).

(a) A licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so on or before August 15, 1997.

(b) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the [~~Executive Secretary~~]Director.

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

(7)(a) A decommissioning plan shall be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the [~~Executive Secretary~~]Director and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(i) procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(ii) workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(iii) procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(iv) procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(b) The [~~Executive Secretary~~]Director may approve an alternate schedule for submittal of a decommissioning plan required pursuant to Subsection R313-22-36(4) if the [~~Executive Secretary~~]Director determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(c) Procedures such as those listed in Subsection R313-22-36(7)(a) with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(d) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(i) a description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(ii) a description of planned decommissioning activities;

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

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

(v) an updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(vi) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in Subsection R313-22-36(8).

(e) The proposed decommissioning plan will be approved by the [~~Executive Secretary~~]Director if the information therein demonstrates that the decommissioning will be completed as soon as practical and that the health and safety of workers and the public will be adequately protected.

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

(b) Except as provided in Subsection R313-22-36(9), when decommissioning involves the entire site, the licensee shall request license termination as soon as practical but no later than 24 months following the initiation of decommissioning.

(9) The [~~Executive Secretary~~]Director may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the [~~Executive Secretary~~]Director determines that the alternative is warranted by consideration of the following:

(a) whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(b) whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(c) whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(d) whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(e) other site-specific factors which the [~~Executive Secretary~~]Director may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

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

(a) certify the disposition of all licensed material, including accumulated wastes, by submitting a completed Form DRC-14 or equivalent information; and

(b) conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in Sections R313-15-401 through R313-15-406. The licensee shall, as appropriate:

(i) report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters--removable and fixed-- for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

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

(11) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the [~~Executive Secretary~~]Director determines that:

(a) radioactive material has been properly disposed;

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

(c) documentation is provided to the [~~Executive Secretary~~]Director that:

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

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

R313-22-37. Renewal of Licenses.

Application for renewal of a specific license shall be filed on a form prescribed by the [~~Executive Secretary~~]Director and in accordance with Section R313-22-32.

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

Applications for amendment of a license shall be filed in accordance with Section R313-22-32 and shall specify the respects in which the licensee desires the license to be amended and the grounds for the amendment.

R313-22-39. [~~Executive Secretary~~]Director Action on Applications to Renew or Amend.

In considering an application by a licensee to renew or amend the license, the [~~Executive Secretary~~]Director will use the criteria set forth in Sections R313-22-33, R313-22-50, and R313-22-75 and in Rules R313-24, R313-25, R313-32, R313-34, R313-36, or R313-38, as applicable.

R313-22-50. Special Requirements for Specific Licenses of Broad Scope.

Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity or other product containing byproduct material whose subsequent possession, use, transfer and disposal by all other persons who are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(1) The different types of broad licenses are set forth below:

(a) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

(b) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Section R313-22-100 for any authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Section R313-22-100, Column I. If two or more radionuclides are possessed thereunder, the possession limits are determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Section R313-22-100, Column I, for that radionuclide. The sum of the ratios for the radionuclides possessed under the license shall not exceed unity.

(c) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Section R313-22-100, for any authorized purpose. The possession limit for a Type C broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Section R313-22-100, Column II. If two or more radionuclides are

possessed thereunder, the possession limits are determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Section R313-22-100, Column II, for that radionuclide. The sum of the ratios for the radionuclides possessed under the license shall not exceed unity.

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

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

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

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

(i) the establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;

(ii) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(iii) the establishment of appropriate administrative procedures to assure:

(A) control of procurement and use of radioactive material,

(B) completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures, and

(C) review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with Subsection R313-22-50(2)(c)(iii)(B) prior to use of the radioactive material.

(3) An application for a Type B specific license of broad scope shall be approved if all of the following are complied with:

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

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

(i) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(ii) the establishment of appropriate administrative procedures to assure:

(A) control of procurement and use of radioactive material,

(B) completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures, and

(C) review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with Subsection R313-22-50(3)(b)(iii)(B) prior to use of the radioactive material.

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

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

(b) the applicant submits a statement that radioactive material will be used only by, or under the direct supervision of individuals, who have received:

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

(ii) at least forty hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

(c) the applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, recordkeeping, material control and accounting, and management review necessary to assure safe operations.

(5) Specific licenses of broad scope are subject to the following conditions:

(a) unless specifically authorized by the [~~Executive Secretary~~]Director, persons licensed pursuant to this section shall not:

(i) conduct tracer studies in the environment involving direct release of radioactive material;

(ii) receive, acquire, own, possess, use, or transfer devices containing 100,000 curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;

(iii) conduct activities for which a specific license issued by the [~~Executive Secretary~~]Director under Section R313-22-75, and Rules R313-25, R313-32 or R313-36 is required; or

(iv) add or cause the addition of radioactive material to a food, beverage, cosmetic, drug or other product designed for ingestion or inhalation by, or application to, a human being.

(b) Type A specific licenses of broad scope issued under Rule R313-22 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(c) Type B specific license of broad scope issued under Rule R313-22 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

(d) Type C specific license of broad scope issued under Rule R313-22 shall be subject to the condition that radioactive material possessed under the license may only be used, by or under the direct supervision of, individuals who satisfy the requirements of Subsection R313-22-50(4).

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

(1) Licensing the introduction of radioactive material in exempt concentrations into products or materials, and transfer of ownership or possession of the products and materials.

(a) The authority to introduce radioactive material in exempt concentrations into equipment, devices, commodities or other products may be obtained only from the Nuclear Regulatory Commission, Washington, D.C. 20555; and

(b) The manufacturer, processor or producer of equipment, devices, commodities or other products containing exempt

concentrations of radioactive materials may obtain the authority to transfer possession or control of the equipment, devices, commodities, or other products containing exempt concentrations to persons who are exempt from regulatory requirements only from the Nuclear Regulatory Commission, Washington, D.C. 20555.

(2) Licensing the distribution of radioactive material in exempt quantities. Authority to transfer possession or control by the manufacturer, processor or producer of equipment, devices, commodities or other products containing byproduct material whose subsequent possession, use, transfer, and disposal by other persons who are exempted from regulatory requirements may be obtained only from the Nuclear Regulatory Commission, Washington, D.C. 20555.

(3) Reserved

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

(a) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under Subsection R313-21-22(4) or equivalent regulations of the Nuclear Regulatory Commission, an Agreement State or a Licensing State will be approved if:

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

(ii) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(A) the device can be safely operated by persons not having training in radiological protection,

(B) under ordinary conditions of handling, storage and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that a person will receive in one year, a dose in excess of ten percent of the annual limits specified in Subsection R313-15-201(1), and

(C) under accident conditions, such as fire and explosion, associated with handling, storage and use of the device, it is unlikely that a person would receive an external radiation dose or dose commitment in excess of the following organ doses:

TABLE

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

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

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

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

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

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

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

(D) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, "Caution-Radioactive Material," the radiation symbol described in Section R313-15-901, and the name of the manufacturer or initial distributor.

(E) Each device meeting the criteria of Subsection R313-21-22(4)(c)(xiii)(A), bears a permanent label, for example, embossed, etched, stamped, or engraved, affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in Section R313-15-901.

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

(i) primary containment, or source capsule;

(ii) protection of primary containment;

(iii) method of sealing containment;

(iv) containment construction materials;

(v) form of contained radioactive material;

(vi) maximum temperature withstood during prototype tests;

(vii) maximum pressure withstood during prototype tests;

(viii) maximum quantity of contained radioactive material;

(ix) radiotoxicity of contained radioactive material; and

(x) operating experience with identical devices or similarly designed and constructed devices.

(c) In the event the applicant desires that the general licensee under Subsection R313-21-22(4), or under equivalent regulations of the Nuclear Regulatory Commission, an Agreement State or a Licensing State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with this activity or activities, and basis for these estimates. The submitted information shall demonstrate that performance of this activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of ten percent of the annual limits specified in Subsection R313-15-201(1).

(d)(i) If a device containing radioactive material is to be transferred for use under the general license contained in Subsection R313-21-22(4), each person that is licensed under Subsection R313-22-75(4) shall provide the information specified in Subsections R313-22-75(4)(d)(i)(A) through (E) to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(A) a copy of the general license contained in Subsection R313-21-22(4); if Subsections R313-21-22(4)(c)(ii) through (iv) or R313-21-22(4)(c)(xiii) do not apply to the particular device, those paragraphs may be omitted;

(B) a copy of Sections R313-12-51, R313-15-1201, and R313-15-1202;

(C) a list of services that can only be performed by a specific licensee;

(D) Information on acceptable disposal options including estimated costs of disposal; and

(E) An indication that the [~~Board's~~]Division's policy is to issue civil penalties for improper disposal.

(ii) If radioactive material is to be transferred in a device for use under an equivalent general license of the Nuclear Regulatory Commission, an Agreement State, or Licensing State, each person that is licensed under Subsection R313-22-75(4) shall provide the information specified in Subsections R313-22-75(4)(d)(ii)(A) through (D) to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(A) A copy of an Agreement State's or Licensing State's regulations equivalent to Sections R313-12-51, R313-15-1201, R313-15-1202, and Subsection R313-21-22(4) or a copy of 10 CFR 31.5, 10 CFR 31.2, 10 CFR 30.51, 10 CFR 20.2201, and 10 CFR 20.2202. If a copy of the Nuclear Regulatory Commission regulations is provided to a prospective general licensee in lieu of the Agreement State's or Licensing State's regulations, it shall be accompanied by a note explaining that use of the device is regulated by the Agreement State or Licensing State; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted;

(B) A list of services that can only be performed by a specific licensee;

(C) Information on acceptable disposal options including estimated costs of disposal; and

(D) The name or title, address, and phone number of the contact at the Nuclear Regulatory Commission, Agreement State, or Licensing State from which additional information may be obtained.

(iii) An alternative approach to informing customers may be proposed by the licensee for approval by the [~~Executive Secretary~~]Director.

(iv) Each device that is transferred after February 19, 2002 must meet the labeling requirements in Subsection R313-22-75(4)(a)(iii).

(v) If a notification of bankruptcy has been made under Section R313-19-34 or the license is to be terminated, each person licensed under Subsection R313-22-75(4) shall provide, upon request, to the [~~Executive Secretary~~]Director, the Nuclear Regulatory Commission, or an appropriate Agreement State or Licensing State, records of final disposition required under Subsection R313-22-75(4)(d)(vii)(H).

(vi) Each person licensed under Subsection R313-22-75(4) to initially transfer devices to generally licensed persons shall comply with the requirements of Subsections R313-22-75(4)(d)(vi) and (vii).

(A) The person shall report all transfers of devices to persons for use under the general license under Subsection R313-21-22(4) and all receipts of devices from persons licensed under Subsection R313-21-22(4) to the [~~Executive Secretary~~]Director. The report must be submitted on a quarterly basis on Form 653, "Transfers of Industrial Devices Report" as prescribed by the Nuclear Regulatory Commission, or in a clear and legible report containing all of the data required by the form.

(B) The required information for transfers to general licensees includes:

(I) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternative address for the general licensee shall be submitted along with information on the actual location of use.

(II) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(III) The date of transfer;

(IV) The type, model number, and serial number of device transferred; and

(V) The quantity and type of radioactive material contained in the device.

(C) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate persons.

(D) For devices received from a Subsection R313-21-22(4) general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial

number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(E) If the licensee makes changes to a device possessed by a Subsection R313-21-22(4) general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(F) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(G) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(H) If no transfers have been made to or from persons generally licensed under Subsection R313-21-22(4) during the reporting period, the report must so indicate.

(vii) The person shall report all transfers of devices to persons for use under a general license in the Nuclear Regulatory Commission's, an Agreement State's, or Licensing State's regulations that are equivalent to Subsection R313-21-22(4) and all receipts of devices from general licensees in the Nuclear Regulatory Commission's, Agreement State's, or Licensing State's jurisdiction to the Nuclear Regulatory Commission, or to the responsible Agreement State or Licensing State agency. The report must be submitted on Form 653, "Transfers of Industrial Devices Report" as prescribed by the Nuclear Regulatory Commission, or in a clear and legible report containing all of the data required by the form.

(A) The required information for transfers to general licensee includes:

(I) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternative address for the general licensee shall be submitted along with information on the actual location of use.

(II) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(III) The date of transfer;

(IV) The type, model number, and serial number of the device transferred; and

(V) The quantity and type of radioactive material contained in the device.

(B) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate persons.

(C) For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(D) If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(E) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(F) The report must clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.

(G) If no transfers have been made to or from a Nuclear Regulatory Commission licensee, or to or from a particular Agreement State or Licensing State licensee during the reporting period, this information shall be reported to the Nuclear Regulatory Commission or the responsible Agreement State or Licensing State agency upon request of the agency.

(H) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by Subsection R313-22-75(4)(d)(vii). Records required by Subsection R313-22-75(4)(d)(vii)(H) must be maintained for a period of three years following the date of the recorded event.

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

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

(b) the applicant satisfies the requirements of 10 CFR 32.53 through 32.56 and 32.101 (2010) or their equivalent.

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

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

(b) the applicant satisfies the requirements of 10 CFR 32.57 through 32.59, 32.102 and 10 CFR 70.39 (2010), or their equivalent.

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

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

(b) the radioactive material is to be prepared for distribution in prepackaged units of:

(i) iodine-125 in units not exceeding 370 kilobecquerel (ten uCi) each;

(ii) iodine-131 in units not exceeding 370 kilobecquerel (ten uCi) each;

(iii) carbon-14 in units not exceeding 370 kilobecquerel (ten uCi) each;

(iv) hydrogen-3 (tritium) in units not exceeding 1.85 megabecquerel (50 uCi) each;

(v) iron-59 in units not exceeding 740.0 kilobecquerel (20 uCi) each;

(vi) cobalt-57 in units not exceeding 370 kilobecquerel (ten uCi) each;

(vii) selenium-75 in units not exceeding 370 kilobecquerel (ten uCi) each; or

(viii) mock iodine-125 in units not exceeding 1.85 kilobecquerel (0.05 uCi) of iodine-129 and 1.85 kilobecquerel (0.05 uCi) of americium-241 each;

(c) prepackaged units bear a durable, clearly visible label:

(i) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 370 kilobecquerel (ten uCi) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 1.85 megabecquerel (50 uCi) of hydrogen-3 (tritium); 740.0 kilobecquerel (20 uCi) of iron-59; or Mock Iodine-125 in units not exceeding 1.85 kilobecquerel (0.05 uCi) of iodine-129 and 1.85 kilobecquerel (0.05 uCi) of americium-241 each; and

(ii) displaying the radiation caution symbol described in Section R313-15-901 and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals";

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

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

.....

Name of Manufacturer"

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

.....

Name of Manufacturer"

(e) the label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source shall also contain directions to the licensee regarding the waste disposal requirements set out in Section R313-15-1001.

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

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

(b) the criteria of 10 CFR 32.61, 32.62, 32.103, 2006 ed. are met.

(9) Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under R313-32.

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

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

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

(A) registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

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

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

(D) operating as a nuclear pharmacy within a medical institution; or

(E) registered with a State Agency as a Positron Emission Tomography (PET) drug production facility.

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

(iv) the applicant satisfies the following labeling requirements:

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

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

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

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

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

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

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

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

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

(iv) May designate a pharmacist, as defined in Rule R313-32 (incorporating 10 CFR 35.2 by reference), as an authorized nuclear pharmacist if:

(A) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator produced radioactive material, and

(B) The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

(v) Shall provide to the [~~Executive Secretary~~]Director:

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

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

(C) the permit issued by a licensee or Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

(D) the permit issued by a U.S. Nuclear Commission master materials licensee; or

(E) documentation that only accelerator produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

(F) a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to Subsections R313-22-75(9)(b)(ii)(A) and R313-22-75(9)(b)(ii)(C), the individual to work as an authorized nuclear pharmacist.

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

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

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

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

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

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

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

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

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

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

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

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

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

(vii) legend and methods for labeling sources and devices as to their radioactive content, and

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

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

(d) in the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include in the application sufficient information to demonstrate that a longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and

(e) in determining the acceptable interval for test of leakage of radioactive material, the [~~Executive Secretary~~]Director shall consider information that includes, but is not limited to:

(i) primary containment or source capsule,

(ii) protection of primary containment,

(iii) method of sealing containment,

(iv) containment construction materials,

(v) form of contained radioactive material,

(vi) maximum temperature withstood during prototype tests,

(vii) maximum pressure withstood during prototype tests,

(viii) maximum quantity of contained radioactive material,

(ix) radiotoxicity of contained radioactive material, and

(x) operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(11) Requirements for license to manufacture and distribute industrial products containing depleted uranium for mass-volume applications.

(a) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to Subsection R313-21-21(5) or equivalent regulations of the Nuclear Regulatory Commission or an Agreement State will be approved if:

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

(ii) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses and potential hazards of the industrial product or device to provide reasonable assurance that possession, use or transfer of the depleted uranium in the product or device is not likely to cause an individual to receive a radiation dose in excess of ten percent of the annual limits specified in Subsection R313-15-201(1); and

(iii) the applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(b) In the case of an industrial product or device whose unique benefits are questionable, the [~~Executive Secretary~~]Director will approve an application for a specific license under Subsection R313-22-75(11) only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(c) The [~~Executive Secretary~~]Director may deny an application for a specific license under Subsection R313-22-75(11) if the end use of the industrial product or device cannot be reasonably foreseen.

(d) Persons licensed pursuant to Subsection R313-22-75(11)(a) shall:

(i) maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

(ii) label or mark each unit to:

(A) identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

(B) state that the receipt, possession, use and transfer of the product or device are subject to a general license or the equivalent and the regulations of the Nuclear Regulatory Commission or an Agreement State;

(iii) assure that the uranium before being installed in each product or device has been impressed with the following legend clearly legible through a plating or other covering: "Depleted Uranium";

(iv) furnish to each person to whom depleted uranium in a product or device is transferred for use pursuant to the general license contained in Subsection R313-21-21(5) or its equivalent:

(A) a copy of the general license contained in Subsection R313-21-21(5) and a copy of form DRC-12; or

(B) a copy of the general license contained in the Nuclear Regulatory Commission's or Agreement State's regulation equivalent to Subsection R313-21-21(5) and a copy of the Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in Subsection R313-21-21(5) and a copy of form DRC-12 with a note explaining that use of the product or device is regulated by the Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in Subsection R313-21-21(5);

(v) report to the [~~Executive Secretary~~]Director all transfers of industrial products or devices to persons for use under the general license in Subsection R313-21-21(5). The report shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the [~~Executive Secretary~~]Director and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within thirty days after the end of the calendar quarter in which the product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under Subsection R313-21-21(5) during the reporting period, the report shall so indicate;

(vi) provide certain other reports as follows:

(A) report to the Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the Nuclear Regulatory Commission general license in 10 CFR 40.25 (2010);

(B) report to the responsible state agency all transfers of devices manufactured and distributed pursuant to Subsection R313-22-75(11) for use under a general license in that state's regulations equivalent to Subsection R313-21-21(5),

(C) reports shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within thirty days after the end of each calendar quarter in which a product or device is transferred to the generally licensed person,

(D) if no transfers have been made to Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the Nuclear Regulatory Commission, and

(E) if no transfers have been made to general licensees within a particular Agreement State during the reporting period, this

information shall be reported to the responsible Agreement State agency upon the request of that agency; and

(vii) records shall be kept showing the name, address and point of contact for each general licensee to whom the person transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in Subsection R313-21-21(5) or equivalent regulations of the Nuclear Regulatory Commission or an Agreement State. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in the product or device transferred, and compliance with the report requirements of Subsection R313-22-75(11).

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

TABLE

Radioactive Material(1)	Release Fraction	Quantity (curies)
Actinium-228	0.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252 (20 mg)	.001	9
Carbon-14	.01 Non CO	50,000
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Germanium-68	.01	2,000
Gadolinium-153	.01	5,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holmium-166m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10
Indium-114m	.01	1,000
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Ruthenium-106	.01	200
Radium-226	.001	100
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment, beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma(2)	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha(2)	.0001	20
Combinations of radioactive materials listed above(1)	-----	-----

(1) For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Section R313-22-90 exceeds one.

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

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

TABLE

RADIOACTIVE MATERIAL	COLUMN I	COLUMN II
	CURIES	
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	1	0.01

Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1
Cesium-134m	100	1
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1
Chromium-51	100	1
Cobalt-57	10	0.1
Cobalt-58m	100	1
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 (9.2h)	10	0.1
Europium-152 (13y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1
Indium-113m	100	1
Indium-114m	1	0.01
Indium-115m	100	1
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.01
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1
Krypton-87	10	0.1
Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1
Osmium-185	1	0.01
Osmium-191m	100	1
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1
Platinum-193	10	0.1
Platinum-197m	100	1
Platinum-197	10	0.1
Polonium-210	0.01	0.0001
Potassium-42	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-186	10	0.1
Rhenium-188	10	0.1
Rhodium-103m	1,000	10
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1
Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85m	1,000	10
Strontium-85	1	0.01
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulphur-35	10	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1
Technetium-99	1	0.01
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01

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

R313-22-201. Serialization of Nationally Tracked Sources.

Each licensee who manufacturers a nationally tracked source after October 19, 2007, shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

R313-22-210. Registration of Product Information.

Licensees who manufacture or initially distribute a sealed source or device containing a sealed source whose product is intended for use under a specific license or general license are deemed to have provided reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and the environment if the sealed source or device has been evaluated in accordance with 10 CFR 32.210 (2010) or equivalent regulations of an Agreement State.

