



State of Utah

GARY R. HERBERT
Governor

SPENCER J. COX
Lieutenant Governor

Department of
Environmental Quality

Alan Matheson
Acting Executive Director

DIVISION OF RADIATION CONTROL
Rusty Lundberg
Director

Radiation Control Board
Peter A. Jenkins, Ph.D., CHP *Chair*
Scott Bird, *Vice-Chair*
Brady Bradford
Dick Codell, Ph.D.
Lindsey Christensen Nesbit, Ph.D.
Ulrich Rassner, MD
Matt W. Rydalch

Alan Matheson – *DEQ Acting Executive Director*

Rusty Lundberg, *Executive Secretary*

RADIATION CONTROL BOARD MEETING – FINAL MEETING

June 9, 2015

**Multi Agency State Office Building (MASOB)
195 North 1950 West, Salt Lake City, Utah**

(One or more members of the Board may participate telephonically)
(Access Number: 1-877-820-7831 Passcode: 396230#)

AGENDA

BOARD MEETING – 1:00 p.m.

I. Call to Order

II. Approval of Minutes from the April 14, 2015 meeting

III. Approval of Mammography Imaging Medical Physicists

IV. Administrative Rulemaking

a. Final Adoption

- i. Proposed changes to sections of R313-19-34, *Requirements of General Applicability to Licensing of Radioactive Material, Terms and Conditions of Licenses*, R313-24-4, *Uranium Mills and Source Material Mill Tailings Disposal Facility Requirements, Clarifications or Exceptions*, and R313-36-3, *Special Requirements for Industrial Radiographic Operations, Clarifications or Exceptions* to incorporate corresponding federal regulations promulgated by the NRC and published in the *Federal Register* of July 6, 2012 (77 FR 39899)
- ii. Proposed changes to R313-12-3, *General Provisions, Definitions*, R313-19-13, *Requirements of General Applicability to Licensing of Radioactive Material, Exemptions*, R313-21, *General Licenses, General Licenses—Radioactive Material Other Than Source Material*, and R313-22, *Specific Licenses*, to incorporate corresponding federal regulations promulgated by the NRC and published in the *Federal Register* of July 25, 2012 (77 FR 43666)
- iii. Proposed new rule R313-27, *Medical Use Advisory Committee*.

Radiation Control Board – Agenda

June 9, 2015

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V. Information Items

- a. **Nuclear Regulatory Commission (NRC) Update**
 - i. Public meeting for proposed changes to 10 CFR Part 61
June 10, 2015, 6:00 pm
Hilton Garden Inn
250 West 600 South
Salt Lake City, UT

(For more information: www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/uw-streams.html)

VI. Public Comment

VII. Other Business

VIII. Final meeting of the Radiation Control Board -- Future meetings will be held as the Waste Management and Radiation Control Board

For those individuals needing special assistance in accordance with the Americans with Disabilities Act, please contact Dana Powers at the Utah Department of Environmental Quality, at 195 North 1950 West, Salt Lake City, UT 84116, Office of Human Resources at (801) 536-4412, TDD (801) 536-4414, or by email at: dpowers@utah.gov.



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Rusty Lundberg, *Executive Secretary*

**MINUTES
OF
THE UTAH RADIATION CONTROL BOARD
April 14, 2015**

Department of Environmental Quality
Multi Agency State Office Building
Conference Room 1015, 195 North 1950 West, Salt Lake City, Utah

BOARD MEMBERS PRESENT

Peter Jenkins, CHP, Ph.D.
Richard Codell, Ph.D.
Matt Rydalch
Brady Bradford (via phone)
Lindsey Christensen Nesbitt, Ph.D. (via phone)
Rusty Lundberg, Executive Secretary