KEY: specific licenses, decommissioning, broad scope, radioactive materials
Date of Enactment or Last Substantive Amendment: [~~January 16, 2012~~|2013]
Notice of Continuation: September 23, 2011
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-3-108

Environmental Quality, Radiation Control
R313-24
Uranium Mills and Source Material Mill Tailings Disposal Facility Requirements

NOTICE OF PROPOSED RULE
(Amendment)
DAR FILE NO.: 37196
FILED: 01/11/2013

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: Changes are required to conform with S.B. 21, 2012 General Session (Chapter 360, Laws of Utah 2012).

SUMMARY OF THE RULE OR CHANGE: S.B. 21 (2012) gave authority to the Director of the Division of Radiation Control to make many regulatory decisions that had previously been made either by the Radiation Control Board or by the Executive Secretary of the Radiation Control Board. This rule change implements these statutory changes by replacing occurrences of both "executive secretary" and "board" with "director."

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Section 19-3-104 and Section 19-3-108

ANTICIPATED COST OR SAVINGS TO:
♦ THE STATE BUDGET: There are no anticipated costs or savings to the state budget as this amendment only changes who has authority to make regulatory decisions.
♦ LOCAL GOVERNMENTS: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.
♦ SMALL BUSINESSES: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.
♦ PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.

COMPLIANCE COSTS FOR AFFECTED PERSONS: There are no compliance costs for affected persons as this amendment only changes who has authority to make regulatory decisions.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: There is no anticipated fiscal impact on businesses as this amendment only changes who has authority to make regulatory decisions.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
ENVIRONMENTAL QUALITY
RADIATION CONTROLROOM THIRD FLOOR
195 N 1950 W
SALT LAKE CITY, UT 84116-3085
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Craig Jones by phone at 801-536-4264, by FAX at 801-533-4097, or by Internet E-mail at cwjones@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 03/04/2013

THIS RULE MAY BECOME EFFECTIVE ON: 03/19/2013

AUTHORIZED BY: Rusty Lundberg, Director

R313. Environmental Quality, Radiation Control.
R313-24. Uranium Mills and Source Material Mill Tailings Disposal Facility Requirements.
R313-24-1. Purpose and Authority.

(1) The purpose of this rule is to prescribe requirements for possession and use of source material in milling operations such as conventional milling, in-situ leaching, or heap-leaching. The rule includes requirements for the possession of byproduct material, as defined in Section R313-12-3 (see "byproduct material" definition (b)), from source material milling operations, as well as, possession and maintenance of a facility in standby mode. In addition, requirements are prescribed for the receipt of byproduct material from other persons for possession and disposal. The rule also prescribes requirements for receipt of byproduct material from other persons for possession and disposal incidental to the byproduct material generated by the licensee's source material milling operations.

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

(3) The requirements of Rule R313-24 are in addition to, and not substitution for, the other applicable requirements of Title R313. In particular, the provisions of Rules R313-12, R313-15, R313-18, R313-19, R313-21, R313-22, and R313-70 apply to applicants and licensees subject to Rule R313-24.

R313-24-2. Scope.

(1) The requirements in Rule R313-24 apply to source material milling operations, byproduct material, and byproduct material disposal facilities.

R313-24-3. Environmental Analysis.

(1) Each new license application, renewal, or major amendment shall contain an environmental report describing the proposed action, a statement of its purposes, and the environment affected. The environmental report shall present a discussion of the following:

(a) An assessment of the radiological and nonradiological impacts to the public health from the activities to be conducted pursuant to the license or amendment;

(b) An assessment of any impact on waterways and groundwater resulting from the activities conducted pursuant to the license or amendment;

(c) Consideration of alternatives, including alternative sites and engineering methods, to the activities to be conducted pursuant to the license or amendment; and

(d) Consideration of the long-term impacts including decommissioning, decontamination, and reclamation impacts, associated with activities to be conducted pursuant to the license or amendment.

(2) Commencement of construction prior to issuance of the license or amendment shall be grounds for denial of the license or amendment.

(3) The [~~Executive Secretary~~]Director shall provide a written analysis of the environmental report which shall be available for public notice and comment pursuant to R313-17-2.

R313-24-4. Clarifications or Exceptions.

For the purposes of Rule R313-24, 10 CFR 40.2a through 40.4; 40.12; 40.20(a); 40.21; 40.26(a) through (c); 40.31(h); 40.41(c); the introduction to 40.42(k) and 40.42(k)(3)(i); 40.61(a) and (b); 40.65; and Appendix A to Part 40(2002) are incorporated by reference with the following clarifications or exceptions:

(1) The exclusion and substitution of the following:

(a) Exclude 10 CFR 40.26(c)(1) and replace with "(1) The provisions of Sections R313-12-51, R313-12-52, R313-12-53, R313-19-34, R313-19-50, R313-19-61, R313-24-1, Rules R313-14, R313-15, R313-18, and R313-24 (incorporating 10 CFR 40.2a, 40.3, 40.4, and 40.26 by reference)";

(b) In Appendix A to 10 CFR 40, exclude Criterion 5B(1) through 5H, Criterion 7A, Criterion 13, and replace the excluded Criterion with "Utah Administrative Code, R317-6, Ground Water Quality Protection"; and

(c) In Appendix A to 10 CFR 40, exclude Criterion 11A through 11F and Criterion 12;

(2) The substitution of the following:

(a) "10 CFR 40" for reference to "this part" as found throughout the incorporated text;

(b) "[~~Executive Secretary~~]Director" for reference to "Commission" in the first and fourth references contained in 10 CFR 40.2a, in 10 CFR 40.3, 40.20(a), 40.26, 40.41(c), 40.61, and 40.65;

(c) "Rules R313-19, R313-21, or R313-22" for "Section 62 of the Act" as found in 10 CFR 40.12(a);

(d) "Rules R313-21 or R313-22" for reference to "the regulations in this part" in 10 CFR 40.41(c);

(e) "Section R313-19-100" for reference to "part 71 of this chapter" as found in 10 CFR 40.41(c);

(f) In 10 CFR 40.42(k)(3)(i), "R313-15-401 through R313-15-406" for reference to "10 CFR part 20, subpart E";

(g) "source material milling" for reference to "uranium milling, in production of uranium hexafluoride, or in a uranium enrichment facility" as found in 10 CFR 40.65(a);

(h) "[~~Executive Secretary~~]Director" for reference to "appropriate NRC Regional Office shown in Appendix D to 10 CFR part 20 of this chapter, with copies to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555," as stated in 10 CFR 65(a)(1);

(i) "require the licensee to" for reference to "require to" in 10 CFR 40.65(a)(1); and

(j) In Appendix A to 10 CFR part 40, the following substitutions:

(i) "R313-12-3" for reference to "Sec. 20.1003 of this chapter" as found in the first paragraph of the introduction to Appendix A;

(ii) "Utah Administrative Code, Rule R317-6, Ground Water Quality Protection" for ground water standards in "Environmental Protection Agency in 40 CFR part 192, subparts D and E" as found in the Introduction, paragraph 4; or "Environmental Protection Agency in 40 CFR part 192, subparts D and E (48 FR 45926; October 7, 1983)" as found in Criterion 5;

(iii) "[~~Board~~]Director as defined in Subsection 19-5-102(6)" for reference to "Commission" in the definition of "compliance period," in paragraph five of the introduction and in Criterion 5A(3);

(iv) "[~~Executive Secretary~~]Director" for reference to "Commission" in the definition of "closure plan", in paragraph five of the introduction, and in Criterions 6(2), 6(4), 6(6), 6A(2), 6A(3), 9, and

10 of Appendix A;

(v) "license issued by the [~~Executive Secretary~~]Director" for reference to "Commission license" in the definition of "licensed site," in the introduction to Appendix A;

(vi) "[~~Executive Secretary~~]Director" for reference to "NRC" in Criterion 4D;

(vii) "representatives of the [~~Executive Secretary~~]Director" for reference to "NRC staff" in Criterion 6(6);

(viii) "[~~Executive Secretary~~]Director-approved" for reference to "Commission-approved" in Criterion 6A(1) and Criterion 9;

(ix) "[~~Executive Secretary~~]Director" for reference to "appropriate NRC regional office as indicated in Criterion 8A" as found, Criterion 8, paragraph 2 or for reference to "appropriate NRC regional office as indicated in Appendix D to 10 CFR part 20 of this chapter, or the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555," as stated in Criterion 8A; and

(x) "[~~Executive Secretary~~]Director" for reference to "the Commission or the State regulatory agency" in Criterion 9, paragraph 2.

KEY: environmental analysis, uranium mills, tailings, monitoring
Date of Enactment or Last Substantive Amendment: [~~October 7, 2002~~]2013
Notice of Continuation: May 24, 2012
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-3-108

Environmental Quality, Radiation Control
R313-30
Therapeutic Radiation Machines

NOTICE OF PROPOSED RULE
(Amendment)
DAR FILE NO.: 37197
FILED: 01/11/2013

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: Changes are required to conform with S.B. 21, 2012 General Session (Chapter 360, Laws of Utah 2012).

SUMMARY OF THE RULE OR CHANGE: S.B. 21 (2012) gave authority to the Director of the Division of Radiation Control to make many regulatory decisions that had previously been made either by the Radiation Control Board or by the Executive Secretary of the Radiation Control Board. This rule change implements these statutory changes by replacing occurrences of both "executive secretary" and "board" with "director." In Subsection R313-30-4(1)(d)(ii), provisions for the Board to grant an exemption were changed so the director may issue a written approval.

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Section 19-3-104 and Section 19-3-108

ANTICIPATED COST OR SAVINGS TO:
♦ THE STATE BUDGET: There are no anticipated costs or savings to the state budget as this amendment only changes who has authority to make regulatory decisions.
♦ LOCAL GOVERNMENTS: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.
♦ SMALL BUSINESSES: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.
♦ PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.

COMPLIANCE COSTS FOR AFFECTED PERSONS: There are no compliance costs for affected persons as this amendment only changes who has authority to make regulatory decisions.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: There is no anticipated fiscal impact on businesses as this amendment only changes who has authority to make regulatory decisions.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
ENVIRONMENTAL QUALITY
RADIATION CONTROLROOM THIRD FLOOR
195 N 1950 W
SALT LAKE CITY, UT 84116-3085
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Craig Jones by phone at 801-536-4264, by FAX at 801-533-4097, or by Internet E-mail at cwjones@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 03/04/2013

THIS RULE MAY BECOME EFFECTIVE ON: 03/19/2013

AUTHORIZED BY: Rusty Lundberg, Director

R313. Environmental Quality, Radiation Control.
R313-30. Therapeutic Radiation Machines.
R313-30-1. Scope and Applicability.

(1) R313-30 establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines. The provisions of R313-30 are in addition to, and not in substitution for, other applicable provisions of these rules.

(2) The use of therapeutic radiation machines shall be by, or under the supervision of, a licensed practitioner of the healing arts who meets the training and experience criteria established by R313-30-3(3).

(3) R313-30 shall only apply to therapeutic radiation machines which accelerate electrons into a target to produce bremsstrahlung or which accelerate electrons to produce a clinically useful electron beam.

R313-30-2. Definitions.

As used in R313-30, the following definitions apply:

"Absorbed dose (D)" means the mean energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is the gray (Gy). The previously used special unit of absorbed dose (rad) is being replaced by the gray.

"Absorbed dose rate" means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

"Accessible surfaces" means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool, or without opening an access panel or door.

"Added filtration" means filtration which is in addition to the inherent filtration.

"Air kerma (K)" means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

"Barrier" See "Protective barrier."

"Beam axis" means the axis of rotation of the radiation head.

"Beam-limiting device" means a field defining collimator which provides a means to restrict the dimensions of the useful beam.

"Beam monitoring system" means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

"Beam scattering foil" means a thin piece of material, usually metallic, placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

"Bent beam linear accelerator" means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

"Changeable filters" means filters, exclusive of inherent filtration, which can be removed from the useful beam through electronic, mechanical, or physical processes.

"Contact therapy system" means a therapeutic radiation machine with a short target to skin distance (TSD), usually less than five centimeters.

"Detector" See "Radiation detector."

"Dose monitor unit (DMU)" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

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

"Field-flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.

"Filter" means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to R313-30-6.

"Gantry" means that part of a therapeutic radiation machine supporting and allowing movements of the radiation head about a center of rotation.

"Gray (Gy)" means the SI unit of absorbed dose, kerma, and specific energy imparted equal to 1 joule per kilogram. The previous unit of absorbed dose (rad) is being replaced by the gray. Note that 1 Gy equals 100 rad.

"Half-value layer (HVL)" means the thickness of a specified material which attenuates x-radiation or gamma radiation to the extent that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-half of the value measured without the material at the same point.

"Interlock" means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

"Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

"Irradiation" means the exposure of a living being or matter to ionizing radiation.

"Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

"Kilovolt (kV) or kilo electron volt (keV)" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum. Current convention is to use kV for photons and keV for electrons.

"Lead equivalent" means the thickness of the material in question affording the same attenuation, under specified conditions, as lead.

"Leakage radiation" means radiation emanating from the therapeutic radiation machine except for the useful beam.

"Light field" means the area illuminated by light, simulating the radiation field.

"mA" means milliampere.

"Megavolt (MV) or mega electron volt (MeV)" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. Current convention is to use MV for photons and MeV for electrons.

"Monitor unit (MU)" See "Dose monitor unit."

"Moving beam radiation therapy" means radiation therapy with continuous displacement of one or more mechanical axes relative to the patient during irradiation. It includes arc therapy, skip therapy, conformal therapy and rotational therapy.

"Nominal treatment distance" means:

(a) For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

(b) For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

"Patient" means an individual subjected to machine produced external beam radiation for the purposes of medical therapy.

"Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

"Periodic quality assurance check" means a procedure which is performed to ensure that a previous calibration continues to be valid.

"Phantom" means an object which attenuates, absorbs, and scatters ionizing radiation in the same quantitative manner as tissue.

"Practical range of electrons" corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung x-rays.

"Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been delivered.

"Primary protective barrier" See "Protective barrier."

"Protective barrier" means a barrier of radiation absorbing materials used to reduce radiation exposure. The types of protective barriers are as follows:

(a) "Primary protective barrier" means the material, excluding filters, placed in the useful beam or a barrier which attenuates the primary beam.

(b) "Secondary protective barrier" means the material which attenuates stray radiation.

"Radiation detector" means a device which, in the presence of radiation provides, by either direct or indirect means a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

"Radiation field" See "Useful beam."

"Radiation head" means the structure from which the useful beam emerges.

"Radiation Therapy Physicist" means an individual qualified in accordance with R313-30-3(4).

"Redundant beam monitoring system" means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

"Scattered radiation" means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation.

"Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

"Secondary protective barrier" See "Protective barrier."

"Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

"Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

"Sievert (Sv)" means the SI unit of dose equivalent. The unit of dose equivalent is the joule per kilogram. The previous unit of dose equivalent (rem) is being replaced by the sievert. Note that 1 Sv equals 100 rem.

"Simulator, or radiation therapy simulation system" means an x-ray system intended for localizing the volume to be exposed during radiation therapy and reproducing the position and size of the therapeutic irradiation field.

"Source" means the region or material from which the radiation emanates.

"Source-skin distance (SSD)" See "Target-skin distance."

"Stationary beam radiation therapy" means radiation therapy without displacement of the radiation source relative to the patient during irradiation.

"Stray radiation" means the sum of leakage and scattered radiation.

"Target" means that part of an x-ray tube or particle accelerator onto which is directed a beam of accelerated particles to produce ionizing radiation or other particles.

"Target-skin distance (TSD)" means the distance measured along the beam axis from the center of the front surface of the x-ray target or electron virtual source to the surface of the irradiated object or patient.

"Tenth-value layer (TVL)" means the thickness of a specified material which, x-radiation or gamma radiation to the extent that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

"Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

"Therapeutic radiation machine" means x-ray or electron-producing equipment designed and used for external beam radiation therapy.

"Tube" means an x-ray tube, unless otherwise specified.

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and filament transformers and other appropriate elements that are contained within the tube housing.

"Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the therapeutic radiation machine to produce radiation.

"Virtual source" means a point from which radiation appears to originate.

"Wedge filter" means a filter which effects continuous change in transmission over all or a part of the radiation field.

"X-ray tube" means an electron tube which is designed to be used primarily for the production of x-rays.

R313-30-3. General Administrative Requirements for Facilities Using Therapeutic Radiation Machines.

(1) Administrative Controls. The registrant shall be responsible for directing the operation of the therapeutic radiation machines which have been registered with the Department. The registrant or the registrant's agent shall ensure that the requirements of R313-30 are met in the operation of the therapeutic radiation machines.

(2) A therapeutic radiation machine which does not meet the provisions of these rules shall not be used for irradiation of patients.

(3) Training for External Beam Radiation Therapy Authorized Users. The registrant for a therapeutic radiation machine subject to R313-30-6 or R313-30-7 shall require the authorized user to be a physician who:

(a) Is certified in:

(i) Radiology or therapeutic radiology by the American Board of Radiology; or

(ii) Radiation oncology by the American Osteopathic Board of Radiology; or

(iii) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(iv) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

(i) To satisfy the requirement for instruction, the classroom and laboratory training shall include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Radiation biology.

(ii) To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include:

(A) Review of the full calibration measurements and periodic quality assurance checks;

(B) Preparing treatment plans and calculating treatment times;

(C) Using administrative controls to prevent misadministrations;

(D) Implementing emergency procedures to be followed in the event of the abnormal operation of a external beam radiation therapy unit or console; and

(E) Checking and using radiation survey meters.

(iii) To satisfy the requirement for a period of supervised clinical experience, training shall include 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. The supervised clinical experience shall include:

(A) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and limitations and contraindications;

(B) Selecting proper dose and how it is to be administered;

(C) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and

(D) Post-administration follow-up and review of case histories.

(iv) An individual who satisfies the requirements in R313-30-3(b), but not R313-30-3(a), must submit an application to the [~~Executive Secretary~~]Director and must satisfy the requirements in R313-30-3(a) within one year of initial application to the [~~Executive Secretary~~]Director.

(c) After December 31, 1994, a physician shall not act as an authorized user for a therapeutic radiation machine until the physician's training has been reviewed and approved by the [~~Executive Secretary~~]Director.

(4) Training for Radiation Therapy Physicist. The registrant for a therapeutic radiation machine subject to R313-30-6 or R313-30-7 shall require the Radiation Therapy Physicist to:

(a) Satisify the provisions of R313-16, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and

(b) Be certified by the American Board of Radiology in:

(i) Therapeutic radiological physics; or

(ii) Roentgen-ray and gamma-ray physics; or

(iii) X-ray and radium physics; or

(iv) Radiological physics; or

(c) Be certified by the American Board of Medical Physics in Radiation Oncology Physics; or

(d) Be certified by the Canadian College of Medical Physics; or

(e) Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full time training in therapeutic radiological physics and also one year of full time work experience under the supervision of a Radiation Therapy Physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in R313-30-4(1), R313-30-6(16), R313-30-7(19), R313-30-6(17), and R313-30-7(20) under the supervision of a Radiation Therapy Physicist during the year of work experience.

(f) Notwithstanding the provisions of R313-30-3(4)(e), certification pursuant to R313-30-3(4)(b), (c) or (d) shall be required on or before December 31, 1999 for all persons currently qualifying as a Radiation Therapy Physicist pursuant to R313-30-3(4)(e).

(5) Qualifications of Operators.

(a) Individuals who will be operating a therapeutic radiation machine for medical use shall be American Registry of Radiologic Technologists (ARRT) Registered Radiation Therapy Technologists.

(b) The names and training of personnel currently operating a therapeutic radiation machine shall be kept on file at the facility. Information on former operators shall be retained for a period of at least two years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

(6) Written safety procedures and rules shall be developed by a Radiation Therapy Physicist and shall be available in the control area of a therapeutic radiation machine, including restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be familiar with these rules as required in R313-18-12(1)(c).

(7) Individuals shall not be exposed to the useful beam except for medical therapy purposes. Exposure for medical therapy purposes shall be ordered in writing by an authorized user who is specifically identified on the Certificate of Registration. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes.

(8) Visiting Authorized User. Notwithstanding the provisions of R313-30-3(7), a registrant may permit a physician to act as a visiting authorized user under the term of the registrant's Certificate of Registration for up to 60 days per calendar year under the following conditions:

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

(b) The visiting authorized user meets the requirements established for authorized users in R313-30-3(3)(a) and R313-30-3(3)(b); and

(c) The registrant maintains copies of records specified by R313-30-3(8) for five years from the date of the last visit.

(9) Individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the registrant's quality management program. In addition to the requirements of R313-30, these individuals are also subject to the requirements of R313-15-201, R313-15-202, R313-15-205 and R313-15-502.

(10) Information and Maintenance Record and Associated Information. The registrant shall maintain the following information in a separate file or package for therapeutic radiation machines, for inspection by the representatives of the [~~Executive Secretary~~]Director:

(a) Report of acceptance testing;

(b) Records of surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by R313-30, as well as the names of persons who performed the activities;

(c) Records of major maintenance and modifications performed on the therapeutic radiation machine after the effective date of these rules, as well as the names of persons who performed the services; and

(d) Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

(11) Records Retention. Records required by R313-30 shall be retained until disposal is authorized by the [~~Executive Secretary~~]Director unless another retention period is specifically authorized in R313-30. Required records shall be retained in an active file from at least the time of generation until the next inspection by a representative of the [~~Executive Secretary~~]Director. A required record generated prior to the last inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until the [~~Executive Secretary~~]Director authorizes final disposal.

R313-30-4. General Technical Requirements for Facilities Using Therapeutic Radiation Machines.

(1) Protection Surveys.

(a) The registrant shall ensure that radiation protection surveys of new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with R313-30-8. The radiation protection survey shall be performed by, or under the direction of, a Radiation Therapy Physicist or a Certified Health Physicist and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation:

(i) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in R313-15-201(1); and

(ii) Radiation levels in unrestricted areas do not exceed the limits specified in R313-15-301(1).

(b) In addition to the requirements of R313-30-4(1)(a), a radiation protection survey shall also be performed prior to subsequent medical use and:

(i) After making changes in the treatment room shielding;

(ii) After making changes in the location of the therapeutic radiation machine within the treatment room;

(iii) After relocation of, or modification of, the therapeutic radiation machine; or

(iv) Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

(c) The survey record shall indicate instances where the facility, in the opinion of the Radiation Therapy Physicist or a Certified Health Physicist, is in violation of applicable radiation protection rules. The survey record shall also include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the therapeutic radiation machine, the instruments used to measure radiation levels, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in areas expressed in microsieverts, millirems, per hour, the calculated maximum level of radiation over a period of one week for restricted and unrestricted areas, and the signature of the individual responsible for conducting the survey;

(d) If the results of the surveys required by R313-30-4(1)(a) or R313-30-4(1)(b) indicate radiation levels in excess of the respective limit specified in R313-30-4(1)(a), the registrant shall lock the control in the "OFF" position and not use the unit:

(i) Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

(ii) Until the registrant has received a [~~specific exemption from the Board~~]written approval from the Director.

(2) Modification of Radiation Therapy Unit or Room Before Beginning a Treatment Program. If the survey required by R313-30-4(1) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by R313-15-301(1) of these rules, before beginning the treatment program the registrant shall:

(a) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with R313-15-301(1) of these rules;

(b) Perform the survey required by R313-30-4(1) again; and

(c) Include in the report required by R313-30-4(4) the results of the initial survey, a description of the modification made to comply with R313-30-4(2)(a), and the results of the second survey; or

(d) Request and receive a registration amendment under R313-15-301(3) of these rules that authorizes radiation levels in unrestricted areas greater than those permitted by R313-15-301(1) of these rules.

(3) Possession of Survey Instruments. Facility locations authorized to use a therapeutic radiation machine in accordance with R313-30-6 and R313-30-7 shall possess appropriately calibrated portable monitoring equipment. As a minimum, the equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 uSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instruments shall be operable and calibrated in accordance with R313-30-8.

(4) Reports of External Beam Radiation Therapy Surveys and Measurements. The registrant for a therapeutic radiation machine subject to R313-30-6 or R313-30-7 shall furnish a copy of the records required in R313-30-4(1) and R313-30-4(2) to the [~~Executive Secretary~~]Director within 30 days following completion of the action that initiated the record requirement.

R313-30-5. Quality Management Program.

(1) In addition to the definitions in R313-30-2, the following definitions are applicable to a quality management program:

"Course" means the entire treatment consisting of multiple fractions as prescribed in the written directive.

"Misadministration" means the administration of an external beam radiation therapy dose:

(a) Involving the wrong patient, wrong treatment modality, or wrong treatment site;

(b) 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;

(c) When the calculated weekly administered dose differs from the weekly prescribed dose by more than 30 percent; or

(d) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose;

"Prescribed dose" means the total dose and dose per fraction as documented in the written directive.

"Recordable event" means the administration of an external beam radiation therapy dose when the calculated weekly administered dose differs by 15 percent or more from the weekly prescribed dose;

"Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation, containing the following information: total dose, dose per fraction, treatment site and overall treatment period.

(2) Scope and Applicability. Applicants or registrants subject to R313-30-6 or R313-30-7 shall establish and maintain a written quality management program to provide high confidence that radiation 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) Prior to administration, a written directive is prepared for an external beam radiation therapy dose;

(i) Notwithstanding R313-30-5(2)(a), a written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to administration of the external beam radiation therapy dose or the next external beam radiation therapy fractional dose;

(ii) Notwithstanding R313-30-5(2)(a), 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 shall be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision;

(iii) Notwithstanding R313-30-5(2)(a), 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 shall 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 and signed by an authorized user within 24 hours of the oral directive.

(b) Prior to the administration of a course of radiation treatments, the patient's identity is verified, by more than one method, as the individual named in the written directive;

(c) External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives;

(d) An administration is in accordance with the written directive; and

(e) Unintended deviations from the written directive is identified and evaluated, and appropriate action are taken.

(3) Development of Quality Management Program.

(a) An application for registration subject to R313-30-6 or R313-30-7 shall include a quality management program that specifies staff, duties and responsibilities, and equipment and procedures as part of the application required by R313-16 of these rules. The registrant shall implement the program upon issuance of a Certificate of Registration by the [~~Executive Secretary~~]Director;

(b) Existing registrants subject to R313-30-6 or R313-30-7 shall submit to the [~~Executive Secretary~~]Director a written certification that a quality management program has been implemented by December 31, 1994.

(4) As a part of the quality management program, the registrant shall:

(a) Develop procedures for, and conduct a review of, the quality management program including, since the last review, an evaluation of a representative sample of patient administrations, recordable events, and misadministrations to verify compliance with the quality management program;

(b) Conduct these reviews annually. The intervals should not exceed 12 months and shall not exceed 13 months;

(c) Evaluate these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the requirements of R313-30-5(2); and

(d) Maintain records of these reviews, including the evaluations and findings of the reviews, in a form that can be readily audited, for three years.

(5) The registrant shall evaluate and respond, within 30 days after discovery of the recordable event, to recordable events by:

(a) Assembling the relevant facts including the cause;

(b) Identifying what corrective actions are required to prevent recurrence; and

(c) Retaining a record, in a form that can be readily audited, for three years, of the relevant facts and what corrective actions were taken.

(6) The registrant shall retain:

(a) Written directives; and

(b) A record of administered radiation doses, in a form that can be readily audited, for three years after the date of administration.

(7) The registrant may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased.

(8) The registrant shall evaluate misadministrations and shall take the following actions in response to a misadministration:

(a) Notify the [~~Executive Secretary~~]Director by telephone no later than the next calendar day after discovery of the misadministration;

(b) Submit a written report to the [~~Executive Secretary~~]Director within 15 days after discovery of the misadministration. The written report shall include: the registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the registrant notified the patient or the patient's responsible relative or guardian, this person will subsequently be referred to as "the patient," 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;

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

(d) Retain a record of misadministrations for five years. The record shall contain the names of individuals involved; including the prescribing physician, allied health personnel, the patient, and the patient's referring physician; the patient's social security number or identification number if one has been assigned; a brief description of the event; why it occurred; the effect on the patient; what improvements are needed to prevent recurrence; and the actions taken to prevent recurrence; and

(e) If the patient was notified, furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either a copy of the report that was submitted to the [~~Executive Secretary~~]Director, or a brief description of both the event and the consequences as they may effect the patient, provided a statement is included that the report submitted to the [~~Executive Secretary~~]Director can be obtained from the registrant;

(9) Aside from the notification requirement, nothing in R313-30-5(8) affects the rights or duties of registrants and physicians in relation to patients, the patient's responsible relatives or guardians, or to others.

R313-30-6. Therapeutic Radiation Machines of Less Than 500 kV.

(1) Leakage Radiation. When the x-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

(a) Systems 5-50 kV. The leakage air kerma rate measured at a position five centimeters from the tube housing assembly shall not exceed 1 mGy (100 mrad) in one hour.

(b) Systems greater than 50 and less than 500 kV. The leakage air kerma rate measured at a distance of one meter from the source in every direction shall not exceed 1 cGy (1 rad) in one hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of five centimeters from the surface of the tube housing assembly shall not exceed 30 cGy (30 rad) per hour.

(2) Permanent Beam Limiting Devices. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

(3) Adjustable or Removable Beam Limiting Devices.

(a) Adjustable or removable beam limiting devices, diaphragms, cones or blocks shall not transmit more than five percent of the useful beam for the most penetrating beam used;

(b) When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

(4) Filter System. The filter system shall be so designed that:

(a) Filters can not be accidentally displaced at every possible tube orientation;

(b) For equipment installed after the effective date of these rules, an interlock system prevents irradiation if the proper filter is not in place;

(c) The air kerma rate escaping from the filter slot shall not exceed 1 cGy (1 rad) per hour at one meter under operating conditions; and

(d) Filters shall be marked as to its material of construction and its thickness.

(5) Tube Immobilization.

(a) The x-ray tube shall be so mounted that it can not accidentally turn or slide with respect to the housing aperture; and

(b) The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

(6) Source Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the source to within five millimeters, and the marking shall be readily accessible for use during calibration procedures.

(7) Beam Block. Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(8) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

(a) A timer which has a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector. The timer shall activate with an indication of "BEAM-ON" and retain its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the timer;

(b) For equipment manufactured after the effective date of these rules, the timer shall be a cumulative timer with an elapsed time indicator. Otherwise, the timer may be a countdown timer;

(c) The timer shall terminate irradiation when a pre-selected time has elapsed, if the dose monitoring system present has not previously terminated irradiation;

(d) The timer shall permit pre-setting and determination of exposure times as short as one second;

(e) The timer shall not permit an exposure if set at zero;

(f) The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

(g) Timer shall be accurate to within one percent of the selected value or to within one second, whichever is greater.

(9) Control Panel Functions. The control panel, in addition to the displays required by other provisions in R313-30-6, shall have:

(a) An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;

(b) An indication of whether x-rays are being produced;

(c) Means for indicating x-ray tube potential and current;

(d) The means for terminating an exposure at any time;

(e) A locking device which will prevent unauthorized use of the therapeutic radiation machine; and

(f) For therapeutic radiation machines manufactured after the effective date of these rules, a positive display of specific filters in the beam.

(10) Multiple Tubes. When a control panel may energize more than one x-ray tube:

(a) It shall be possible to activate only one x-ray tube at a time;

(b) There shall be an indication at the control panel identifying which x-ray tube is activated; and

(c) There shall be an indication at the tube housing assembly when that tube is energized.

(11) Target-to-Skin Distance (TSD). There shall be a means of determining the central axis TSD to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

(12) Shutters. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five seconds after the x-ray "ON" switch is energized, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel. An indication of shutter position shall appear at the control panel.

(13) Low Filtration X-ray Tubes. Therapeutic radiation machines equipped with a beryllium or other low-filtration window shall have a label clearly marked on the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

(14) Facility Design Requirements for Therapeutic Radiation Machines Capable of Operating in the Range 50 kV to 500 kV. In addition to shielding adequate to meet requirements of R313-30-9, the treatment room shall meet the following design requirements:

(a) Aural Communication. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel;

(b) Viewing Systems. Provision shall be made to permit continuous observation of the patient during irradiation and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(15) Additional Requirements. Treatment rooms which contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

(a) Protective barriers shall be fixed except for entrance doors or beam interceptors;

(b) The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;

(c) Interlocks shall be provided so that entrance doors, including doors to interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by a door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

(d) When a door referred to in R313-30-6(15)(c) is opened while the x-ray tube is activated, the irradiation shall be interrupted either electrically or by the closure of the shutter.

(16) Full Calibration Measurements.

(a) Full calibration of a therapeutic radiation machine subject to R313-30-6 shall be performed by, or under the direct supervision of, a Radiation Therapy Physicist:

(i) Before the first medical use following installation or reinstallation of the therapeutic radiation machine;

(ii) Annually. The intervals should not exceed 12 months and shall not exceed 13 months; and

(iii) Before medical use under the following conditions:

(A) Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be reconciled; and

(B) Following a component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

(iv) Notwithstanding the requirements of R313-30-6(16)(a)(iii):

(A) Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes and energies that are not within their acceptable range; and

(B) If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in R313-30-6(16)(a)(iii)(A).

(v) The registrant shall use the dosimetry system described in R313-30-8(6)(a) to perform the full calibration required in R313-30-6(16)(b);

(b) To satisfy the requirement of R313-30-6(16)(a), full calibration shall include measurements recommended for annual calibration by NCRP Report 69, "Dosimetry of X-Ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV," 1981 ed., which is adopted and incorporated by reference.

(c) The registrant shall maintain a record of calibrations for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the x-ray tube, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the Radiation Therapy Physicist responsible for performing the calibration.

(17) Periodic Quality Assurance Checks.

(a) Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to R313-30-6, which are capable of operation at greater than 50 kV.

(b) To satisfy the requirement of R313-30-6(17)(a), quality assurance checks shall meet the following requirements:

(i) The registrant shall perform quality assurance checks in accordance with written procedures established by the Radiation Therapy Physicist; and

(ii) The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in R313-30-6(16)(a). The acceptable tolerance for parameters measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in R313-30-6(16)(a), shall be stated.

(c) The cause for a parameter exceeding a tolerance set by the Radiation Therapy Physicist shall be investigated and corrected before the system is used for patient irradiation;

(d) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Radiation Therapy Physicist's quality assurance check procedures, the system shall be recalibrated as required in R313-30-6(16)(a);

(e) The registrant shall use the dosimetry system described in R313-30-8(6)(b) to make the quality assurance check required in R313-30-6(17)(b);

(f) The registrant shall have the Radiation Therapy Physicist review and sign the results of radiation output quality assurance checks monthly. The interval should not exceed 30 days and shall not exceed 40 days;

(g) Therapeutic radiation machines subject to R313-30-6 shall have safety quality assurance checks of external beam radiation therapy facilities performed monthly. The interval should not exceed 30 days and shall not exceed 40 days;

(h) Notwithstanding the requirements of R313-30-6(17)(f) and R313-30-6(17)(g), the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by R313-30-6(17)(f) and R313-30-6(17)(g) have been performed within the required interval immediately prior to the administration;

(i) To satisfy the requirement of R313-30-6(17)(g), safety quality assurance checks shall ensure proper operation of:

(i) Electrical interlocks at external beam radiation therapy room entrances;

(ii) Proper operation of the "BEAM-ON" and termination switches;

(iii) Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

(iv) Viewing systems;

(v) If applicable, electrically operated treatment room doors from inside and outside the treatment room;

(j) The registrant shall maintain a record of quality assurance checks required by R313-30-6(17)(a) and R313-30-6(17)(g) for three years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instruments used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

(18) Operating Procedures.

(a) The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of R313-30-6(16) and R313-30-6(17) have been met;

(b) Therapeutic radiation machines shall not be left unattended unless secured pursuant to R313-30-6(9)(e);

(c) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

(d) The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require holding and the peak tube potential of the system does not exceed 50 kV. In these cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;

(e) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

(f) No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, individuals, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of R313-15-201 of these rules.

R313-30-7. Therapeutic Radiation Machines - Photon Therapy Systems (500 kV and Above) and Electron Therapy Systems (500 keV and Above).

(1) Leakage Radiation Outside the Maximum Useful Beam in Photon and Electron Modes.

(a) The absorbed dose rate due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance, that is at the plane of the patient, shall not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose rate on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane;

(b) Except for the area defined in R313-30-7(1)(a), the absorbed dose rate, excluding that from neutrons, at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 percent of the absorbed dose rate on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters;

(c) For equipment manufactured after the effective date of these rules, the neutron absorbed dose outside the useful beam shall be in compliance with applicable acceptance criteria; and

(d) For therapeutic radiation machines, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in R313-30-7(1)(a) through R313-30-7(1)(c) for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by representatives of the [~~Executive Secretary~~]Director.

(2) Leakage Radiation Through Beam Limiting Devices.

(a) Photon Radiation.

(i) Adjustable or interchangeable beam limiting devices, such as the collimating jaws or x-ray cones, shall attenuate the useful beam so that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting devices shall not exceed two percent of the maximum absorbed dose on the central axis of the useful beam measured in a ten centimeters by ten centimeters radiation field; and

(ii) Interchangeable beam limiting devices, such as auxiliary beam blocking material, shall attenuate the useful beam so that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the interchangeable beam limiting device shall not exceed five percent of the maximum absorbed dose on the central axis of the useful beam measured in a ten centimeter by ten centimeter radiation field.

(b) Electron Radiation. Adjustable or interchangeable electron applicators shall attenuate the radiation, including but not

limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, so that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

(i) A maximum of two percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and

(ii) A maximum of ten percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam.

(c) Measurement of Leakage Radiation.

(i) Photon Radiation. Measurements of leakage radiation through the beam limiting devices shall be made with the beam limiting devices closed and residual apertures blocked by at least two tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through the sets of beam limiting devices shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding ten square centimeters;

(ii) Electron Radiation. Measurements of leakage radiation through the electron applicators shall be made with an appropriate radiation detector suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using an appropriate amount of water equivalent build up material for the energies being measured.

(3) Filters and Wedges.

(a) Filters and wedges which are removable from the system shall be clearly marked with an identification number;

(i) For removable wedge filters, the nominal wedge angle shall appear on the wedge, or on the wedge tray if the wedge filter is permanently mounted to the tray.

(ii) If the wedge or wedge tray is damaged, the Radiation Therapy Physicist will decide if the wedge transmission factor shall be redetermined;

(b) For equipment manufactured after the effective date of these rules which utilize a system of wedge filters:

(i) Irradiation shall not be possible until a selection of a wedge filter or a positive selection to use "no wedge filter" has been made at the treatment control panel;

(ii) An interlock system shall be provided to prevent irradiation if the wedge filter selected is not in the correct position;

(iii) A display shall be provided at the treatment control panel showing the wedge filters in use; and

(iv) An interlock shall be provided to prevent irradiation if a wedge filter selection operation, either manual or automatic, carried out in the treatment room does not agree with the wedge filter selection operation carried out at the treatment control panel.

(c) If the absorbed dose rate information required by R313-30-7(8) relates exclusively to operation with a field flattening filter or beam scattering foil in place, the filter or foil shall be removable only by the use of tools. If removable, the filter or foil shall be interlocked to prevent incorrect selection and incorrect positioning.

(d) For equipment manufactured after the effective date of these rules which utilize a system of interchangeable field flattening filters or interchangeable beam scattering foils:

(i) An interlock system shall be provided to prevent irradiation if the appropriate flattening filter for the x-ray energy selected is not in the correct position in the beam;

(ii) An interlock system shall be provided to prevent irradiation if the appropriate beam scattering foil for the electron energy selected is not in the correct position in the beam;

(iii) An interlock system shall be provided to prevent irradiation if no scattering foil is in place for the electron beams, or if no flattening filter is in place for the x-ray beams; and

(iv) A display shall be provided at the treatment control panel showing a fault indicator when the interlock system has prevented irradiation. The fault indicator will identify a filter or foil error.

(4) Stray Radiation in the Useful Beam. For equipment manufactured after the effective date of these rules, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that x-ray stray radiation in the useful electron beam, absorbed dose at the surface during x-ray irradiation and stray neutron radiation in the useful x-ray beam meet applicable acceptance criteria.

(5) Beam Monitors. Therapeutic radiation machines subject to R313-30-7 shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate, and to monitor other beam parameters.

(a) Equipment manufactured after the effective date of these rules shall be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of a common element.

(b) Equipment manufactured on or before the effective date of these rules shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system;

(c) The detector and the system into which that detector is incorporated shall meet the following requirements:

(i) Detectors shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;

(ii) Detectors shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;

(iii) The beam monitoring systems shall be capable of independently monitoring, interrupting, and terminating irradiation; and

(iv) For equipment manufactured after the effective date of these rules, the design of the beam monitoring systems shall ensure that the:

(A) Malfunctioning of one system shall not affect the correct functioning of the secondary system; and

(B) Failure of an element common to both systems which could affect the correct function of both systems shall terminate irradiation or prevent the initiation of radiation.

(v) Beam monitoring systems shall have a legible display at the treatment control panel. For equipment manufactured after the effective date of these rules, displays shall:

(A) Maintain a reading until intentionally reset;

(B) Have only one scale and no electrical or mechanical scale multiplying factors;

(C) Utilize a design so that increasing dose monitor units are displayed by increasing numbers; and

(D) In the event of power failure, the dose monitor units delivered up to the time of failure, or the beam monitoring information required in R313-30-7(5)(c)(v)(C) displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20 minute period of time.

(6) Beam Symmetry.

(a) Bent-beam linear accelerators subject to R313-30-7 shall be provided with auxiliary devices to monitor beam symmetry;

(b) The devices referenced in R313-30-7(6)(a) shall be able to detect field asymmetry greater than ten percent; and

(c) The devices referenced in R313-30-7(6)(a) shall be configured to terminate irradiation if the specifications in R313-30-7(6)(b) can not be maintained.

(7) Selection and Display of Dose Monitor Units.

(a) Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel;

(b) The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation;

(c) After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

(d) For equipment manufactured after the effective date of these rules, after termination of irradiation, it shall be necessary for the operator to reset the preselected dose monitor units before irradiation can be initiated.

(8) Air Kerma Rate and Absorbed Dose Rate. For equipment manufactured after the effective date of these rules, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. The radiation detectors specified in R313-30-7(5) may form part of this system. In addition:

(a) The dose monitor unit dose rate shall be displayed at the treatment control panel;

(b) If the equipment can deliver an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

(c) If the equipment can deliver, under any fault condition, an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 4 Gy (400 rad); and

(d) For therapeutic radiation machines, the registrant shall determine, or obtain from the manufacturer, the maximum values specified in R313-30-7(8)(b) and R313-30-7(8)(c) for the specified operating conditions. Records of these maximum values shall be maintained at the installation for inspection by representatives of the [~~Executive Secretary~~]Director.

(9) Termination of Irradiation by the Beam Monitoring System or Systems During Stationary Beam Radiation Therapy.

(a) Primary systems shall terminate irradiation when the preselected number of dose monitor units has been detected by the system;

(b) If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

(c) For equipment manufactured after the effective date of these rules, an indicator on the control panel shall show which monitoring system has terminated irradiation.

(10) Termination Switches. It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

(11) Interruption Switches. If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without a reselection of operating conditions. If a change is made of a pre-selected value during an interruption, irradiation and equipment movements shall be automatically terminated.

(12) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

(a) A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator;

(b) The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

(c) The timer shall terminate irradiation when a preselected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

(13) Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

(a) Irradiation shall not be possible until a selection of radiation type (x-rays or electrons) has been made at the treatment control panel;

(b) The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

(c) An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type which has been selected;

(d) An interlock system shall be provided to prevent irradiation with x-rays, except to obtain a verification film, when electron applicators are fitted;

(e) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and

(f) An interlock system shall be provided to prevent irradiation if selected operations carried out in the treatment room do

not agree with the selected operations carried out at the treatment control panel.