**BOARD MEMBERS
ABSENT/EXCUSED**

Amanda Smith, Executive Director DEQ
Scott Bird
Ulrich Rassner, MD

**DRC STAFF/OTHER DEO MEMBERS
PRESENT**

John Hultquist, DRC Section Manager
Phil Goble, DRC Section Manager
Connie Rauen, DRC Staff
Karen Wehking, DRC Staff
Lisa Mechem, DRC Staff
Loren Morten, Program Manager
Spencer Wickham, DRC Staff
Eric Boone, DRC Staff
Mike Givens, DRC Staff
Laura Lockhart, AG's Office
Donna Spangler, DEQ
Brad Johnson, DEQ

PUBLIC

Dan Shrum, EnergySolutions
Vern Rogers, EnergySolutions
Matt Pacenza, HEAL Utah
Tim Gillie, Tooele Transcript
George Chapman
Janet Jenson, Jenson & Guelker
Ashley Sollyslak, HEAL Utah
Brian Maffley, S.L. Tribune
Mike Garner (via phone)

I. Welcome

Dr. Peter Jenkins, Chairman, called the meeting to order at 1:00 p.m. He welcomed the Board Members and the public.

II. Approval of the Minutes from the March 10, 2015 Board Meeting

Dr. Peter Jenkins, Chairman, asked if any members of the Board had any corrections to the minutes for the March 10, 2015 Board Meeting. None were requested.

MOTION MADE BY MR. BRADY BRADFORD TO APPROVE THE MINUTES OF MARCH 10, 2015.

SECONDED BY MR. MATT RYDALCH.

MOTION CARRIED AND PASSED UNANIMOUSLY.

III. Administrative Rulemaking

a. Proposed Rule Changes:

i. Mr. Spencer Wickham, DRC Staff, reviewed the proposed changes and rulemaking process for R313-19-34, R313-36-3 and R313-24-4. He informed the Board that the proposed revisions are in response to incorporate corresponding federal regulations at (10 CFR) Parts 30, 34, 40, and 71. The Nuclear Regulatory Commission (NRC) notified the Utah Division of Radiation Control that the revised regulations need to be adopted by agreement states before August 6, 2015. Mr. Wickham recommended that the Board accept the Director's recommendation to initiate rulemaking by filing the proposed rule changes with the Division of Administrative rules, publishing it in the May 1, 2015 issue of the Utah State Bulletin and to initiate a 30-day comment period.

MOTION MADE BY DR. RICHARD CODELL TO ACCEPT RECOMMENDATION MADE BY THE DIVISION STAFF'S TO ADOPT THE PROPOSED CHANGES TO R313-19-34, R313-36-3, R313-24-4 AND TO INITIATE 30-DAY PUBLIC COMMENT PERIOD.

SECONDED BY MR. MATT RYDALCH.

MOTION CARRIED AND PASSED UNANIMOUSLY.

ii. Mr. Spencer Wickham, DRC Staff, reviewed the proposed changes and rulemaking process for rules R313-12-3, R313-21 and R313-22. He informed the Board that the proposed revisions are in response to incorporate corresponding federal regulations at (10 CFR) Parts 30, 31, 32, 40 and 70. The NRC notified the Utah Division of Radiation Control that the revised regulations need to be adopted by agreement states before October 23, 2015. Mr. Wickham recommended that the Board accept the Director's recommendation and to initiate rulemaking by filing the proposed rule changes with the Division of Administrative rules, publishing it in the May 1, 2015 issue of the Utah State Bulletin and to initiate a 30-day comment period

MOTION MADE BY MR. MATT RYDALCH TO ACCEPT RECOMMENDATION MADE BY THE DIVISION STAFF'S TO ADOPT THE PROPOSED CHANGES TO R313-12-3, R313-21, R313-22 AND TO INITIATE 30-DAY PUBLIC COMMENT PERIOD.

SECONDED BY DR. RICHARD CODELL.

MOTION CARRIED AND PASSED UNANIMOUSLY.

IV. Information Items

a. Nuclear Regulatory Commission (NRC)

- i. Mr. Rusty Lundberg, Executive Secretary, gave a status update on proposed changes to 10 CFR Part 61, Licensing Requirements for Land Disposal of Radioactive Waste, that was published in Federal Register on March 26, 2015 (80 FR 15930) and provided in the Board packet. The comment period will be 120-days, closing on July 24, 2015. Final rule should be published by mid-2016. Dr. Richard Codell asked how this would affect the depleted uranium, Mr. Lundberg responded that would be further evaluated once the rule is finalized.

b. Low-level Radioactive Waste

- i. EnergySolutions – Depleted Uranium Performance Assessment – Mr. Rusty Lundberg, Director, gave a status update on the formal public period that was initiated April 13, 2015 and the final Safety Evaluation Report (SER) for the proposed disposal of large quantities of depleted uranium was released to the public for review and comment. He informed the Board of the public meetings that have been scheduled and the public comment period is expected to end on May 29, 2015. However, on April 14, 2015 the DRC received a written request from EnergySolutions to place the public comment period on hold until EnergySolutions could provide the information identified in the SER as being unresolved due to the need for additional information. The Board and members of the public had a lengthy discussion, with comments, concerns, and objections regarding the request for the extension. Mr. Dan Shrum of EnergySolutions gave their reasoning behind the request. The Board made a recommendation to the Division to reconsider the request for extension and to move forward with the public comment period that had been initiated and extend the length of the comment period rather than delay it indefinitely.

- c. **First Quarter 2015 Activities Report** – Mr. Rusty Lundberg, Director, gave an update and summary on the on the activities conducted by the division on various programs monitored by the Division of Radiation Control. Mr. Peter Jenkins. Board Chairman asked for a brief update on NOV's. Mr. Lundberg stated there was no notices of deficiency in the quarter and gave a summary on previous NOV's. Mr. Jenkins asked for further explanation on an incident on gauges described in the report that stated: *“As a result members of the public were exposed on accident to radiation from the gauge the exposures were not significant enough with no detectable health issues.”* Mr. Rusty Lundberg, explained the steps that had been taken in regards to the

issue which was still under investigation. Mr. Mike Givens, DRC Staff, provided additional information on the observed dose rates and inspection he had conducted.

- d. **Public Availability of Information** – Mr. John Hultquist, DRC Program Manager, reviewed and presented the DEQ EZ Records Search system that was in the process of being implemented for public access to records.

V. Public Comment

No comments were received.

VI. Next Scheduled Board Meeting: June 9, 2015

Multi Agency State Office Building, Board Conference Room #1015
195 North 1950 West
Salt Lake City, Utah

Meeting Adjourned 2:38 PM

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Rusty Lundberg
Director

MEMORANDUM

TO: Utah Radiation Control Board

FROM: Lisa Mechem 

DATE: May 29, 2015

SUBJECT: Mammography Imaging Medical Physicists

I have reviewed the applications and supporting documentation for a number of individuals who seek recertification as a Mammography Imaging Medical Physicist. The following physicists submitted a complete application and demonstrated they are eligible to be recertified:

Adam Arndt, M.S.	Robert J. Hoffman, M.S.
Lisa M. Bosworth, M.S.	Peter A. Jenkins, Ph.D..
Dan Dugan, M.S.	Ann M. Jones, M.S.
Byron L. Hardy, Ph.D.	Angela Phares, M.S.
Jeremy Hawk, M.S.	Kyle Siwek, M.S.
Stephen Henry, M.S.	Gene L. Wollan, M.S.

Recommendation

The Division of Radiation Control Director recommends that the Board approve each individual named above as a Mammography Imaging Medical Physicist. The effective date of the approval should be from June 9, 2015 to May 31, 2016.

Board Meeting June 9, 2015



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Director

MEMORANDUM

TO: Rusty Lundberg, Director
FROM: Lisa Mechem 
DATE: May 29, 2015
SUBJECT: Mammography Imaging Medical Physicist

I have reviewed the application and supporting documentation for Kelli Silvertrim, PhD, who seeks certification as a Mammography Imaging Medical Physicist. Dr. Silvertrim submitted a complete application and has demonstrated that she is eligible to be certified.