(14) Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

(a) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

(b) The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation; and

(c) Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location.

(15) Selection of Stationary Beam Radiation Therapy or Moving Beam Radiation Therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

(a) Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;

(b) The mode of operation shall be displayed at the treatment control panel;

(c) An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected;

(d) An interlock system shall be provided to prevent irradiation if a selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

(e) Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement. For equipment manufactured after the effective date of these rules:

(i) An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in increments of ten degrees of rotation or one centimeter of motion differs by more than 20 percent from the selected value;

(ii) Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units shall differ by less than five percent from the dose monitor unit value selected;

(iii) An interlock shall be provided to prevent motion of more than five degrees or one centimeter beyond the selected limits during moving beam radiation therapy;

(iv) For equipment manufactured after the effective date of these rules, an interlock shall be provided to require that a selection of direction be made at the treatment control panel in units which are capable of both clockwise and counter-clockwise moving beam radiation therapy.

(v) Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

(f) Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by R313-30-7(9); and

(g) For equipment manufactured after the effective date of these rules, an interlock system shall be provided to terminate irradiation if movement:

(i) Occurs during stationary beam radiation therapy; or

(ii) Does not start or stops during moving beam radiation therapy unless the stoppage is a preplanned function.

(16) Facility Design Requirements for Therapeutic Radiation Machines Operating above 500 kV. In addition to shielding adequate to meet requirements of R313-30-9, the following design requirements are made:

(a) Protective Barriers. Protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors;

(b) Control Panel. In addition to other requirements specified in R313-30, the control panel shall also:

(i) Be located outside the treatment room;

(ii) Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

(iii) Provide an indication of whether radiation is being produced; and

(iv) Include an access control device which will prevent unauthorized use of the therapeutic radiation machine;

(c) Viewing Systems. Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational;

(d) Aural Communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible;

(e) Room Entrances. Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of access doors, which will indicate when the useful beam is "ON;"

(f) Entrance Interlocks. Interlocks shall be provided so that access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by an access control, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel;

(g) Beam Interceptor Interlocks. If the shielding material in a protective barrier requires the presence of a beam interceptor to ensure compliance with R313-30-301(1), interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barriers;

(h) Emergency Cutoff Switches. At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by R313-30-7(11). Emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control panel without resetting the emergency cutoff switch. Alternatively, power cannot be restarted without pressing a RESET button in the treatment room after resetting the power breaker, and the operator shall check the treatment room and patient prior to turning the power back on;

(i) Safety Interlocks. Safety interlocks shall be designed so that defects or component failures in the safety interlock system prevent or terminate operation of the therapeutic radiation machine; and

(j) Surveys for Residual Radiation. Surveys for residual activity shall be conducted on therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production.

(17) Radiation Therapy Physicist Support.

(a) The services of a Radiation Therapy Physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The Radiation Therapy Physicist shall be responsible for:

(i) Full calibrations required by R313-30-7(19) and protection surveys required by R313-30-4(1);

(ii) Supervision and review of dosimetry;

(iii) Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;

(iv) Quality assurance, including quality assurance check review required by R313-30-7(20)(e) of these rules;

(v) Consultation with the authorized user in treatment planning, as needed; and

(vi) Perform calculations and assessments regarding misadministrations.

(b) If the Radiation Therapy Physicist is not a full-time employee of the registrant, the operating procedures required by R313-30-7(18) shall also specifically address how the Radiation Therapy Physicist is to be contacted for problems or emergencies, as well as the specific actions to be taken until the Radiation Therapy Physicist can be contacted.

(18) Operating Procedures.

(a) No individual, other than the patient, shall be in the treatment room during treatment or during an irradiation for testing or calibration purposes;

(b) Therapeutic radiation machines shall not be made available for medical use unless the requirements of R313-30-4(1), R313-30-7(19) and R313-30-7(20) have been met;

(c) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

(d) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used;

(e) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

(f) When adjustable beam limiting devices or beam limiting devices that do not contact the skin are used, the position and shape of the radiation field shall be indicated by a light field.

(19) Full Calibration Measurements.

(a) Full calibration of a therapeutic radiation machine subject to R313-30-7 shall be performed by, or under the direct supervision of, a Radiation Therapy Physicist:

(i) Before the first medical use following installation or reinstallation of the therapeutic radiation machine;

(ii) Annually. The intervals should not exceed 12 months and shall not exceed 13 months; and

(iii) Before medical use under the following conditions:

(A) Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be easily reconciled; and

(B) Following component replacement, major repair, or modification of components, if the appropriate Quality Assurance checks demonstrate that the characteristics of the radiation beam have been significantly affected as determined by a Radiation Therapy Physicist. The Quality Assurance checks shall be performed by, or under the direct supervision of a Radiation Therapy Physicist. The determination of the need for a full calibration shall be made by a Radiation Therapy Physicist.

(iv) Notwithstanding the requirements of R313-30-7(19)(a)(iii):

(A) Full calibration of therapeutic radiation machines with multi-energy and multi-mode capabilities is required only for those modes and energies that are not within their range and the difference cannot be easily reconciled; and

(B) If the repair, replacement or modification does not affect all modes and energies, full calibration shall be performed on the effected mode or energy if the Quality Assurance checks demonstrate that the characteristics of the radiation beam have been significantly affected as determined by a Radiation Therapy Physicist. The Quality Assurance checks shall be performed by, or under the direct supervision of, a Radiation Therapy Physicist. The determination of the need for a full calibration shall be made by a Radiation Therapy Physicist. The remaining energies or modes may be validated with quality assurance check procedures against the criteria in R313-30-7(19)(a)(iii)(A).

(b) To satisfy the requirement of R313-30-7(19)(a), full calibration shall include measurements required for annual calibration by American Association of Physicists in Medicine (AAPM) Report 46, "Comprehensive Quality Assurance for Radiation Oncology," 1994 ed., which is adopted and incorporated by reference;

(c) The registrant shall use the dosimetry system described in R313-30-8(6) to measure the radiation output for one set of exposure conditions. The remaining radiation measurements required in R313-30-7(19)(b) may then be made using a dosimetry system that indicates relative dose rates; and

(d) The registrant shall maintain a record of calibrations for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the Radiation Therapy Physicist responsible for performing the calibration.

(20) Periodic Quality Assurance Checks.

(a) Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to R313-30-7. These checks should be performed at intervals not to exceed those intervals recommended in American Association of Physicists in Medicine (AAPM) Report 46, "Comprehensive Quality Assurance for Radiation Oncology," 1994 ed., which is adopted and incorporated by reference.

(i) Determination of parameters for central axis radiation output shall be done at least weekly. The interval shall not exceed ten days.

(ii) The interval at which periodic quality assurance checks are to be performed shall be determined by the Radiation Therapy Physicist and shall be documented in the registrant's quality management program. The interval for a specific performance check may be based on the history of that performance check for a particular machine. The interval may be increased above the recommended limits only if the Radiation Therapy Physicist determines the increase

is justified based on the history of the performance check for that machine or a machine of the same manufacturer and the same model.

(iii) If the performance check demonstrates a need to decrease the interval, the Radiation Therapy Physicist shall decide if the interval should be decreased. The decreased interval shall be continued until the performance check demonstrates that the decreased interval is not necessary.

(b) To satisfy the requirement of R313-30-7(20)(a), quality assurance checks shall include determination of central axis radiation output and shall include a representative sampling of periodic quality assurance checks contained in American Association of Physicists in Medicine (AAPM) Report 46, "Comprehensive Quality Assurance for Radiation Oncology," 1994 ed., which is adopted and incorporated by reference.

(i) A representative sampling shall include those referenced periodic quality assurance checks necessary to assure that the radiation beam and alignment parameters for all therapy machines and modes of operation are within limits prescribed by AAPM Report 46.

(ii) The intervals for a representative sampling of referenced periodic quality assurance checks should not exceed 12 consecutive months and shall not exceed 13 consecutive months.

(c) The registrant shall use a dosimetry system which has been inter-compared semi-annually. The intervals should not exceed six months and shall not exceed seven months, with a dosimetry system described in R313-30-8(6)(a) to make the periodic quality assurance checks required in R313-30-7(20)(a)(i);

(d) The registrant shall perform periodic quality assurance checks required by R313-30-7(20)(a) in accordance with procedures established by the Radiation Therapy Physicist;

(e) The registrant shall review the results of periodic radiation output checks according to the following procedures:

(i) The authorized user and Radiation Therapy Physicist shall be immediately notified if a parameter is not within its acceptable range. The therapeutic radiation machine shall not be made available for subsequent medical use until the Radiation Therapy Physicist has determined that all parameters are within their acceptable range;

(ii) If periodic radiation output check parameters appear to be within their acceptable range, the periodic radiation output check shall be reviewed and signed by either the authorized user or Radiation Therapy Physicist within two weeks;

(iii) The Radiation Therapy Physicist shall review and sign the results of radiation output quality assurance checks at intervals not to exceed one month; and

(iv) Other Quality Assurance checks shall be reviewed at intervals specified in the Quality Management Program, as required by R313-30-5.

(f) Therapeutic radiation machines subject to R313-30-7 shall have safety quality assurance checks of external beam radiation therapy facilities performed weekly at intervals not to exceed ten days;

(g) To satisfy the requirement of R313-30-7(20)(f), safety quality assurance checks shall ensure proper operation of:

(i) Electrical interlocks at external beam radiation therapy room entrances;

(ii) Proper operation of the "BEAM-ON", interrupt and termination switches;

(iii) Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

(iv) Viewing and aural communication systems;

(v) Electrically operated treatment room doors from inside and outside the treatment room;

(vi) At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, switches shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.

(h) The registrant shall promptly repair a system identified in R313-30-7(20)(g) that is not operating properly; and

(i) The registrant shall maintain a record of quality assurance checks required by R313-30-7(20)(a) and R313-30-7(20)(g) for three years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instruments used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

R313-30-8. Calibration and Check of Survey Instruments and Dosimetry Equipment.

(1) The registrant shall ensure that the survey instruments used to show compliance with R313-30 have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

(2) To satisfy the requirements of R313-30-8(1), the registrant shall:

(a) Calibrate required scale readings up to 10 mSv (1000 mrem) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST);

(b) Calibrate at least two points on the scales to be calibrated. These points should be at approximately 1/3 and 2/3 of scale rating; and

(3) To satisfy the requirements of R313-30-8(2), the registrant shall:

(a) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than ten percent; and

(b) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent if a correction factor or graph is conspicuously attached to the instrument.

(4) The registrant shall retain a record of calibrations required in R313-30-8(1) for three years. The record shall include:

(a) A description of the calibration procedure; and

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

(5) The registrant may obtain the services of individuals licensed by the Board, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations which contain information required by R313-30-8(4) shall be maintained by the registrant.

(6) Dosimetry Equipment.

(a) The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated for by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited

Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within 24 months prior to use and after servicing that may have affected system calibration.

(i) For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60;

(ii) For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy or energy range appropriate for the radiation being used.

(b) The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with R313-30-8(6)(a). This comparison shall have been performed within the previous 12 months (six months if the dosimetry system is an ionization chamber) and after servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in R313-30-8(6)(a);

(c) The registrant shall maintain a record of dosimetry system calibration, intercomparison, and comparison for the duration of the license and registration. For calibrations, intercomparisons, or comparisons, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by R313-30-8(6)(a) and R313-30-8(6)(b), the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the calibration, intercomparison, or comparison was performed by, or under the direct supervision of, a Radiation Therapy Physicist.

R313-30-9. Shielding and Safety Design Requirements.

(1) Therapeutic radiation machines subject to R313-30-6 or R313-30-7 shall be provided with the primary and secondary barriers that are necessary to ensure compliance with R313-15-201 and R313-30-301 of these rules.

(2) Facility design information for new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for approval by the [~~Executive Secretary~~]Director prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in R313-30-10.

R313-30-10. Information on Radiation Shielding Required for Plan Reviews.

(1) Therapeutic Radiation Machines

(a) Basic facility information including: name, telephone number and Department registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address, including room number, of the external beam radiation therapy facility. The plan should also indicate whether this is a new structure or a modification to existing structures.

(b) Wall, floor, and ceiling areas struck by the useful beam shall have primary barriers. For an adjacent area that is normally unoccupied, barrier thicknesses may be less than the required thickness, if:

(i) That area where the exposure rates and exposures exceed the limits specified in R313-15-301(1) is permanently fenced or walled to prevent access;

(ii) The appropriate warning signs are posted at appropriate intervals and locations on the fence or wall;

(iii) The exposure rates and exposures outside the fence or wall are less than the limits specified in R313-15-301(1);

(iv) Access to the area is controlled by the operator, and once access is gained, the therapeutic radiation machine cannot be operated until the area has been cleared and access is again controlled by the operator;

(v) The ceiling is of sufficient thickness to reduce exposure due to skyshine, so that the exposure rates and exposures surrounding the facility are less than the limits specified in R313-15-301(1); and

(vi) The primary barrier is of sufficient thickness to ensure that the exposure rates and exposures from the primary beam in spaces in adjacent buildings are less than the limits specified in R313-15-301(1).

(c) Secondary barriers shall be provided in wall, floor, and ceiling areas not having primary barriers.

(2) Therapeutic Radiation Machines up to 150 kV (photons only). In addition to the requirements listed in R313-30-10(1), therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, as a minimum, the following additional information:

(a) Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors.

(b) Maximum design workload for the facility including total weekly radiation output, expressed in gray (rad) or air kerma at one meter, total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

(c) A facility blueprint or drawing indicating: the scale of the blueprint or drawing; direction of North; normal location of the therapeutic radiation machine's radiation ports; the port's travel and traverse limits; general directions of the useful beam; locations of windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the external beam radiation therapy treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with R313-15-101 of these rules.

(d) The structural composition and thickness or the lead or concrete equivalent of walls, doors, partitions, floor, and ceiling of the rooms concerned.

(e) The type of occupancy of adjacent areas inclusive of space above and below the rooms concerned. If there is an exterior wall, show distance to the closest areas where it is likely that individuals may be present.

(f) At least one example calculation which shows the methodology used to determine the amount of shielding required for the physical conditions; that is the primary and secondary or leakage barriers, restricted and unrestricted areas, entry doors; and shielding material in the facility.

(i) If commercial software is used to generate shielding requirements, please also identify the software used and the version or revision date.

(ii) If the software used to generate shielding requirements is not in the open literature, please also submit quality control sample calculations to verify the result obtained with the software.

(3) Therapeutic Radiation Machines over 150 kV. In addition to the requirements listed in R313-30-10(1), therapeutic radiation machine facilities which produce photons with a maximum energy in excess of 150 kV and electrons and protons or other subatomic particles shall submit shielding plans which contain, as a minimum, the following additional information:

(a) Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energies and types of radiation produced, that is photon and electron. The source to isocenter distance shall be specified.

(b) Maximum design workload for the facility including total weekly radiation output, expressed in gray (rad) at one meter, total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

(c) Facility blueprint or drawing, including both floor plan and elevation views, indicating relative orientation of the therapeutic radiation machine; scale; types; thickness and minimum density of shielding materials; direction of North; the locations and size of penetrations through shielding barriers, ceiling, walls and floor; as well as details of the doors and maze.

(d) The structural composition and thickness or concrete equivalent of walls, doors, partitions, floor, and ceiling of the rooms concerned.

(e) The type of occupancy of adjacent areas inclusive of space above and below the rooms concerned. If there is an exterior wall, show distance to the closest areas where it is likely that individuals may be present.

(f) Description of assumptions that were used in shielding calculations including, but not limited to; design energy, for example a room may be designed for 6 MV unit although only a 4 MV unit is currently proposed; workload; presence of integral beam-stop in unit; occupancy and uses of adjacent areas; fraction of time that useful beam will intercept permanent barriers, walls, floor and ceiling; and "allowed" radiation exposure in both restricted and unrestricted areas.

(g) At least one example calculation which shows the methodology used to determine the amount of shielding required for the physical conditions; that is the primary and secondary or leakage barriers, restricted and unrestricted areas, small angle scatter, entry doors and maze; and shielding material in the facility.

(i) If commercial software is used to generate shielding requirements, also identify the software used and the version or revision date.

(ii) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

(4) Neutron Shielding. In addition to the requirements listed in R313-30-10(3), therapeutic radiation machine facilities which are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

(a) The structural composition, thickness, minimum density and location of neutron shielding material.

(b) Description of assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron flux rate, absorbed dose and dose equivalent, due to neutrons, in both restricted and unrestricted areas.

(c) At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for the physical conditions, that is, restricted and unrestricted areas, entry doors and maze and neutron shielding material utilized in the facility.

(i) If commercial software is used to generate shielding requirements, also identify the software used and the version or revision date.

(ii) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

(d) The methods and instrumentation which will be used to verify the adequacy of neutron shielding installed in the facility.

KEY: x-rays, survey, radiation, radiation safety
Date of Enactment or Last Substantive Amendment: [~~August 13, 1999~~]2013
Notice of Continuation: October 14, 2008
Authorizing, and Implemented or Interpreted Law: 19-3-104

Environmental Quality, Radiation Control
R313-35
Requirements for X-Ray Equipment Used for Non-Medical Applications

NOTICE OF PROPOSED RULE
(Amendment)
DAR FILE NO.: 37198
FILED: 01/11/2013

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: Changes are required to conform with S.B. 21, 2012 General Session (Chapter 360, Laws of Utah 2012).

SUMMARY OF THE RULE OR CHANGE: S.B. 21 (2012) gave authority to the Director of the Division of Radiation Control to make many regulatory decisions that had previously been made either by the Radiation Control Board or by the Executive Secretary of the Radiation Control Board. This rule change implements these statutory changes by replacing occurrences of both "executive secretary" and "board" with "director."

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Section 19-3-104 and Section 19-3-108

ANTICIPATED COST OR SAVINGS TO:
♦ THE STATE BUDGET: There are no anticipated costs or savings to the state budget as this amendment only changes who has authority to make regulatory decisions.
♦ LOCAL GOVERNMENTS: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.

♦ SMALL BUSINESSES: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.
♦ PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES: There are no anticipated costs or savings as this amendment only changes who has authority to make regulatory decisions.

COMPLIANCE COSTS FOR AFFECTED PERSONS: There are no compliance costs for affected persons as this amendment only changes who has authority to make regulatory decisions.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: There is no anticipated fiscal impact on businesses as this amendment only changes who has authority to make regulatory decisions.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
ENVIRONMENTAL QUALITY
RADIATION CONTROLROOM THIRD FLOOR
195 N 1950 W
SALT LAKE CITY, UT 84116-3085
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Craig Jones by phone at 801-536-4264, by FAX at 801-533-4097, or by Internet E-mail at cwjones@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 03/04/2013

THIS RULE MAY BECOME EFFECTIVE ON: 03/19/2013

AUTHORIZED BY: Rusty Lundberg, Director

R313. Environmental Quality, Radiation Control.
R313-35. Requirements for X-Ray Equipment Used for Non-Medical Applications.
R313-35-1. Purpose and Scope.

(1) R313-35 establishes radiation safety requirements for registrants who use electronic sources of radiation for industrial radiographic applications, analytical applications or other non-medical applications. Registrants engaged in the production of radioactive material are also subject to the requirements of R313-19 and R313-22. The requirements of R313-35 are an addition to, and not a substitution for, the requirements of R313-15, R313-16, R313-18 and R313-70.

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

R313-35-2. Definitions.

As used in R313-35:

"Analytical x-ray system" means a group of components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials by either x-ray fluorescence or diffraction analysis.

"Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure, hereinafter termed "cabinet," which, independent of existing architectural structure except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x-radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad and bus terminals, and similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

"Collimator" means a device used to limit the size, shape and direction of the primary radiation beam.

"Direct reading dosimeter" means an ion-chamber pocket dosimeter or an electronic personal dosimeter.

"External surface" means the outside surfaces of cabinet x-ray systems, including the high-voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware and including the plane across an aperture or port.

"Fail-safe characteristics" means design features which cause beam port shutters to close, or otherwise prevent emergence of the primary beam, upon the failure of a safety or warning device.

"Nondestructive testing" means the examination of the macroscopic structure of materials by nondestructive methods utilizing x-ray sources of radiation.

"Non-medical applications" means uses of x-ray systems except those used for providing diagnostic information or therapy on human patients.

"Normal operating procedures" means instructions necessary to accomplish the x-ray procedure being performed. These procedures shall include positioning of the equipment and the object being examined, equipment alignment, routine maintenance by the registrant, and data recording procedures which are related to radiation safety.

"Open-beam configuration" means a mode of operation of an analytical x-ray system in which individuals could accidentally place some part of the body into the primary beam during normal operation if no further safety devices are incorporated.

"Portable package inspection system" means a portable x-ray system designed and used for determining the presence of explosives in a package.

"Primary beam" means ionizing radiation which passes through an aperture of the source housing via a direct path from the x-ray tube located in the radiation source housing.

"Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in individuals 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.

"X-ray system" means an assemblage of components for the controlled production of x-rays. It includes, minimally, an x-ray high-voltage generator, an x-ray control, a tube housing assembly, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

R313-35-20. Personnel Monitoring.

Registrants using x-ray systems in non-medical applications shall meet the requirements of R313-15-502.

R313-35-30. Locking of X-ray Systems Other Than Veterinary X-Ray Systems.

The control panel of x-ray systems located in uncontrolled areas shall be equipped with a locking device that will prevent the unauthorized use of a x-ray system or the accidental production of radiation. Non-cabinet x-ray systems shall be kept locked with the key removed when not in use.

R313-35-40. Storage Precautions.

X-ray systems shall be secured to prevent tampering or removal by unauthorized personnel.

R313-35-50. Training Requirements.