Recommendation

The Division of Radiation Control Director recommends that the Board approve the individual named above as a Mammography Imaging Medical Physicist. The effective date of the approval should be from June 9, 2015 to May 31, 2016.

Board Meeting June 9, 2015

**UTAH RADIATION CONTROL BOARD
BOARD ACTION ITEM
June 9, 2015**

**PROPOSED RULE AMENDMENTS – FINAL ADOPTION
for**

**R313-19-34, REQUIREMENTS OF GENERAL
APPLICABILITY TO LICENSING OF RADIOACTIVE
MATERIAL, TERMS AND CONDITIONS OF
LICENSES**

and

**R313-24-4, URANIUM MILLS AND SOURCE
MATERIAL MILL TAILINGS DISPOSAL
FACILITY REQUIREMENTS, CLARIFICATIONS
OR EXCEPTIONS**

and

**R313-36-3, SPECIAL REQUIREMENTS FOR
INDUSTRIAL RADIOGRAPHIC OPERATIONS,
CLARIFICATIONS OR EXCEPTIONS**

Background

On July 6, 2012, the Nuclear Regulatory Commission (NRC) promulgated revisions to selected portions of the federal radiation control regulations found in Title 10 Code of Federal Regulations (10 CFR). All Agreement States (including Utah) are required to maintain rules compatible with NRC regulations. As a means to assist Agreement States in preparing and performing the necessary rulemaking changes, the NRC prepares a compatibility action table (RATS ID 2012-3) that lists each rule change and its corresponding compatibility category.

The NRC notified the Utah Division of Radiation Control (DRC) that the revised regulations need to be adopted by Agreement States before August 06, 2015. The DRC proposes to revise the existing rules by incorporating the federal rules found in 10 CFR Parts 30, 34, 40, and 71 and published in the July 6, 2012 *Federal Register* (77FR 39899).

During the April 14, 2015, Board meeting, Notice of Proposed Rule Amendments for Sections R313-19-34, R313-24-4, and R313-36-3 were discussed. The Board approved the proposed changes, directed staff to file the proposed changes with the Division of Administrative Rules for publication in the Utah State Bulletin. A thirty-day public comment period began on May 1, 2015.

The Director received no comments from the public during the comment period.

Recommendation

The Director recommends that the Board approve the proposed changes as published in the May 1, 2015, issue of the Utah State Bulletin and set an effective date of June 16, 2015, for the rule amendments to R313-19-34, R313-24-4 and R313-36-3.

UTAH RADIATION CONTROL BOARD
BOARD ACTION ITEM
June 9, 2015

PROPOSED RULE AMENDMENTS – FINAL ADOPTION
for

R313-27, MEDICAL USE ADVISORY COMMITTEE

Background

During the March 14, 2015, Board meeting, Dr. Peter Jenkins, Chairman, proposed changes to create a new section (R313-27) to provide for the creation of an advisory committee to address administrative rulemaking matters associated with the Board for purposes of administering the radiation control program as authorized by the Radiation Control Act. The Board approved the proposed changes and directed staff to file the proposed changes with the Division of Administrative Rules for publication in the Utah State Bulletin. A thirty-day public comment period began on May 1, 2015.

The Director received no comments from the public during the comment period.

Recommendation

The Director recommends that the Board approve the proposed changes as published in the May 1, 2015, issue of the Utah State Bulletin and set an effective date of June 16, 2015, for the rule amendments to R313-27.

UTAH STATE BULLETIN

OFFICIAL NOTICES OF UTAH STATE GOVERNMENT
Filed April 02, 2015, 12:00 a.m. through April 15, 2015, 11:59 p.m.

Number 2015-9
May 01, 2015

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 Division of Administrative Rules, part of the Department of Administrative Services, produces the *Bulletin* under authority of Section 63G-3-402.

The Portable Document Format (PDF) version of the *Bulletin* is the official version. The PDF version of this issue is available at <http://www.rules.utah.gov/publicat/bulletin.htm>. Any discrepancy between the PDF version and other versions will be resolved in favor of the PDF version.

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. 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)* of the same volume and issue number. The *Digest* is available by e-mail subscription or online. Visit <http://www.rules.utah.gov/publicat/digest.htm> for additional information.

Division of Administrative Rules, Salt Lake City 84114

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Authorizing, and Implemented or Interpreted Law: Art X Sec 3; 53A-1-402(1)(a); 53A-6; 53A-1-401(3)

Environmental Quality, Radiation Control **R313-12-3** Definitions

NOTICE OF PROPOSED RULE

(Amendment)

DAR FILE NO.: 39277

FILED: 04/14/2015

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: The State of Utah entered into an agreement with the U.S. Nuclear Regulatory Commission (NRC) to establish and maintain a compatible program for the control of radioactive material in Utah. To maintain compatibility with NRC requirements, the State of Utah is required to modify the Utah Radiation Control Rules in order to incorporate the appropriate regulations published by the NRC in 77 FR 43666.

SUMMARY OF THE RULE OR CHANGE: This rulemaking addresses the adoption of appropriate requirements found in 79 FR 43666. This rule change amends regulations in Rule R313-12 to make requirements for distributors of radioactive material clearer, less prescriptive, and more risk-informed and up to date. This amendment also redefines categories of devices to be used under exemptions, adding explicit provisions regarding the sealed source and device registration process, and adding flexibility to the licensing of users of sealed sources and devices. This amendment is primarily intended to make the licensing process more efficient and effective. The definition for "sealed source and device registry" is being added to Section R313-12-3.

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 is no anticipated cost or savings to the state budget. The proposed changes do not add or remove significant requirements that affect radiation. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause the state budget to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

◆ **LOCAL GOVERNMENTS:** There is no anticipated cost or savings to the local government. The proposed changes do not add or remove significant requirements that affect radiation. The proposed rule changes are adopting required

federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause local government to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

◆ **SMALL BUSINESSES:** Small businesses may hold a radioactive material license, but there is no anticipated cost or savings for small businesses. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause small businesses to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

◆ **PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES:** Small businesses and persons other than businesses may hold a radioactive material license, but there is no anticipated cost or savings for small businesses and persons other than businesses. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause local government to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

COMPLIANCE COSTS FOR AFFECTED PERSONS: There are no anticipated costs for affected persons since the proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause affected persons to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: The proposed changes to the rule are necessary for the Utah Radiation Control Rules to be compatible with NRC requirements, and to ensure that the Division's program activities are adequate to protect the public health and safety. The Division is not aware of any business that would be impacted fiscally due to the proposed rule changes.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:

ENVIRONMENTAL QUALITY
RADIATION CONTROL
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:

◆ Spencer Wickham by phone at 801-536-0082, by FAX at 801-533-4097, or by Internet E-mail at swickham@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 06/01/2015

THIS RULE MAY BECOME EFFECTIVE ON: 06/16/2015

AUTHORIZED BY: Rusty Lundberg, Director

R313. Environmental Quality, Radiation Control.

R313-12. General Provisions.

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.

"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.

"Commencement of construction" means taking any action defined as "construction" or any other activity at the site of a facility subject to these rules that have a reasonable nexus to radiological health and safety.

"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.

"Construction" means the installation of wells associated with radiological operations; for example, production, injection, or monitoring well networks associated with in-situ recovery or other facilities; the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to these rules that are related to radiological safety or security. The term "construction" does not include:

(a) changes for temporary use of the land for public recreational purposes;

(b) site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

(c) preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

(d) erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this part;

(e) excavation;

(f) erection of support buildings; for example, construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings; for use in connection with the construction of the facility;

(g) building of service facilities; for example, paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines;

(h) procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or

(i) taking any other action that has no reasonable nexus to radiological health and safety.