In addition to the requirements of R313-18-12, an individual operating x-ray systems for non-medical applications shall be trained in the operating procedures for the x-ray system and the emergency procedures related to radiation safety for the facility. Records of training shall be made and maintained for three years after the termination date of the individual.

R313-35-60. Surveys.

In addition to the requirements of R313-15-501, radiation surveys of x-ray systems shall be performed:

(1) upon installation of the x-ray system; and

(2) following change to or maintenance of components of an x-ray system which effect the output, collimation, or shielding effectiveness.

R313-35-70. Radiation Survey Instruments.

Survey instruments used in determining compliance with R313-15 and R313-35 shall meet the following requirements:

(1) Instrumentation shall be capable of measuring a range from 0.02 millisieverts (2 millirem) per hour through 0.01 sievert (1 rem) per hour.

(2) Instrumentation shall be calibrated at intervals not to exceed 12 months and after instrument servicing, except for battery changes.

(3) For linear scale instruments, calibration shall be shown at two points located approximately one-third and two-thirds of full-scale on each scale. For logarithmic scale instruments, calibration shall be shown at mid-range of each decade, and at two points of at least one decade. For digital instruments, calibration shall be shown at three points between 0.02 and 10 millisieverts (2 and 1000 millirems) per hour.

(4) An accuracy of plus or minus 20 percent of the calibration source shall be demonstrated for each point checked pursuant to R313-35-70(3).

(5) The registrant shall perform visual and operability checks of survey instruments before use on each day the survey instrument is to be used to ensure that the equipment is in good working condition. If survey instrument problems are found, the equipment shall be removed from service until repaired.

(6) Results of the instrument calibrations showing compliance with R313-35-70(3) and R313-35-70(4) shall be recorded and maintained for a period of three years from the date the record is made.

(7) Records demonstrating compliance with R313-35-70(5) shall be made when a problem is found. The records shall be maintained for a period of three years from the date the record is made.

R313-35-80. Cabinet X-ray Systems.

(1) The requirements as found in 21 CFR 1020.40, 1996 ed., are adopted and incorporated by reference.

(2) Individuals operating cabinet x-ray systems with conveyor belts shall be able to observe the entry port from the operator's position.

R313-35-90. Portable Package Inspection Systems.

Portable package inspection systems shall be registered in accordance with R313-16 and shall be exempt from inspection by representatives of the [~~Executive Secretary~~]Director.

R313-35-100. Analytical X-Ray Systems Excluding Cabinet X-Ray Systems.

(1) Equipment. Analytical x-ray systems not contained in cabinet x-ray systems shall meet all the following requirements.

(a) A device which prevents the entry of portions of an individual's body into the primary x-ray beam path, or which causes the beam to be shut off upon entry into its path, shall be provided for open-beam configurations.

(i) Pursuant to R313-12-55(1), an application for an exemption from R313-35-100(1)(a) shall contain the following information:

(A) a description of the various safety devices that have been evaluated;

(B) the reason that these devices cannot be used; and

(C) a description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

(ii) applications for exemptions to R313-35-100(1)(a) shall be submitted to the [~~Executive Secretary of the Board~~]Director.

(b) Open-beam configurations shall be provided with a readily discernible indication of:

(i) the "on" or "off" status of the x-ray tube which shall be located near the radiation source housing if the primary beam is controlled in this manner; or

(ii) the "open" or "closed" status of the shutters which shall be located near ports on the radiation source housing, if the primary beam is controlled in this manner.

(c) Warning devices shall be labeled so that their purpose is easily identified and the devices shall be conspicuous at the beam port. On equipment installed after July 1, 1989, warning devices shall have fail-safe characteristics.

(d) Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening. Security requirements will be deemed met if the beam port cannot be opened without the use of tools that are not part of the closure.

(e) Analytical x-ray systems shall be labeled with a readily discernable sign or signs bearing a radiation symbol which meets the requirements of R313-15-901 and the words:

(i) "CAUTION-HIGH INTENSITY X-RAY BEAM," or words having a similar intent, on the x-ray tube housing; and

(ii) "CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near switches that energize an x-ray tube.

(f) On analytical x-ray systems with open-beam configurations which are installed after July 1, 1989, ports on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

(g) An easily visible warning light labeled with the words "X-RAY ON," or words having a similar intent, shall be located near switches that energize an x-ray tube and near x-ray ports. They shall be illuminated only when the tube is energized.

(h) On analytical x-ray systems installed after July 1, 1989, warning lights shall have fail-safe characteristics.

(i) X-ray generators shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of five centimeters from its surface so that they are not capable of producing a dose equivalent in excess of 2.5 microsieverts (0.25 millirem) in one hour.

(j) The components of an analytical x-ray system located in an uncontrolled area shall be arranged and include sufficient shielding or access control so that no radiation levels exist in areas surrounding the component group which could result in a dose to an individual present therein in excess of the dose limits given in R313-15-301.

(2) Personnel Requirements.

(a) An individual shall not be permitted to operate or maintain an analytical x-ray system unless the individual has received instruction which satisfies the requirements of R313-18-12(1). The instruction shall include:

(i) identification of radiation hazards associated with the use of the analytical x-ray system;

(ii) the significance of the various radiation warnings and safety devices incorporated into the analytical x-ray system, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in these cases;

(iii) proper operating procedures for the analytical x-ray system;

(iv) symptoms of an acute localized exposure; and

(v) proper procedures for reporting an actual or suspected exposure.

(b) Registrants shall maintain records which demonstrate compliance with the requirements of R313-35-100(2)(a) for a period of three years after the termination of the individual.

(c) Normal operating procedures shall be written and available to analytical x-ray system workers. An individual shall not be permitted to operate analytical x-ray systems using procedures other than those specified in the normal operating procedures unless the individual has obtained written approval of the registrant or the registrant's designee.

(d) An individual shall not bypass a safety device unless the individual has obtained the written approval of the registrant or the registrant's designee. Approval shall be for a specified period of time. When a safety device has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING," or words having a similar intent, shall be placed on the radiation source housing.

(3) Personnel Monitoring. In addition to the requirements of R313-15-502, finger or wrist dosimetric devices shall be provided to and shall be used by:

(a) analytical x-ray system workers using equipment having an open-beam configuration and not equipped with a safety device; and

(b) personnel maintaining analytical x-ray systems if the maintenance procedures require the presence of a primary x-ray beam when local components in the analytical x-ray system are disassembled or removed.

(4) Posting. Areas or rooms containing analytical x-ray systems not considered to be cabinet x-ray systems shall be conspicuously posted to satisfy the requirements in R313-15-902.

R313-35-110. Veterinary X-Ray Systems.

(1) Equipment. X-ray systems shall meet the following standards to be used for veterinary radiographic examinations.

(a) The leakage radiation from the diagnostic source assembly measured at a distance of one meter shall not exceed 25.8 uC/kg (100 milliroentgens) in one hour when the x-ray tube is operated at its leakage technique factors.

(b) Diaphragms, cones, or a stepless adjustable collimator shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the diagnostic source housing.

(c) A device shall be provided to terminate the exposure after a preset time or exposure.

(d) A "dead-man type" exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator may stand out of the useful beam and at least six feet from the animal during x-ray exposures.

(e) For stationary or mobile x-ray systems, a method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed six percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(f) For portable x-ray systems, a method shall be provided to align the center of the x-ray field with respect to the center of the image receptor to within six percent of the source to image receptor distance, and to indicate the source to image receptor distance to within six percent.

(2) Structural shielding. For stationary x-ray systems, the wall, ceiling, and floor areas shall provide enough shielding to meet the requirements of R313-15-301.

(3) Operating procedures.

(a) Where feasible, the operator shall stand well away from the useful beam and the animal during radiographic exposures.

(b) In applications in which the operator is not located beyond a protective barrier, clothing consisting of a protective apron having a lead equivalent of not less than 0.5 millimeters shall be worn by the operator and other individuals in the room during exposures.

(c) An individual other than the operator shall not be in the x-ray room while exposures are being made unless the individual's assistance is required.

(d) If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, for

example, protective gloves and apron. The individual shall be so positioned that no unshielded part of that individual's body will be struck by the useful beam.

R313-35-120. X-Ray Systems Less than 1 MeV used for Non-Destructive Testing.

(1) Cabinet x-ray systems.

Cabinet x-ray systems shall meet the requirements of R313-35-80.

(2) Fixed Gauges.

(a) Warning Devices. A light, which is clearly visible from all accessible areas around the x-ray system, shall indicate when the x-ray system is operating.

(b) Personnel Monitoring. Notwithstanding R313-15-502(1)(a), individuals conducting x-ray system maintenance requiring the x-ray beam to be on shall be provided with and required to wear personnel monitoring devices.

(3) Industrial and Other X-ray Systems.

(a) Equipment.

(i) The registrant shall perform visual and operability checks of indication lights and warning lights before use on each day the equipment is to be used to ensure that the equipment is in good working condition. If equipment problems are found, the equipment shall be removed from service until repaired.

(ii) Inspection and routine maintenance of x-ray systems, interlocks, indication lights, exposure switches, and cables shall be made at intervals not to exceed six months or before the first use thereafter to ensure the proper functioning of components important to safety. If equipment problems are found, the equipment shall be removed from service until repaired.

(iii) Records demonstrating compliance with R313-35-120(3)(a)(i) shall be made when problems with the equipment are found. These records shall be maintained for a period of three years.

(iv) Records demonstrating compliance with R313-35-120(3)(a)(ii) shall be made. These records shall be maintained for a period of three years.

(b) Controls. X-ray systems which produce a high radiation area shall be controlled to meet the requirements of R313-15-601.

(c) Personnel Monitoring Requirements.

(i) Registrants shall not permit individuals to conduct x-ray operations unless all of the following conditions are met.

(A) Individuals shall wear a thermoluminescent dosimeter or film badge.

(I) Each film badge or thermoluminescent dosimeter shall be assigned to and worn by only one individual.

(II) Film badges shall be replaced at periods not to exceed one month and thermoluminescent dosimeters shall be replaced at periods not to exceed three months.

(B) Individuals shall wear a direct reading dosimeter if conducting non-destructive testing at a temporary job site or in a room or building not meeting the requirements of R313-15-301.

(I) Pocket dosimeters shall have a range from zero to two millisieverts (200 millirem) and must be recharged at the beginning of each shift.

(II) Direct reading dosimeters shall be read and the exposures recorded at the beginning and end of each shift. Records shall be maintained for three years after the record is made.

(III) Direct reading dosimeters shall be checked at intervals not to exceed 12 months for correct response to radiation and the results shall be recorded. Records shall be maintained for a period three years from the date the record is made. Acceptable dosimeters shall read within plus or minus 20 percent of the true radiation exposure.

(IV) If an individual's ion-chamber pocket dosimeter is found to be off scale or if the individual's electronic personnel dosimeter reads greater than 2 millisieverts (200 millirems), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's film badge or thermoluminescent dosimeter shall be sent for processing within 24 hours. In addition, the individual shall not resume work with sources of radiation until a determination of the individual's radiation exposure has been made.

(d) Controls. In addition to the requirements of R313-15-601, barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified in accordance with R313-15-902.

(e) Surveillance. During non-destructive testing applications conducted at a temporary job site or in a room or building not meeting the requirements of R313-15-301, the operator shall maintain continuous direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area.

R313-35-130. X-Ray Systems Greater than 1 MeV used for Non-Destructive Testing.

(1) Equipment.

(a) Individuals shall not receive, possess, use, transfer, own, or acquire a particle accelerator unless it is registered pursuant to R313-16-231.

(b) The registrant shall perform visual and operability checks of indication lights and warning lights before use on each day the equipment is to be used to ensure that the equipment is in good working condition. If equipment problems are found, the equipment shall be removed from service until repaired.

(c) Inspection and routine maintenance of x-ray systems, interlocks, indication lights, exposure switches, and cables shall be made at intervals not to exceed three months or before the first use thereafter to ensure the proper functioning of components important to safety. If equipment problems are found, the equipment shall be removed from service until repaired.

(d) Records demonstrating compliance with R313-35-130(1)(b) shall be made when problems with the equipment are found. These records shall be maintained for a period of three years.

(e) Records demonstrating compliance with R313-35-130(1)(c) shall be made. These records shall be maintained for a period of three years.

(f) Maintenance performed on x-ray systems shall be in accordance with the manufacturer's specifications.

(g) Instrumentation, readouts and controls on the particle accelerator control console shall be clearly identified and easily discernible.

(h) A switch on the accelerator control console shall be routinely used to turn the accelerator beam off and on. The safety interlock system shall not be used to turn off the accelerator beam, except in an emergency.

(2) Shielding and Safety Design Requirements.

(a) An individual who has satisfied a criterion listed in R313-16-400, shall be consulted in the design of a particle accelerator's installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.

(b) Particle accelerator installations shall be provided with primary or secondary barriers which are sufficient to assure compliance with R313-15-201 and R313-15-301.

(c) Entrances into high radiation areas or very high radiation areas shall be provided with interlocks that shut down the machine under conditions of barrier penetration.

(d) When a radiation safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls first at the position where the interlock has been tripped, and then at the main control console.

(e) Safety interlocks shall be on separate electrical circuits which shall allow their operation independently of other safety interlocks.

(f) Safety interlocks shall be fail-safe. This means that they must be designed so that defects or component failures in the interlock system prevent operation of the accelerator.

(g) The registrant may apply to the [~~Executive Secretary~~]Director for approval of alternate methods for controlling access to high or very high radiation areas. The [~~Executive Secretary~~]Director may approve the proposed alternatives if the registrant demonstrates that the alternative methods of control will prevent unauthorized entry into a high or very high radiation area, and the alternative method does not prevent individuals from leaving a high or very high radiation area.

(h) A "scram" button or other emergency power cutoff switch shall be located and easily identifiable in high radiation areas or in very high radiation areas. The cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

(i) Safety and warning devices, including interlocks, shall be checked for proper operation at intervals not to exceed three months, and after maintenance on the safety and warning devices. Results of these tests shall be maintained for inspection at the accelerator facility for three years.

(j) A copy of the current operating and emergency procedures shall be maintained at the accelerator control panel.

(k) Locations designated as high radiation areas or very high radiation areas and entrances to locations designated as high radiation areas or very high radiation areas shall be equipped with easily observable flashing or rotating warning lights that operate when radiation is being produced.

(l) High radiation areas or very high radiation areas shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of the high radiation area or the very high radiation area. Warning devices shall be clearly discernible in high radiation areas or in very high radiation areas. The registrant shall instruct personnel in the vicinity of the particle accelerator as to the meaning of this audible warning signal.

(m) Barriers, temporary or otherwise, and pathways leading to high radiation areas or very high radiation areas shall be identified in accordance with R313-15-902.

(3) Personnel Requirements.

(a) Registrants shall not permit individuals to act as particle accelerator operators until the individuals have complied with the following:

(i) been instructed in radiation safety; and

(ii) been instructed pursuant to R313-35-50 and the applicable requirements of R313-15.

(iii) Records demonstrating compliance with R313-35-130(3)(a)(i) and R313-35-130(3)(a)(ii) shall be maintained for a period of three years from the termination date of the individual.

(b) Registrants shall not permit an individual to conduct x-ray operations unless the individual meets the personnel monitoring requirements of R313-35-120(3)(c).

(4) Radiation Monitoring Requirements.

(a) At particle accelerator facilities, there shall be available appropriate portable monitoring equipment which is operable and has been calibrated for the radiations being produced at the facility. On each day the particle accelerator is to be used, the portable monitoring equipment shall be tested for proper operation.

(b) When changes have been made in shielding, operation, equipment, or occupancy of adjacent areas, a radiation protection survey shall be performed and documented by an individual who has satisfied a criterion listed in R313-16-400 or the individual designated as being responsible for radiation safety.

(c) Records of radiation protection surveys, calibrations, and instrumentation tests shall be maintained at the accelerator facility for inspection by representatives of the [~~Board or the Executive Secretary~~]Director for a period of three years.

R313-35-140. Duties and Authorities of a Radiation Safety Officer.

Facilities operating x-ray systems under R313-35-130 shall appoint a Radiation Safety Officer. The specific duties and authorities of the Radiation Safety Officer include, but are not limited to:

(1) establishing and overseeing all operating, emergency, and ALARA procedures as required by R313-15;

(2) ensuring that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the registrant's program;

(3) overseeing and approving the training program for radiographic personnel, ensuring that appropriate and effective radiation protection practices are taught;

(4) ensuring that required radiation surveys are performed and documented in accordance with the R313-35-130(4);

(5) ensuring that personnel monitoring devices are calibrated and used properly by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by R313-15-1203; and

(6) ensuring that operations are conducted safely and to assume control for instituting corrective actions including stopping of operations when necessary.

KEY: industry, x-ray, veterinarians, surveys
Date of Enactment or Last Substantive Amendment: [~~August 13, 1999~~]2013
Notice of Continuation: March 2, 2012
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-3-108

Governor, Economic Development
R357-2
Rural Broadband Service Fund

NOTICE OF PROPOSED RULE

(Repeal)
DAR FILE NO.: 37204
FILED: 01/15/2013

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: When conducting the five-year review, the office determined that the program has not been funded for several years, will likely not be funded, and that the rule is no longer needed.

SUMMARY OF THE RULE OR CHANGE: This rule is repealed in its entirety.

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Section 63M-1-2304

ANTICIPATED COST OR SAVINGS TO:
♦ THE STATE BUDGET: None as the program is no longer being funded.
♦ LOCAL GOVERNMENTS: None as the program is no longer being funded.
♦ SMALL BUSINESSES: None as the program is no longer being funded.
♦ PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES: None affected as the program is no longer being funded.

COMPLIANCE COSTS FOR AFFECTED PERSONS: None as the program is no longer being funded.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: When conducting the five-year review, the office determined that the program has not been funded for several years, will likely not be funded, and that the rule is no longer needed.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
GOVERNOR
ECONOMIC DEVELOPMENT
60 E SOUTH TEMPLE 3RD FLR
SALT LAKE CITY, UT 84111
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Zachary Derr by phone at 801-538-8746, by FAX at 801-538-8888, or by Internet E-mail at zderr@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 03/04/2013

THIS RULE MAY BECOME EFFECTIVE ON: 03/11/2013

AUTHORIZED BY: Spencer Eccles, Executive Director

R357. Governor, Economic Development.
[~~R357-2. Rural Broadband Service Fund.~~
~~R357-2-1. Purpose.~~
~~(1) The purpose of these rules is to provide:~~
~~(a) the procedures for and content of applications to the Governor's Office of Economic Development for grants from the Rural Broadband Service Fund;~~
~~(b) the method for providing public notice of applications and receipt of public comment on applications or competing applications;~~
~~(c) the criteria upon which the Governor's Office of Economic Development will determine whether to award a grant from the Rural Broadband Service Fund; and~~
~~(d) the procedures for receiving payments from the Rural Broadband Service Fund.~~

~~R357-2-2. Authority.~~
~~(1) Subsection 63M-1-2304 requires the office to make rules governing the following aspects of the Rural Broadband Service Fund:~~
~~(a) the method of providing public notice;~~
~~(b) the time period for public comment; and~~
~~(c) the manner of filing a competing application.~~
~~(2) Subsection 63M-1-2306 permits the office to make additional rules governing the Rural Broadband Service Fund as it deems necessary to administer the Rural Broadband Service Fund, with the advice of the board, and in accordance with 63G-3-101, Utah Administrative Rulemaking Act.~~

~~R357-2-3. Definitions.~~
~~(1) As used in these rules the following terms are used as defined in section 63M-1-2302:~~
~~(a) "Broadband service" means any wire line technology identified by the director as having the capacity to transmit data from and to a subscriber's computer to the Internet or Internet-related services at a minimum rate of data transmission of 256 kilobits per second.~~
~~(b) "Fund" means the restricted account known as the Rural Broadband Service Fund created in Section 63M-1-2303.~~
~~(c) "Provider" means an entity that will install or have installed under its supervision, and will own facilities and use them to provide retail broadband service to subscribers in a rural area.~~
~~(d) "Rural area" means any territory in the state:~~
~~(i) within a city, town, or unincorporated area with a population of 10,000 or less based on the most recently published data of the United States Census Bureau; and~~
~~(ii) in which broadband service is not available.~~
~~(2) As used in these rules:~~
~~(a) "Act" means the Rural Broadband Service Fund Act as provided in Section 63M-1-2301, et seq.~~
~~(b) "Board" means the Board of Business and Economic Development as provided in Section 63M-1-301.~~
~~(i) Any member of the board that represents or has a financial interest in any provider competing for grants under the act shall be disqualified from participation in review of or deliberations regarding applications or other activities of the board under the act or these rules.~~
~~(c) "Cost of deployment of broadband service" means all costs associated with the installation of broadband service, including~~

~~the cost of materials and supplies, the cost of professional services, labor, equipment and permit fees incurred in installation, cost of right-of-way and real property required for the installation, normal overheads, costs of supervision, costs for any interconnection facilities necessary to provide broadband service, and any other deployment costs identified by the provider as one-time network installation costs.~~

~~(i) "Cost of deployment of broadband service" does not include any recurring operational costs.~~

~~(d) "Director" means the executive director of the Governor's Office of Economic Development as provided in Section 63M-1-202.~~

~~(e) "Office" means the Governor's Office of Economic Development as provided in Section 63M-1-201.~~

~~(f) "Project" means the installation of broadband service in a rural area by a provider.~~

~~(g) "Wire line technology" means a technology under which the broadband signal is carried between the provider and the subscriber over a wire, coaxial cable, or fiber optic cable. The office may not discriminate against any accepted technology for provision of broadband service other than for reasons stated in subsection 63M-1-2304.~~

~~R357-2-4. Method of Providing Public Notice and Time Period for Public Comment and Notice for Competitive Applications.~~

~~(1) Upon acceptance of an application for deployment of broadband service in a rural area that complies with R357-2-6 and which is without deficiencies and complete, the office will open a 30-day competing application period following the issuance of public notice. During this time period the office will accept competing applications that comply with R357-2-6 to provide broadband service in exactly the same rural area as proposed in the first application received as specified in R357-2-6 (3).~~

~~(2) Public notice of acceptance of an application for deployment of broadband service in a rural area shall be provided within 15 days of acceptance by the office as follows:~~

~~(a) notice of the application shall be posted by the office on its official website;~~

~~(b) notice shall be provided by the office through email to any person that has previously requested a copy of such notices; and~~

~~(c) notice by the office may be facilitated through associations, providers or applicants as directed by the office.~~

~~(3) Notice of the application shall be delivered by the provider through registered mail or personal delivery to the chief executive officer or executive body of:~~

~~(a) any town or city included in whole or in part within the proposed service area of the project; and~~

~~(b) any county in which an unincorporated area is included in whole or in part within the proposed service area of the project.~~

~~(4) The notice from the provider shall:~~

~~(a) identify the provider and the project generally, including its proposed service area and wire line technology, but need not disclose the proposed installation budget and timeline, business plan, or any other information designated by the provider as competitively sensitive and accepted by the office as sensitive: and~~

~~(b) inform interested persons that they have 15 days within which to provide written comments on the application.~~

~~R357-2-5. Manner of Filing a Competing Application, Public Notice and Public Comment on a Competing Application.~~

~~(1) Any competing application submitted to the office shall comply with the requirements of R357-2-6, and the office shall review a competing application for acceptance in the same manner as an initial application; and~~

~~(a) if a competing application is rejected by the office, the provider submitting the competing application may have the opportunity to complete, correct and resubmit the application as provided in R357-2-6 (4)(a) provided it is completed, corrected and resubmitted within the 30-day competing application period.~~

~~(2) Both the initial application and the competing application will be publicly noticed as provided by R357-2-4; and~~

~~(a) written comments on the applications will be received for 15 days following the close of the competing application period; and~~

~~(b) no additional competing applications may be submitted after the close of the 30-day competing application period.~~

~~R357-2-6. Procedures for Applications for Grants from Fund.~~

~~(1) A provider that wishes to deploy broadband service in a rural area may file an application for a grant from the fund with the office.~~

~~(2) An application shall:~~

~~(a) be accompanied by an affidavit executed by an officer, general partner, member, principal, or other authorized representative of the provider under oath verifying that the information in the application is true and correct to the best of the knowledge, information and belief of the individual signing the affidavit and that the individual signing the affidavit has the authority to submit the application on behalf of the provider;~~

~~(b) include the following information regarding the provider:~~

~~(i) the company name, street and mailing address, telephone number, fax number, and email address and federal tax ID number of the provider;~~

~~(ii) the name, title, address, telephone number, fax number, and email address of the individual or individuals with whom contacts regarding the application should be made;~~

~~(iii) evidence that the provider is properly organized and authorized to do business in the state;~~

~~(iv) information, including financial statements, demonstrating the provider's technical, managerial, and financial qualifications to deploy the broadband service and to continue to provide broadband service to customers subscribing to the broadband service;~~

~~(c) provide Incumbent Local Exchange Carrier (ILEC) or Competitive Local Exchange Carrier (CLEC) certification as granted by the Utah Public Service Commission and information regarding prior deployments of broadband service by the provider.~~

~~(3) An application shall provide the following information regarding the proposed project:~~

~~(a) a description of the proposed project, including:~~

~~(i) the location of the proposed project; and~~

~~(ii) a map showing the proposed service area;~~

~~(b) Information demonstrating that the proposed service area is a rural area, including:~~

(i) information on the population of the proposed service area or any municipality in which it is located from the most recently published data of the United States Census Bureau; and

(e) a description of the facilities that the provider plans to install, including:

(i) the wire line technology that will be used in providing broadband service;

(d) the number of potential subscribers;

(e) the budget for the project;

(f) the timeline for deployment of broadband service;

(g) the proposed initial set up charge, if any, to subscribers, including any equipment charge;

(i) the terms and conditions upon which broadband service will be established and will continue to be provided to subscribers;

(h) include a form of public notice of the application consistent with R357-2-4 (4); and

(i) such other information as the provider wishes to provide.

(4) Within 60 days after an initial application is received by the office, the office shall review the application to determine if it is complete and if it proposes a project that appears to be eligible for a grant from the fund. If the application is complete and proposes a project that appears eligible, the office shall notify the provider that it is accepted for consideration. If the application is deficient, the office shall promptly return it to the provider, identifying the areas of deficiency.

(a) A provider shall have 15 business days to correct, complete and resubmit any application found deficient by the office. Any application resubmitted after 15 business days shall be deemed to be a new application.

(5) Once an initial application is accepted by the office as complete, the office shall within 15 days open a competing application period and provide public notice per R357-2-4 (2).

(6) The office shall treat all competitively sensitive information submitted in an application as confidential and protected business records under the Government Records Access and Management Act.

R357-2-7. Ranking and Approval of Applications.

(1) The office shall review and rank for approval accepted applications, based upon the following criteria:

(a) the financial, managerial, and technical qualification of the provider;

(b) the number of potential subscribers to be served;

(c) the reasonableness of the cost of deployment;

(d) the timeline of deployment;

(e) the initial set up charge, if any, to subscribers, including any equipment charge; and

(f) the terms and conditions on which broadband service will be provided.

(2) In ranking applications, the office may:

(a) obtain information from the provider or others;

(b) conduct its own analysis of any issue relevant to the application, including economic development impacts of the proposed project;

(c) consider economic benefits to potential subscribers or to the state likely to accrue as a result of completion of the project;

(d) require the submission of a business plan and consider the viability of the provider's business plan to continue providing broadband service to all or some subscribers in the rural area;

(e) require the provider to make one or more presentations to the office, director or the board;

(f) require the provider to agree to make reasonable adjustments to the application or agree to reasonable conditions if necessary to make the application consistent with the act in order for the application to continue to receive consideration;

(g) consult with the Division of Public Utilities created in Section 13-1-2;and

(h) not discriminate against any accepted technology for provision of broadband service other than for reasons of cost or the terms and conditions upon which a provider proposes to provide broadband service to potential subscribers.

(3) If after the process of ranking the applications the office is unable to substantially differentiate between competing applications it may give preference to the application which was filed first.

(4) Based on the ranking of the applications in subsections R357-2-7(1), (2), and (3), the office shall inform the highest ranked provider that its application, including any modification to the application accepted by the provider pursuant to subsection R357-2-7 (2)(f) is approved, subject to entry into an agreement with the office and successful performance of the agreement.

(5) Once an application for a given rural area is approved and the office has entered into an agreement with the selected provider for deployment of broadband service to that rural area, other applications for deployment of broadband service to the same rural area will be held in abeyance by the office until successful completion of the project as confirmed by the office at which time the competing applications will be removed from the ranking and shall be deemed denied.

(6) If a project is determined by the office as unable to be completed by the selected provider, the office may consider competing applications if in the judgment of the director the project cannot be completed by the provider originally selected.

(7) The office or director may continue approving applications in the order of ranking from highest to lowest until the office has entered into agreements with providers that provide for total grants equal to the lesser of:

(a) the total amount available for grants from the fund; or

(b) the total amount of grants sought by all approved applications.

(8) No grant will be approved for an amount greater than the lesser of one-half of:

(a) the actual cost of deployment of broadband service in the rural area as established by verified accounts filed with the office by the provider after completion of the project; or

(b) the budgeted amount for deployment of broadband service in the rural area as established by the application as modified prior to approval pursuant to subsection R357-2-3(c).

R357-2-8. Procedures Verification of Completion and for Payment of Grants from the Fund.

(1) Upon completion of an approved project in accordance with the terms of the agreement between the provider and the office, the provider shall provide a report to the office. The report shall:

(a) be accompanied by an affidavit executed by an officer, general partner, member, principal, or other authorized representative of the provider under oath verifying that the information in the report is true and correct to the best of the knowledge, information and belief of the individual signing the affidavit and that the individual signing the

~~affidavit has the authority to submit the report on behalf of the provider;~~

~~(b) state that the project has been completed in accordance with the agreement; and~~

~~(c) provide accounts establishing the actual cost of deployment.~~

~~(2) The office shall examine the report of the provider submitted pursuant to subsection R357-2-8(1) and may reasonably investigate any matter related to the report. If the office determines that there is any material deficiency in the provider's performance of its obligations under the agreement, it shall notify the provider of each deficiency and the provider shall have reasonable opportunity to correct the deficiency or to dispute that any deficiency exists.~~

~~(3) The director shall disburse the grant as provided in the agreement to the provider following:~~

~~(a) the provider's submission of the report;~~

~~(b) the office's determination that the project has been completed in accordance with the agreement; and~~

~~(c) the office's review and acceptance of the accounts establishing the actual cost of deployment as submitted by the provider pursuant to R357-2-8 (1);or~~

~~(d) if the office identifies deficiencies, following the provider's certification that it has corrected the deficiencies and the director has verified that the deficiencies are corrected.~~

~~(4) If the provider contests the specification of deficiencies by the office, the board and director shall review the report and the office claim and determine whether material deficiencies exist. If after consultation with the board, the director determines that no material deficiency exists, the director shall disburse the grant. If the director determines that material deficiencies continue to exist, the director shall notify the provider of each material deficiency and the provider shall have reasonable opportunity to correct the material deficiency or to dispute that any material deficiency exists.~~

~~**KEY: broadband, job creation, rural economic development, Rural Broadband Service Fund**~~

~~**Date of Enactment or Last Substantive Amendment: January 30, 2008**~~

~~**Authorizing, and Implemented or Interpreted Law: 63M-1-2301; 63M-1-2302; 63M-1-2303; 63M-1-2304; 63M-1-2305; 63M-1-2306]**~~

Natural Resources, Parks And Recreation

R651-633

Special Closures or Restrictions

NOTICE OF PROPOSED RULE

(Amendment)
DAR FILE NO.: 37205
FILED: 01/15/2013

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: In the 1998 Snow Canyon State Park Resource Management Plan, participants and team members recommended controlled, seasonal access into Johnson Canyon from November 15 to March 1. Outside of this period access would be by guided hikes. In 2000, after purchasing the property, Johnson Canyon was re-opened to the public between November 15 and March 1 annually. In 2001, the Johnson Canyon seasonal closure was reduced by one month with access from November 1 to March 15 annually. Guided hikes were offered during the closed period. This same year the Utah State Parks Board approved the revised seasonal closure. The seasonal closure only impacts the last 1/2 mile of trail - the first 1/2 mile of trail is open year-round. The seasonal closure was also recommended in the 2004 Snow Canyon State Park Desert Tortoise Management Plan, required by and paid for by Washington County under the desert tortoise Habitat Conservation Plan. This plan was reviewed and approved by both the Utah State Parks Board and Washington County Habitat Conservation Advisory Committee. In January 2012, Snow Canyon State Park received a request from Washington County elected officials to reconsider the closure dates. The parties making the request desired a shorter closure period. A proposal was developed and as required under the Red Cliffs Desert Reserve, went through review by both the Habitat Conservation Advisory and Technical Committees. Three separate alternatives were reviewed. This is an extremely sensitive area due to its riparian habitat and breeding wildlife species. Due to the sensitivity, the technical committee recommended maintaining a reduced seasonal closure date. Although reduced, a seasonal closure would still protect the riparian area from increasing recreational pressure during the most sensitive periods for wildlife which are spring, summer and early fall. Access would be provided from March 15 to September 14 through guided ranger hikes. Johnson Canyon expanded seasonal access from September 15 through March 15 was approved through the Red Cliffs Desert Reserve Habitat Conservation Advisory Committee as well.

SUMMARY OF THE RULE OR CHANGE: In January 2012, Snow Canyon State Park received a request from Washington County elected officials to reconsider the closure dates. The parties making the request desired a shorter closure period. A proposal was developed and as required under the Red Cliffs Desert Reserve, went through review by both the Habitat Conservation Advisory and Technical Committees. Three separate alternatives were reviewed. This is an extremely sensitive area due to its riparian habitat and breeding wildlife species. Due to the sensitivity, the technical committee recommended maintaining a reduced seasonal closure date. Although reduced, a seasonal closure would still protect the riparian area from increasing recreational pressure during the most sensitive periods for wildlife which are spring, summer and early fall. Access would be provided from March 15 to September 14 through guided ranger hikes.

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Section 79-4-203 and Section 79-4-304 and Section 79-4-501

ANTICIPATED COST OR SAVINGS TO:
♦ THE STATE BUDGET: The agency does not anticipate additional costs or savings to the state budget as a result of this action. The current law enforcement staffing level will remain the same. Officer time will simply be allocated to other management areas of the park.
♦ LOCAL GOVERNMENTS: No cost savings/expenses as local government entities are not funding law enforcement time or other needs for this area of the park.
♦ SMALL BUSINESSES: The agency currently has 13 private business partners under contract with the park. Ten of those business partners utilize this trail/area of the park. The partners provide services such as technical climbing instruction, canyoneering, and guided hikes. This change will likely be profitable for their individual businesses as their access is now expanded.
♦ PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES: The general public will benefit as their access has now been expanded. Since this area is currently not a fee area it should not affect revenue either positively or negatively.

COMPLIANCE COSTS FOR AFFECTED PERSONS: No compliance costs are foreseen by this action. No special permits, fees, or requirements will be altered by this action.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: There should be no impact on businesses.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
NATURAL RESOURCES
PARKS AND RECREATIONROOM 116
1594 W NORTH TEMPLE
SALT LAKE CITY, UT 84116-3154
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Tammy Wright by phone at 801-538-7359, by FAX at 801-538-7378, or by Internet E-mail at tammywright@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 03/04/2013

THIS RULE MAY BECOME EFFECTIVE ON: 03/11/2013

AUTHORIZED BY: Fred Hayes, Director

R651. Natural Resources, Parks and Recreation.
R651-633. Special Closures or Restrictions.
R651-633-1. Emergency Closures or Restrictions.

No person shall be in a closed area or participate in a restricted activity which has been posted by the park manager to protect public safety or park resources.

R651-633-2. General Closures or Restrictions.

Persons are prohibited from being in a closed area or participating in a restricted activity as listed for the following park areas:

(1) Coral Pink Sand Dunes State Park - Motorized vehicle use is prohibited in the non-motorized area of the sand dunes, except for limited and restricted access through the travel corridor;

(2) Dead Horse State Park - Hang gliding, para gliding and B.A.S.E. jumping is prohibited;

(3) Deer Creek State Park - Dogs are prohibited below high water line and in or on the reservoir except for guide or service dogs as authorized by Section 26-30-2;

(4) Jordanelle State Park - Dogs are prohibited in the Rock Cliff area except for the Perimeter Trail and designated parking areas except for guide or service dogs as authorized by Section 26-30-2;

(5) Palisade State Park - Cliff diving is prohibited;

(6) Red Fleet State Park - Cliff diving/jumping is prohibited; and

(7) Snow Canyon State Park -

(a) All hiking and walking in the park is limited to roadways, designated trails and slick rock areas and the Sand Dunes area,

(b) Jenny's Canyon Trail is closed annually from March 15 to June 1,

(c) [~~Johnson's Arch Canyon access~~]The last half-mile of the Johnson Canyon Trail is closed annually from [~~March 15 to October 31~~]March 15 through September 14 except by permit or guided walk[~~;~~]; [~~the canyon is open from November 1 to March 14~~]this portion of trail is open from September 15 through March 14.

(d) Black Rocks Canyon is closed annually from March 15 to June 30,

(e) West Canyon climbing routes are closed annually from February 1 to June 1.

(f) Dogs are prohibited on all trails and natural areas of the park unless posted open, except for guide or service dogs as authorized by Section 26-30-2.

(g) Hang gliding, para gliding and B.A.S.E. jumping is prohibited.

KEY: parks
Date of Enactment or Last Substantive Amendment: March 26, 2009
Notice of Continuation: October 30, 2008
Authorizing, and Implemented or Interpreted Law: 79-4-203; 79-4-304; 79-4-501

End of the Notices of Proposed Rules Section

NOTICES OF
120-DAY (EMERGENCY) RULES

An agency may file a **120-Day (Emergency) Rule** when it finds that the regular rulemaking procedures would:

(a) cause an imminent peril to the public health, safety, or welfare;
(b) cause an imminent budget reduction because of budget restraints or federal requirements; or
(c) place the agency in violation of federal or state law (Subsection 63G-3-304(1)).

As with a **Proposed Rule**, a **120-Day Rule** is preceded by a **Rule Analysis**. This analysis provides summary information about the **120-Day Rule** including the name of a contact person, justification for filing a **120-Day Rule**, anticipated cost impact of the rule, and legal cross-references. A row of dots in the text (**. . . . . .**) indicates that unaffected text was removed to conserve space.

A **120-Day Rule** is effective at the moment the Division of Administrative Rules receives the filing, or on a later date designated by the agency. A **120-Day Rule** is effective for 120 days or until it is superseded by a permanent rule.

Because **120-Day Rules** are effective immediately, the law does not require a public comment period. However, when an agency files a **120-Day Rule**, it usually files a **Proposed Rule** at the same time, to make the requirements permanent. Comments may be made on the **Proposed Rule**. Emergency or **120-Day Rules** are governed by Section 63G-3-304; and Section R15-4-8.

Health, Health Care Financing, Coverage And Reimbursement Policy
R414-303
Coverage Groups

NOTICE OF 120-DAY (EMERGENCY) RULE
DAR FILE NO.: 37173
FILED: 01/07/2013

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: The purpose of this change is to extend Medicaid coverage for Transitional Medical Assistance (TMA) and the Qualifying Individual (QI) program in accordance with the American Taxpayer Relief Act of 2012, House Resolution (H.R.) 8.

SUMMARY OF THE RULE OR CHANGE: This change extends Medicaid coverage for TMA and the QI program in accordance with the American Taxpayer Relief Act of 2012, H.R. 8. (DAR NOTE: This emergency rule supersedes the emergency rule filed under DAR No. 37120, effective 01/01/2013, and published in the January 15, 2013, issue of the Bulletin.)

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Section 26-1-5 and Section 26-18-3

EMERGENCY RULE REASON AND JUSTIFICATION: REGULAR RULEMAKING PROCEDURES WOULD cause an imminent budget reduction because of budget restraints or federal requirements; and place the agency in violation of federal or state law.
JUSTIFICATION: The Department needs to file this emergency rule to extend coverage of TMA and the QI program. Because Congress did not pass legislation to extend these two programs before 01/01/2013, the Department had to file an emergency rule (Rule R414-303, DAR No. 37120, published in the January 15, 2013, issue of the Bulletin) to end coverage for these two programs and avoid being in violation of federal law. With the passage of Sections 621 and 622 of H.R. 8, this emergency rule restores these programs and supersedes the previous emergency rule.

MATERIALS INCORPORATED BY REFERENCE:

- Updates Section 1902(a)(10)(E)(i) through (iv) of Title XIX of the Social Security Act, published by Social Security Administration, 11/19/2012

ANTICIPATED COST OR SAVINGS TO:
- THE STATE BUDGET: There is no impact to the state budget because this rule simply continues coverage of TMA and the QI program.
- LOCAL GOVERNMENTS: There is no impact to local governments because they neither fund Medicaid services nor determine Medicaid eligibility.
- SMALL BUSINESSES: There is no impact to small businesses because this rule simply continues coverage of TMA and the QI program.
- PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES: There is no impact to Medicaid providers and to Medicaid recipients because this rule simply continues coverage of TMA and the QI program.

COMPLIANCE COSTS FOR AFFECTED PERSONS: There are no compliance costs to a single Medicaid provider or to a Medicaid recipient because this rule simply continues coverage of TMA and the QI program.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: Reinstatement of funding under H.R. 8, signed into law on 01/02/2013, allows Medicaid to re-open the eligibility group that had been closed in the prior emergency rule when such funding was not available.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:

HEALTH
HEALTH CARE FINANCING, COVERAGE AND REIMBURSEMENT POLICY
CANNON HEALTH BLDG
288 N 1460 W
SALT LAKE CITY, UT 84116-3231
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:

♦ Craig Devashrayee by phone at 801-538-6641, by FAX at 801-538-6099, or by Internet E-mail at cdevashrayee@utah.gov

EFFECTIVE: 01/07/2013

AUTHORIZED BY: David Patton, Executive Director

R414. Health, Health Care Financing, Coverage and Reimbursement Policy.

R414-303. Coverage Groups.

R414-303-3. Medicaid for Individuals Who Are Aged, Blind or Disabled for Community and Institutional Coverage Groups.

(1) The Department provides Medicaid coverage to individuals as described in 42 CFR 435.120, 435.122, 435.130 through 435.135, 435.137, 435.138, 435.139, 435.211, 435.232, 435.236, 435.301, 435.320, 435.322, 435.324, 435.340, and 435.350, 2011 ed., which are incorporated by reference. The Department provides coverage to individuals as required by 1634(b), (c) and (d), 1902(a)(10)(A)(i)(II), 1902(a)(10)(A)(ii)(X), and 1902(a)(10)(E)(i) through ([~~iii~~]iv) of Title XIX of the Social Security Act in effect November 19, 2012, which are incorporated by reference. The Department provides coverage to individuals described in Section 1902(a)(10)(A)(ii)(XIII) of Title XIX of the Social Security Act in effect April 2, 2012, which is incorporated by reference. Coverage under Section 1902(a)(10)(A)(ii)(XIII) is known as the Medicaid Work Incentive Program.

(2) Proof of disability includes a certification of disability from the State Medicaid Disability Office, Supplemental Security Income (SSI) status, or proof that a disabled client is recognized as disabled by the Social Security Administration (SSA).

(3) An individual can request a disability determination from the State Medicaid Disability Office. The Department adopts the disability determination requirements described in 42 CFR 435.541, 2011 ed., and Social Security's disability requirements for the Supplemental Security Income program as described in 20 CFR 416.901 through 416.998, 2011 ed., which are incorporated by reference, to decide if an individual is disabled. The Department notifies the eligibility agency of its disability decision, who then sends a disability decision notice to the client.

(a) If an individual has earned income, the State Medicaid Disability Office shall review medical information to determine if the client is disabled without regard to whether the earned income exceeds the Substantial Gainful Activity level defined by the Social Security Administration.

(b) If, within the prior 12 months, SSA has determined that the individual is not disabled, the eligibility agency must follow SSA's decision. If the individual is appealing SSA's denial of disability, the State Medicaid Disability Office must follow SSA's decision throughout the appeal process, including the final SSA decision.

(c) If, within the prior 12 months, SSA has determined an individual is not disabled but the individual claims to have become disabled since the SSA decision, the State Medicaid Disability Office shall review current medical information to determine if the client is disabled.

(d) Clients must provide the required medical evidence and cooperate in obtaining any necessary evaluations to establish disability.

(e) Recipients must cooperate in completing continuing disability reviews as required by the State Medicaid Disability Office unless they have a current approval of disability from SSA. Medicaid eligibility as a disabled individual will end if the individual fails to cooperate in a continuing disability review.

(4) If an individual denied disability status by the Medicaid Disability Review Office requests a fair hearing, the Disability Review Office may reconsider its determination as part of fair hearing process. The individual must request the hearing within the time limit defined in Section R414-301-6.

(a) The individual may provide the eligibility agency additional medical evidence for the reconsideration.

(b) The reconsideration may take place before the date the fair hearing is scheduled to take place.

(c) The eligibility agency notifies the individual of the reconsideration decision. Thereafter, the individual may choose to pursue or abandon the fair hearing.

(5) If the eligibility agency denies an individual's Medicaid application because the Medicaid Disability Review Office or SSA has determined that the individual is not disabled and that determination is later reversed on appeal, the eligibility agency determines the individual's eligibility back to the application that gave rise to the appeal. The individual must meet all other eligibility criteria for such past months.

(a) Eligibility cannot begin any earlier than the month of disability onset or three months before the month of application subject to the requirements defined in Section R414-306-4, whichever is later.

(b) If the individual is not receiving medical assistance at the time a successful appeal decision is made, the individual must contact the eligibility agency to request the Disability Medicaid coverage.

(c) The individual must provide any verifications the eligibility agency needs to determine eligibility for past and current months for which the individual is requesting medical assistance.

(d) If an individual is determined eligible for past or current months, but must pay a spenddown or Medicaid Work Incentive (MWI) premium for one or more months to receive coverage, the

spenddown or MWI premium must be met before Medicaid coverage may be provided for those months.

(6) The age requirement for Aged Medicaid is 65 years of age.

(7) For children described in Section 1902(a)(10)(A)(i)(II) of the Social Security Act in effect April 4, 2012, the agency shall conduct periodic redeterminations to assure that the child continues to meet the SSI eligibility criteria as required by such section.

(8) Coverage for qualifying individuals described in Section 1902(a)(10)(E)(iv) of Title XIX of the Social Security Act in effect November 19, 2012, is limited to the amount of funds allocated under Section 1933 of Title XIX of the Social Security Act in effect November 19, 2012, for a given year, or as subsequently authorized by Congress under the American Taxpayer Relief Act, House Resolution 8, signed into law on January 2, 2013. The eligibility agency shall deny coverage to applicants when the uncommitted allocated funds are insufficient to provide such coverage.

(9[~~8~~]) To determine eligibility under Section 1902(a)(10)(A)(ii)(XIII), if the countable income of the individual and the individual's family does not exceed 250% of the federal poverty guideline for the applicable family size, the agency shall disregard an amount of earned and unearned income of the individual, the individual's spouse, and a minor individual's parents that equals the difference between the total income and the Supplemental Security Income maximum benefit rate payable.

(10[~~9~~]) The agency shall require individuals eligible under Section 1902(a)(10)(A)(ii)(XIII) to apply for cost-effective health insurance that is available to them.

R414-303-5. 12 Month Transitional Family Medicaid[~~Reserved~~].

The agency provides transitional Medicaid coverage in accordance with the provisions of Title XIX of the Social Security Act Section 1925 for households that lose eligibility for 1931 Family Medicaid as described in 1931(c)(2).

KEY: income, coverage groups, independent foster care adolescent
Date of Enactment or Last Substantive Amendment: January 7, 2013
Notice of Continuation: January 25, 2008
Authorizing, and Implemented or Interpreted Law: 26-18-3; 26-1-5

Health, Health Care Financing, Coverage And Reimbursement Policy
R414-306
Program Benefits and Date of Eligibility

NOTICE OF 120-DAY (EMERGENCY) RULE
DAR FILE NO.: 37174
FILED: 01/07/2013

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: The purpose of this change is to restore technical changes to the rule text that extend Medicaid coverage for the Qualifying Individual (QI) program in accordance with the American Taxpayer Relief Act of 2012, House Resolution (H.R.) 8.

SUMMARY OF THE RULE OR CHANGE: This change restores language about the benefits and coverage period for individuals eligible for the QI program in accordance with the American Taxpayer Relief Act of 2012, H.R. 8. (DAR NOTE: This emergency rule supersedes the emergency rule filed under DAR No. 37121, effective 01/01/2013, and published in the January 15, 2013, issue of the Bulletin.)

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Section 26-1-5 and Section 26-18-3

EMERGENCY RULE REASON AND JUSTIFICATION:
REGULAR RULEMAKING PROCEDURES WOULD cause an imminent budget reduction because of budget restraints or federal requirements; and place the agency in violation of federal or state law.
JUSTIFICATION: The Department needs to file this emergency rule to extend coverage of the QI program. Because Congress did not pass legislation to extend this program before 01/01/2013, the Department had to file an emergency rule (Rule R414-306, DAR No. 37121, published in the January 15, 2013, issue of the Bulletin) to remove language that extends this program and avoid being in violation of federal law. With the passage of Section 621 of H.R. 8, this emergency rule restores language that extends this program and supersedes the previous emergency rule.

ANTICIPATED COST OR SAVINGS TO:
♦ THE STATE BUDGET: There is no impact to the state budget because this rule simply continues coverage of the QI program.
♦ LOCAL GOVERNMENTS: There is no impact to local governments because they neither fund Medicaid services nor determine Medicaid eligibility.
♦ SMALL BUSINESSES: There is no impact to small businesses because this rule simply continues coverage of the QI program.
♦ PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES: There is no impact to Medicaid providers and to Medicaid recipients because this rule simply continues coverage of the QI program.

COMPLIANCE COSTS FOR AFFECTED PERSONS: There are no compliance costs to a single Medicaid provider or to a Medicaid recipient because this rule simply continues coverage of the QI program.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: Reinstatement of funding under H.R. 8, signed into law on 01/01/2013, allows Medicaid to re-open the eligibility group that had been closed in the prior emergency rule when such funding was not available.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
HEALTH
HEALTH CARE FINANCING, COVERAGE AND REIMBURSEMENT POLICY
CANNON HEALTH BLDG
288 N 1460 W
SALT LAKE CITY, UT 84116-3231
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Craig Devashrayee by phone at 801-538-6641, by FAX at 801-538-6099, or by Internet E-mail at cdevashrayee@utah.gov

EFFECTIVE: 01/07/2013

AUTHORIZED BY: David Patton, Executive Director

R414. Health, Health Care Financing, Coverage and Reimbursement Policy.
R414-306. Program Benefits and Date of Eligibility.
R414-306-2. QMB,[~~and~~] SLMB, and QI Benefits.

(1) The Department must provide the services outlined under 42 U.S.C. 1396d(p) and 42 U.S.C. 1396u-3 for Qualified Medicare Beneficiaries.

(2) The Department provides the benefits outlined under 42 U.S.C. 1396d(p)(3)(ii) for Specified Low-Income Medicare Beneficiaries and Qualifying Individuals. Benefits for Qualifying Individuals are subject to the provisions of 42 U.S.C. 1396u-3.

(3) The Department does not cover premiums for enrollment with any health insurance plans except for Medicare.

R414-306-4. Effective Date of Eligibility.

(1) Subject to the exceptions in Subsection R414-306-4(3), eligibility for any Medicaid program, and for the Specified Low-income Medicare Beneficiary (SLMB) or Qualified Individual (QI) programs begins the first day of the application month if the individual is determined to meet the eligibility criteria for that month.

(2) An applicant for Medicaid, [~~or~~]SLMB or QI benefits may request medical coverage for the retroactive period. The retroactive period is the three months immediately preceding the month of application.

(a) An applicant may request coverage for one or more months of the retroactive period.

(b) Subject to the exceptions in Subsection R414-306-4(3), eligibility for retroactive medical coverage begins no earlier than the first day of the month that is three months before the application month.

(c) The applicant must receive medical services during the retroactive period and be determined eligible for the month he receives services.

(3) To determine the date eligibility for medical assistance may begin for any month, the following requirements apply:

(a) Eligibility of an individual cannot begin any earlier than the date the individual meets the state residency requirement defined in Section R414-302-2;

(b) Eligibility of a qualified alien subject to the five-year bar on receiving regular Medicaid services cannot begin earlier than the date that is five years after the date the person became a qualified alien, or the date the five-year bar ends due to other events defined in statute;

(c) Eligibility of a qualified alien not subject to the five-year bar on receiving regular Medicaid services can begin no earlier than the date the individual meets qualified alien status.

(d) An individual who is ineligible for Medicaid while residing in a public institution or an Institution for Mental Disease (IMD) may become eligible on the date the individual is no longer a resident of either one of these institutions. If an individual is under the age of 22 and is a resident of an IMD, the individual remains a resident of the IMD until he is unconditionally released.

(4) If an applicant is not eligible for the application month, but requests retroactive coverage, the agency will determine eligibility for the retroactive period based on the date of that application.

(5) The agency may use the same application to determine eligibility for the month following the month of application if the applicant is determined ineligible for both the retroactive period and the application month. In this case, the application date changes to the date eligibility begins. The retroactive period associated with the application changes to the three months preceding the new application date.

(6) Medicaid eligibility for certain services begins when the individual meets the following criteria:

(a) Eligibility for coverage of institutional services cannot begin before the date that the individual has been admitted to a medical institution and meets the level of care criteria for admission. The medical institution must provide the required admission verification to the Department within the time limits set by the Department in Rule R414-501. Medicaid eligibility for institutional services does not begin earlier than the first day of the month that is three months before the month of application for Medicaid coverage of institutional services.

(b) Eligibility for coverage of home and community-based services under a Medicaid waiver cannot begin before the first day of the month the client is determined by the case management agency to meet the level of care criteria and home and community-based services are scheduled to begin within the month. The case management agency must verify that the individual meets the level of care criteria for waiver services. Medicaid eligibility for waiver services does not begin earlier than the first day of the month that is three months before the month of application for Medicaid coverage of waiver services.

(7) An individual determined eligible for QI benefits in a calendar year is eligible to receive those benefits throughout the remainder of the calendar year, if the individual continues to meet the eligibility criteria and the program still exists. Receipt of QI benefits in one calendar year does not entitle the individual to QI benefits in any succeeding year.

([~~7~~]8) After being approved for Medicaid, a client may later request coverage for the retroactive period associated with the approved application if the following criteria are met:

(a) The client did not request retroactive coverage at the time of application; and

(b) The agency did not make a decision about eligibility for medical assistance for that retroactive period; and

(c) The client states that he received medical services and provides verification of his eligibility for the retroactive period.

([8]9) A client cannot request coverage for the retroactive period associated with a denied application. The client, however, may reapply and a new retroactive coverage period is considered based on the new application date.

KEY: effective date, program benefits, medical transportation
Date of Enactment or Last Substantive Amendment: January 7, 2013
Notice of Continuation: January 25, 2008
Authorizing, and Implemented or Interpreted Law: 26-18

End of the Notices of 120-Day (Emergency) Rules Section

FIVE-YEAR NOTICES OF REVIEW AND STATEMENTS OF CONTINUATION

Within five years of an administrative rule's original enactment or last five-year review, the agency is required to review the rule. This review is intended to remove obsolete rules from the Utah Administrative Code. Upon reviewing a rule, an agency may: repeal the rule by filing a **Proposed Rule**; continue the rule as it is by filing a **Notice of Review and Statement of Continuation (Notice)**; or amend the rule by filing a **Proposed Rule** and by filing a **Notice**. By filing a Notice, the agency indicates that the rule is still necessary.

Notices are not followed by the rule text. The rule text that is being continued may be found in the most recent edition of the *Utah Administrative Code*. The rule text may also be inspected at the agency or the Division of Administrative Rules. **Notices** are effective upon filing.

Notices are governed by Section 63G-3-305.

Health, Health Care Financing, Coverage And Reimbursement Policy
R414-27
Medicaid Certification of Nursing Care Facilities

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION
DAR FILE NO.: 37177
FILED: 01/09/2013

NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

CONCISE EXPLANATION OF THE PARTICULAR STATUTORY PROVISIONS UNDER WHICH THE RULE IS ENACTED AND HOW THESE PROVISIONS AUTHORIZE OR REQUIRE THE RULE: Section 26-18-503 authorizes the Department to certify nursing facility programs to provide cost effective services to Medicaid recipients. In addition, Section 26-18-3 requires the Department to implement by rule standards to administer nursing facilities within the Medicaid program.

SUMMARY OF WRITTEN COMMENTS RECEIVED DURING AND SINCE THE LAST FIVE YEAR REVIEW OF THE RULE FROM INTERESTED PERSONS SUPPORTING OR OPPOSING THE RULE: The Department received written comments on this rule after it filed a proposed change that defined third party ownership. The comments suggested the definition was too broad in making third party owners assume Medicaid liabilities of a previous nursing facility program in the case of a sale or transfer of a facility, and would discourage lessors, lenders, and management companies from making purchases of distressed nursing facilities. Another comment on this change suggested removing a provision that wrongfully limited the mile radius necessary for a nursing facility operating in a new or renovated facility to be eligible for recertification. A final comment on this change suggested the rule include an exception (in accordance with Section 26-18-505 to the provision that requires nursing facilities to always receive approval from the Medicaid Director for the transfer of Medicaid-certified beds to other nursing facilities or to build new nursing facilities within the same or different counties.

REASONED JUSTIFICATION FOR THE CONTINUATION OF THE RULE, INCLUDING REASONS WHY THE AGENCY DISAGREES WITH COMMENTS IN OPPOSITION TO THE RULE, IF ANY: The Department filed a change to the proposed rule to address the written comments. The Department will continue this rule because it provides cost effective services to nursing facility residents and governs the certification of nursing care facilities to receive Medicaid payments for services to Medicaid eligible individuals.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
HEALTH
HEALTH CARE FINANCING, COVERAGE AND REIMBURSEMENT POLICY
CANNON HEALTH BLDG
288 N 1460 W
SALT LAKE CITY, UT 84116-3231
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Craig Devashrayee by phone at 801-538-6641, by FAX at 801-538-6099, or by Internet E-mail at cdevashrayee@utah.gov

AUTHORIZED BY: David Patton, Executive Director

EFFECTIVE: 01/09/2013

Human Services, Recovery Services
R527-39
Applicant/Recipient Cooperation

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION
DAR FILE NO.: 37164
FILED: 01/02/2013

NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

CONCISE EXPLANATION OF THE PARTICULAR STATUTORY PROVISIONS UNDER WHICH THE RULE IS ENACTED AND HOW THESE PROVISIONS AUTHORIZE OR REQUIRE THE RULE: Section 62A-11-107 gives the Office of Recovery Services (ORS) the authority to adopt, amend, and enforce rules necessary to carry out its responsibilities under state law. Section 62A-11-104 gives ORS the authority to determine whether an applicant or recipient of cash assistance or Medicaid is cooperating in good faith as required by Section 62A-11-307.2. Section 62A-11-307.2 specifies that unless a good cause or other exception applies, the applicant/recipient must cooperate in good faith and provide the name and other identifying information of the other parent. In addition, the applicant/recipient must supply additional necessary information and appear at interviews, hearings, and legal proceedings when it is necessary. When paternity needs to be established, the statute requires the applicant/recipient and the appropriate child to submit to genetic testing. Section 62A-11-307.2 requires ORS to determine and redetermine, when appropriate, whether a recipient has cooperated in establishing paternity or in establishing, modifying or enforcing a child support order. When a determination of non-cooperation is made, the statute requires ORS to provide notice to the applicant/recipient including information that the determination may be contested. This rule also describes the options available to an applicant/ recipient who wishes to contest a non-cooperation determination when a good cause or other exception does not apply. Additionally, this rule explains that if an applicant/recipient disagrees with the Decision and Order that is issued, the recipient may request a reconsideration within a certain time frame or petition the district court to review the order.

SUMMARY OF WRITTEN COMMENTS RECEIVED DURING AND SINCE THE LAST FIVE YEAR REVIEW OF THE RULE FROM INTERESTED PERSONS SUPPORTING OR OPPOSING THE RULE: There have been no comments received since the last five-year review of the rule.

REASONED JUSTIFICATION FOR THE CONTINUATION OF THE RULE, INCLUDING REASONS WHY THE AGENCY DISAGREES WITH COMMENTS IN OPPOSITION TO THE RULE, IF ANY: This rule should be continued because of the laws that require ORS to determine and redetermine whether an applicant or recipient of cash assistance or Medicaid is cooperating. The rule provides the office with the requirements that are necessary for the recipient/applicant to be considered cooperating. Also, this rule provides the applicant/recipient the additional option to contest a non-cooperation determination informally at the agency level rather than proceeding under the Utah Administrative Procedures Act or through the district court. In addition, the rule provides each progressive level of appeal.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
HUMAN SERVICES
RECOVERY SERVICES
515 E 100 S
SALT LAKE CITY, UT 84102-4211
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Shancie Nance by phone at 801-536-8191, by FAX at 801-536-8509, or by Internet E-mail at snance@utah.gov

AUTHORIZED BY: Mark Brasher

EFFECTIVE: 01/02/2013

Human Services, Recovery Services
R527-56
In-kind Support

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION
DAR FILE NO.: 37165
FILED: 01/02/2013

NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

CONCISE EXPLANATION OF THE PARTICULAR STATUTORY PROVISIONS UNDER WHICH THE RULE IS ENACTED AND HOW THESE PROVISIONS AUTHORIZE OR REQUIRE THE RULE: Section 62A-11-107 gives the Office of Recovery Services (ORS) the authority to adopt, amend, and enforce rules necessary to carry out its responsibilities under state law. In accordance with Section 62A-11-104, ORS is responsible for collecting child support when an application has been received for child support services, the state has provided public assistance, or a child lives out of the home in the protective custody, temporary custody, or custody or care of the state. Section 62A-11-307.2 specifies the duties of a custodial parent after support rights have been assigned to the state. The custodial parent may not prejudice the rights of the Office of Recovery Services to establish paternity, enforce health insurance provisions, or establish and collect support. In addition, the custodial parent may not agree to change the court or administratively ordered manner or amount of payment of past, present, or future support without the office's written

consent. Under this statute, the custodial parent must immediately deliver any payment to ORS that is received from the non-custodial parent. In 1991 a court decision (Utah Dept. of Social Servs. V. Adams, 806 P.2d. 1193 (Utah CR. App. 1991)) required that ORS give credit under certain conditions for in-kind support payments made where a court order exists.

SUMMARY OF WRITTEN COMMENTS RECEIVED DURING AND SINCE THE LAST FIVE YEAR REVIEW OF THE RULE FROM INTERESTED PERSONS SUPPORTING OR OPPOSING THE RULE: There have been no comments received since the last five-year review of the rule.

REASONED JUSTIFICATION FOR THE CONTINUATION OF THE RULE, INCLUDING REASONS WHY THE AGENCY DISAGREES WITH COMMENTS IN OPPOSITION TO THE RULE, IF ANY: This rule defines in-kind payments and establishes when and under what conditions the ORS is required to give the non-custodial parent credit for in-kind support payments. It also describes the conditions for ORS to require payment of court ordered cash support in case only, and when to take action to recover the case equivalent of "in-kind support" that has been paid to the custodial parent. Therefore, this rule should be continued.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
HUMAN SERVICES
RECOVERY SERVICES
515 E 100 S
SALT LAKE CITY, UT 84102-4211
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Shancie Nance by phone at 801-536-8191, by FAX at 801-536-8509, or by Internet E-mail at snance@utah.gov

AUTHORIZED BY: Mark Brasher

EFFECTIVE: 01/02/2013

Human Services, Recovery Services
R527-305
High-Volume, Automated Administrative Enforcement in Interstate Child Support Cases

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION
DAR FILE NO.: 37168
FILED: 01/03/2013

NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

CONCISE EXPLANATION OF THE PARTICULAR STATUTORY PROVISIONS UNDER WHICH THE RULE IS ENACTED AND HOW THESE PROVISIONS AUTHORIZE OR REQUIRE THE RULE: Subsection 466(a)(14) of the Social Security Act requires a state to use automatic data processing to search various state databases to identify the location of the non-custodial parent and his/her assets in response to a request made by another state to enforce a support order. Section 62A-11-305 specifies services that must be provided to another state when a request for "High-Volume, Automated Administrative Enforcement" is received.

SUMMARY OF WRITTEN COMMENTS RECEIVED DURING AND SINCE THE LAST FIVE YEAR REVIEW OF THE RULE FROM INTERESTED PERSONS SUPPORTING OR OPPOSING THE RULE: No comments have been received.

REASONED JUSTIFICATION FOR THE CONTINUATION OF THE RULE, INCLUDING REASONS WHY THE AGENCY DISAGREES WITH COMMENTS IN OPPOSITION TO THE RULE, IF ANY: This rule should to be continued because it provides and establishes procedures for the Office of Recovery Services to provide services to another state IV-D child support agency requesting High-Volume Automated Administrative Enforcement. It also states that an automated interstate enforcement request is given the same priority as a regular interstate case that is referred to the Office by another state for collection services, or establishment, modification, or registration of an order.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
HUMAN SERVICES
RECOVERY SERVICES
515 E 100 S
SALT LAKE CITY, UT 84102-4211
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ LeAnn Wilber by phone at 801-536-8950, by FAX at 801-536-8509, or by Internet E-mail at lwilber@utah.gov

AUTHORIZED BY: Mark Brasher

EFFECTIVE: 01/03/2013

Human Services, Recovery Services
R527-430
Administrative Notice of Lien-Levy Procedures

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION
DAR FILE NO.: 37169
FILED: 01/03/2013

NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

CONCISE EXPLANATION OF THE PARTICULAR STATUTORY PROVISIONS UNDER WHICH THE RULE IS ENACTED AND HOW THESE PROVISIONS AUTHORIZE OR REQUIRE THE RULE: Section 62A-11-107 gives the Office of Recovery Services (ORS) the authority to adopt, amend, and enforce rules necessary to carry out its responsibilities under state law. Section 62A-11-304.1 authorizes ORS to implement lines to satisfy past-due support, subject to the obligor's right to contest the lien-levy action and the amount claimed to be past due. The statute also permits ORS to intercept and seize the assets of an obligor held in financial institutions and attach retirement funds if the obligor is receiving periodic payment or has the authority to make withdrawals from the retirement account.

SUMMARY OF WRITTEN COMMENTS RECEIVED DURING AND SINCE THE LAST FIVE YEAR REVIEW OF THE RULE FROM INTERESTED PERSONS SUPPORTING OR OPPOSING THE RULE: No comments have been received.

REASONED JUSTIFICATION FOR THE CONTINUATION OF THE RULE, INCLUDING REASONS WHY THE AGENCY DISAGREES WITH COMMENTS IN OPPOSITION TO THE RULE, IF ANY: This rule is based on Section 62A-11-304.1, which is still in effect and the lien-levy procedures described in the rule are reflected in current ORS policy and procedures. The rule establishes procedures regarding the release of funds to an unobligated spouse when the unobligated spouse is a co-owner of a financial account or joint-recipient of certain non-means tested payments and contests a lien-levy action upon any of those assets. Therefore, this rule should be continued.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
HUMAN SERVICES
RECOVERY SERVICES
515 E 100 S
SALT LAKE CITY, UT 84102-4211
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ LeAnn Wilber by phone at 801-536-8950, by FAX at 801-536-8509, or by Internet E-mail at lwilber@utah.gov

AUTHORIZED BY: Mark Brasher

EFFECTIVE: 01/03/2013

Insurance, Administration
R590-157
Surplus Lines Insurance Premium Tax and Stamping Fee

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION
DAR FILE NO.: 37171
FILED: 01/07/2013

NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

CONCISE EXPLANATION OF THE PARTICULAR STATUTORY PROVISIONS UNDER WHICH THE RULE IS ENACTED AND HOW THESE PROVISIONS AUTHORIZE OR REQUIRE THE RULE: Subsection 31A-3-303(2) requires the commissioner to prescribe by rule accounting and reporting forms and procedures to be used in calculating and paying the surplus lines premium tax. Subsection 31A-15-103(11)(d) requires the commissioner to specify by rule the stamping fee amount and how it is to be collected. Section R590-157-4 of the rule sets the stamping fee amount and authorizes the Surplus Lines Association to collect the fee and Section R590-157-6 sets accounting procedures for this process.

SUMMARY OF WRITTEN COMMENTS RECEIVED DURING AND SINCE THE LAST FIVE YEAR REVIEW OF THE RULE FROM INTERESTED PERSONS SUPPORTING OR OPPOSING THE RULE: The department has not received written comment regarding this rule in the past five years.

REASONED JUSTIFICATION FOR THE CONTINUATION OF THE RULE, INCLUDING REASONS WHY THE AGENCY DISAGREES WITH COMMENTS IN OPPOSITION TO THE RULE, IF ANY: This rule provides procedures and reporting forms to be used by insurers, brokers, and policyholders in calculating the tax due. As a result of the regulation, all who charge the tax, use the same calculation to determine the amount of the fee. It makes the payment uniform and fair. Therefore, this rule should be continued.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
INSURANCE
ADMINISTRATION
ROOM 3110 STATE OFFICE BLDG
450 N MAIN ST
SALT LAKE CITY, UT 84114-1201
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Jilene Whitby by phone at 801-538-3803, by FAX at 801-538-3829, or by Internet E-mail at jwhitby@utah.gov

AUTHORIZED BY: Neal Gooch

EFFECTIVE: 01/07/2013

Insurance, Administration
R590-218
Permitted Language for Reservation of Discretion Clauses

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION
DAR FILE NO.: 37176
FILED: 01/09/2013

NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

CONCISE EXPLANATION OF THE PARTICULAR STATUTORY PROVISIONS UNDER WHICH THE RULE IS ENACTED AND HOW THESE PROVISIONS AUTHORIZE OR REQUIRE THE RULE: Section 31A-2-201 gives the commissioner the authority to write rules to enforce the provisions of Title 31A. Subsections 31A-21-201(3) and 31A-21-314(2) authorize the department to regulate the use of "reservation of discretion clauses" in policy forms filed with the department. The rule prohibits their use in forms not associated with ERISA employee benefit plans and prescribes language to be used in reservation of discretion clauses used in ERISA employee benefit plans.

SUMMARY OF WRITTEN COMMENTS RECEIVED DURING AND SINCE THE LAST FIVE YEAR REVIEW OF THE RULE FROM INTERESTED PERSONS SUPPORTING OR OPPOSING THE RULE: The department has not received written comments regarding this rule in the past five years.

REASONED JUSTIFICATION FOR THE CONTINUATION OF THE RULE, INCLUDING REASONS WHY THE AGENCY DISAGREES WITH COMMENTS IN OPPOSITION TO THE RULE, IF ANY: This rule creates a safe harbor for insurance companies that provide insurance to ERISA employee benefit plans sponsored by employers, allowing insurers to know what language in insurance forms is acceptable to the department. Therefore, this rule should be continued.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
INSURANCE
ADMINISTRATION
ROOM 3110 STATE OFFICE BLDG
450 N MAIN ST
SALT LAKE CITY, UT 84114-1201
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Jilene Whitby by phone at 801-538-3803, by FAX at 801-538-3829, or by Internet E-mail at jwhitby@utah.gov

AUTHORIZED BY: Neal Gooch

EFFECTIVE: 01/09/2013

Insurance, Administration
R590-243
Commercial Motor Vehicle Insurance Coverage

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION
DAR FILE NO.: 37172
FILED: 01/07/2013

NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

CONCISE EXPLANATION OF THE PARTICULAR STATUTORY PROVISIONS UNDER WHICH THE RULE IS ENACTED AND HOW THESE PROVISIONS AUTHORIZE OR REQUIRE THE RULE: Subsection 31A-22-315(1)(b) requires the department to write rules defining commercial motor vehicle insurance coverage, which is what this rule does in Section R590-243-3.

SUMMARY OF WRITTEN COMMENTS RECEIVED DURING AND SINCE THE LAST FIVE YEAR REVIEW OF THE RULE FROM INTERESTED PERSONS SUPPORTING OR OPPOSING THE RULE: No comments have been received by the department regarding this rule in the past five years.

REASONED JUSTIFICATION FOR THE CONTINUATION OF THE RULE, INCLUDING REASONS WHY THE AGENCY DISAGREES WITH COMMENTS IN OPPOSITION TO THE RULE, IF ANY: The purpose of this rule is to define commercial motor vehicle insurance coverage as it applies to motor vehicle insurance reporting. Therefore, this rule should be continued.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
INSURANCE
ADMINISTRATION
ROOM 3110 STATE OFFICE BLDG
450 N MAIN ST
SALT LAKE CITY, UT 84114-1201
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Jilene Whitby by phone at 801-538-3803, by FAX at 801-538-3829, or by Internet E-mail at jwhitby@utah.gov

AUTHORIZED BY: Neal Gooch

EFFECTIVE: 01/07/2013

Natural Resources, Wildlife Resources
R657-58
Fishing Contests and Clinics

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

DAR FILE NO.: 37203
FILED: 01/15/2013

NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

CONCISE EXPLANATION OF THE PARTICULAR STATUTORY PROVISIONS UNDER WHICH THE RULE IS ENACTED AND HOW THESE PROVISIONS AUTHORIZE OR REQUIRE THE RULE: Under Sections 23-14-8 and 23-14-19, the Wildlife Board is authorized to provide standards and procedures for taking fish and crayfish.

SUMMARY OF WRITTEN COMMENTS RECEIVED DURING AND SINCE THE LAST FIVE YEAR REVIEW OF THE RULE FROM INTERESTED PERSONS SUPPORTING OR OPPOSING THE RULE: No written comments supporting or opposing Rule R657-58 were received since 01/15/2008 when the rule was first enacted.

REASONED JUSTIFICATION FOR THE CONTINUATION OF THE RULE, INCLUDING REASONS WHY THE AGENCY DISAGREES WITH COMMENTS IN OPPOSITION TO THE RULE, IF ANY: Rule R657-58 provides the procedures, standards, and requirements for holding a fishing contest or clinic on a body of water in the state of Utah. The provisions adopted in this rule are effective. Continuation of this rule is necessary for continued success for allowing anglers of Utah to take fish and to protect the resource.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:

NATURAL RESOURCES
WILDLIFE RESOURCES
1594 W NORTH TEMPLE
SALT LAKE CITY, UT 84116-3154
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:
♦ Staci Coons by phone at 801-538-4718, by FAX at 801-538-4709, or by Internet E-mail at stacicoons@utah.gov

AUTHORIZED BY: Gregory Sheehan, Director

EFFECTIVE: 01/15/2013

End of the Five-Year Notices of Review and Statements of Continuation Section

NOTICES OF
RULE EFFECTIVE DATES

State law provides for agencies to make their rules effective and enforceable after publication in the Utah State Bulletin. In the case of Proposed Rules or Changes in Proposed Rules with a designated comment period, the law permits an agency to file a notice of effective date any time after the close of comment plus seven days. In the case of Changes in Proposed Rules with no designated comment period, the law permits an agency to file a notice of effective date on any date including or after the thirtieth day after the rule's publication date. If an agency fails to file a Notice of Effective Date within 120 days from the publication of a Proposed Rule or a related Change in Proposed Rule the rule lapses and the agency must start the rulemaking process over.

Notices of Effective Date are governed by Subsection 63G-3-301(12), 63G-3-303, and Sections R15-4-5a and 5b.

Abbreviations
AMD = Amendment
CPR = Change in Proposed Rule
NEW = New Rule
R&R = Repeal & Reenact
REP = Repeal

Agriculture and Food
Animal Industry
No. 36962 (AMD): R58-21.Trichomoniasis
Published: 11/15/2012
Effective: 01/04/2013

Capitol Preservation Board (State)
Administration
No. 37064 (AMD): R131-2.Capitol Hill Complex Facility Use
Published: 12/01/2012
Effective: 01/07/2013

Commerce
Occupational and Professional Licensing
No. 37040 (AMD): R156-37.Utah Controlled Substances Act Rule
Published: 12/01/2012
Effective: 01/08/2013

No. 37039 (NEW): R156-37f.Controlled Substance Database Act Rule
Published: 12/01/2012
Effective: 01/08/2013

Real Estate
No. 36973 (AMD): R162-2g.Real Estate Appraiser Licensing and Certification Administrative Rules
Published: 11/15/2012
Effective: 01/02/2013

Securities
No. 37042 (AMD): R164-31-1.Guidelines for the Assessment of Administrative Fines
Published: 12/01/2012
Effective: 01/08/2013

Crime Victim Reparations
Administration
No. 37061 (AMD): R270-1.Award and Reparation Standards
Published: 12/01/2012
Effective: 01/07/2013

No. 37063 (AMD): R270-2.Crime Victim Reparations Adjudicative Proceedings
Published: 12/01/2012
Effective: 01/07/2013

Education
Administration
No. 37058 (AMD): R277-502.Educator Licensing and Data Retention
Published: 12/01/2012
Effective: 01/07/2013

No. 37059 (AMD): R277-509.Licensure of Student Teachers and Interns
Published: 12/01/2012
Effective: 01/07/2013

Health
Health Care Financing
No. 37045 (AMD): R410-14.Administrative Hearing Procedures
Published: 12/01/2012
Effective: 01/09/2013

Natural Resources
Parks and Recreation
No. 36856 (REP): R651-408.Off-Highway Vehicle Education Curriculum Standards
Published: 10/15/2012
Effective: 01/15/2013

Public Service Commission
Administration
No. 37041 (AMD): R746-320.Uniform Rules Governing Natural Gas Service
Published: 12/01/2012
Effective: 01/07/2013

Tax Commission
Administration
No. 36991 (AMD): R861-1A-12.Policies and Procedures Regarding Public Disclosure Pursuant to Utah Code Ann. Sections 41-3-209, 59-1-210, 59-1-403, and 59-1-405
Published: 11/15/2012
Effective: 01/10/2013

Workforce Services
Employment Development
No. 37025 (AMD): R986-700-710.Income Limits for ES CC
Published: 11/15/2012
Effective: 01/02/2013

No. 37067 (AMD): R986-900-902.Options and Waivers
Published: 12/01/2012
Effective: 01/08/2013

Unemployment Insurance
No. 37066 (AMD): R994-305.Collection of Contributions
Published: 12/01/2012
Effective: 01/08/2013

No. 37023 (AMD): R994-305-1201.Offer in Compromise
Published: 11/15/2012
Effective: 01/02/2013

No. 37024 (AMD): R994-406.Fraud, Fault and Nonfault Overpayments
Published: 11/15/2012
Effective: 01/02/2013

End of the Notices of Rule Effective Dates Section

RULES INDEX
BY AGENCY (CODE NUMBER)
AND
BY KEYWORD (SUBJECT)

The Rules Index is a cumulative index that reflects all effective changes to Utah's administrative rules. The current Index lists changes made effective from January 2, 2013 through January 15, 2013. The Rules Index is published in the Utah State Bulletin and in the annual Utah Administrative Rules Index of Changes. Nonsubstantive changes, while not published in the Bulletin, do become part of the Utah Administrative Code (Code) and are included in this Index, as well as 120-Day (Emergency) rules that do not become part of the Code. The rules are indexed by Agency (Code Number) and Keyword (Subject).

Questions regarding the index and the information it contains should be addressed to Nancy Lancaster (801-538-3218), Mike Broschinsky (801-538-3003), or Kenneth A. Hansen (801-538-3777).

A copy of the Rules Index is available for public inspection at the Division of Administrative Rules (5110 State Office Building, Salt Lake City, UT), or may be viewed online at the Division’s web site (http://www.rules.utah.gov/).

RULES INDEX - BY AGENCY (CODE NUMBER)

ABBREVIATIONS

AMD = Amendment
CPR = Change in proposed rule
EMR = Emergency rule (120 day)
NEW = New rule
EXD = Expired
NSC = Nonsubstantive rule change
REP = Repeal
R&R = Repeal and reenact
5YR = Five-Year Review

CODE REFERENCE	TITLE	FILE NUMBER	ACTION	EFFECTIVE DATE	BULLETIN ISSUE/PAGE
AGRICULTURE AND FOOD					
Animal Industry					
R58-21	Trichomoniasis	36962	AMD	01/04/2013	2012-22/16
CAPITOL PRESERVATION BOARD (STATE)					
Administration					
R131-2	Capitol Hill Complex Facility Use	37064	AMD	01/07/2013	2012-23/9
COMMERCE					
Occupational and Professional Licensing					
R156-37	Utah Controlled Substances Act Rule	37040	AMD	01/08/2013	2012-23/18
R156-37f	Controlled Substance Database Act Rule	37039	NEW	01/08/2013	2012-23/21
Real Estate					
R162-2g	Real Estate Appraiser Licensing and Certification Administrative Rules	36973	AMD	01/02/2013	2012-22/19
Securities					
R164-31-1	Guidelines for the Assessment of Administrative Fines	37042	AMD	01/08/2013	2012-23/26
CRIME VICTIM REPARATIONS					
Administration					
R270-1	Award and Reparation Standards	37061	AMD	01/07/2013	2012-23/27
R270-2	Crime Victim Reparations Adjudicative Proceedings	37063	AMD	01/07/2013	2012-23/33
EDUCATION					
Administration					
R277-502	Educator Licensing and Data Retention	37058	AMD	01/07/2013	2012-23/34
R277-509	Licensure of Student Teachers and Interns	37059	AMD	01/07/2013	2012-23/39
HEALTH					
Health Care Financing					
R410-14	Administrative Hearing Procedures	37045	AMD	01/09/2013	2012-23/44
Health Care Financing, Coverage and Reimbursement Policy					
R414-27	Medicaid Certification of Nursing Care Facilities	37177	5YR	01/09/2013	Not Printed
R414-303	Coverage Groups	37173	EMR	01/07/2013	Not Printed
R414-306	Program Benefits and Date of Eligibility	37174	EMR	01/07/2013	Not Printed

HUMAN SERVICES

Recovery Services

R527-39	Applicant/Recipient Cooperation	37164	5YR	01/02/2013	Not Printed
R527-56	In-kind Support	37165	5YR	01/02/2013	Not Printed
R527-305	High-Volume, Automated Administrative Enforcement in Interstate Child Support Cases	37168	5YR	01/03/2013	Not Printed
R527-430	Administrative Notice of Lien-Levy Procedures	37169	5YR	01/03/2013	Not Printed

INSURANCE

Administration

R590-157	Surplus Lines Insurance Premium Tax and Stamping Fee	37171	5YR	01/07/2013	Not Printed
R590-218	Permitted Language for Reservation of Discretion Clauses	37176	5YR	01/09/2013	Not Printed
R590-243	Commercial Motor Vehicle Insurance Coverage	37172	5YR	01/07/2013	Not Printed

NATURAL RESOURCES

Parks and Recreation

R651-408	Off-Highway Vehicle Education Curriculum Standards	36856	REP	01/15/2013	2012-20/77

Wildlife Resources

R657-58	Fishing Contests and Clinics	37203	5YR	01/15/2013	Not Printed

PUBLIC SERVICE COMMISSION

Administration

R746-320	Uniform Rules Governing Natural Gas Service	37041	AMD	01/07/2013	2012-23/48

TAX COMMISSION

Administration

R861-1A-12	Policies and Procedures Regarding Public Disclosure Pursuant to Utah Code Ann. Sections 41-3-209, 59-1-210, 59-1-403, and 59-1-405	36991	AMD	01/10/2013	2012-22/144

WORKFORCE SERVICES

Employment Development

R986-700-710	Income Limits for ES CC	37025	AMD	01/02/2013	2012-22/146
R986-900-902	Options and Waivers	37067	AMD	01/08/2013	2012-23/50

Unemployment Insurance

R994-305	Collection of Contributions	37066	AMD	01/08/2013	2012-23/52
R994-305-1201	Offer in Compromise	37023	AMD	01/02/2013	2012-22/147
R994-406	Fraud, Fault and Nonfault Overpayments	37024	AMD	01/02/2013	2012-22/148

RULES INDEX - BY KEYWORD (SUBJECT)

ABBREVIATIONS

AMD = Amendment
CPR = Change in proposed rule
EMR = Emergency rule (120 day)
NEW = New rule
EXD = Expired
NSC = Nonsubstantive rule change
REP = Repeal
R&R = Repeal and reenact
5YR = Five-Year Review

KEYWORD AGENCY	FILE NUMBER	CODE REFERENCE	ACTION	EFFECTIVE DATE	BULLETIN ISSUE/PAGE
administrative fines					
Commerce, Securities	37042	R164-31-1	AMD	01/08/2013	2012-23/26
administrative procedures					
Commerce, Real Estate	36973	R162-2g	AMD	01/02/2013	2012-22/19
Crime Victim Reparations, Administration	37063	R270-2	AMD	01/07/2013	2012-23/33
appellate procedures					
Crime Victim Reparations, Administration	37063	R270-2	AMD	01/07/2013	2012-23/33
bulls					
Agriculture and Food, Animal Industry	36962	R58-21	AMD	01/04/2013	2012-22/16
cattle					
Agriculture and Food, Animal Industry	36962	R58-21	AMD	01/04/2013	2012-22/16
child care					
Workforce Services, Employment Development	37025	R986-700-710	AMD	01/02/2013	2012-22/146
child support					
Human Services, Recovery Services	37164	R527-39	5YR	01/02/2013	Not Printed
	37165	R527-56	5YR	01/02/2013	Not Printed
	37168	R527-305	5YR	01/03/2013	Not Printed
	37169	R527-430	5YR	01/03/2013	Not Printed
commercial motor vehicle insurance					
Insurance, Administration	37172	R590-243	5YR	01/07/2013	Not Printed
controlled substance database					
Commerce, Occupational and Professional Licensing	37039	R156-37f	NEW	01/08/2013	2012-23/21
controlled substances					
Commerce, Occupational and Professional Licensing	37040	R156-37	AMD	01/08/2013	2012-23/18
coverage groups					
Health, Health Care Financing, Coverage and Reimbursement Policy	37173	R414-303	EMR	01/07/2013	Not Printed
developmental disabilities					
Tax Commission, Administration	36991	R861-1A-12	AMD	01/10/2013	2012-22/144
disclosure requirements					
Tax Commission, Administration	36991	R861-1A-12	AMD	01/10/2013	2012-22/144
discretion clauses					
Insurance, Administration	37176	R590-218	5YR	01/09/2013	Not Printed
disease control					
Agriculture and Food, Animal Industry	36962	R58-21	AMD	01/04/2013	2012-22/16
educator licensing					
Education, Administration	37058	R277-502	AMD	01/07/2013	2012-23/34