"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 3.7×10^{10} 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.

"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/cm²).

"License" means a license issued by the 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 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 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 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 Director or is legally obligated to register with the 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 2.58×10^{-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.

"Sealed source and device registry" means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

"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:

$(175(\text{Grams contained U-235})/350) + (50(\text{Grams U-233}/200) + (50(\text{Grams Pu}/200))$ 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 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.

KEY: definitions, units, inspections, exemptions

Date of Enactment or Last Substantive Amendment: [~~October 21, 2014~~2015]

Notice of Continuation: July 7, 2011

Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-3-108

Environmental Quality, Radiation Control R313-19-13 Exemptions

NOTICE OF PROPOSED RULE

(Amendment)

DAR FILE NO.: 39280

FILED: 04/14/2015

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: The State of Utah entered into an agreement with the U.S. Nuclear Regulatory Commission (NRC) to establish and maintain a compatible program for the control of radioactive material in Utah. To maintain compatibility with NRC requirements, the State of Utah is required to modify the Utah Radiation Control Rules in order to incorporate the appropriate regulations published by the NRC in 77 FR 43666.

SUMMARY OF THE RULE OR CHANGE: This rulemaking addresses the adoption of appropriate requirements found in 79 FR 43666. This rule change amends regulations in Rule R313-19 to make requirements for distributors of radioactive material clearer, less prescriptive, and more risk-informed and up to date. This amendment also redefines categories of devices to be used under exemptions, adding explicit provisions regarding the sealed source and device registration process, and adding flexibility to the licensing of users of sealed sources and devices. This amendment is primarily intended to make the licensing process more efficient and effective.

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 is no anticipated cost or savings to the state budget. The proposed changes do not add or remove significant requirements that affect radiation. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause the state budget to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

◆ **LOCAL GOVERNMENTS:** There is no anticipated cost or savings to the local government. The proposed changes do not add or remove significant requirements that affect radiation. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause local government to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

◆ **SMALL BUSINESSES:** Small businesses may hold a radioactive material license, but there is no anticipated cost or savings for small businesses. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause small businesses to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

◆ **PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES:** Small businesses and persons other than businesses may hold a radioactive material license, but there is no anticipated cost or savings for small businesses and persons other than businesses. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause local government to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

COMPLIANCE COSTS FOR AFFECTED PERSONS: There are no anticipated costs for affected persons since the proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state.

These changes do not add new requirements that would cause affected persons to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: The proposed changes to the rule are necessary for the Utah Radiation Control Rules to be compatible with NRC requirements, and to ensure that the Division's program activities are adequate to protect the public health and safety. The Division is not aware of any business that would be impacted fiscally due to the proposed rule changes.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:

ENVIRONMENTAL QUALITY
RADIATION CONTROL
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:

◆ Spencer Wickham by phone at 801-536-0082, by FAX at 801-533-4097, or by Internet E-mail at swickham@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 06/01/2015

THIS RULE MAY BECOME EFFECTIVE ON: 06/16/2015

AUTHORIZED BY: Rusty Lundberg, Director

**R313. Environmental Quality, Radiation Control.
R313-19. Requirements of General Applicability to Licensing of Radioactive Material.**

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 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)(I) Static elimination devices which contain, as sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 uCi) of polonium-210 per device.

(II) Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 uCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.

(III) Such devices authorized before October 23, 2012 for use under the general license then provided in R313-21-22(1)(a) or equivalent regulations of the Commission or an Agreement State and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Commission or Agreement State.

~~(B)~~(C) Precision balances containing not more than one millicurie (37.0 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part manufactured before June 9, 2010.

~~(C)~~(D) 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)~~(E) 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)~~(F) 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)~~(G) 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)] (G), 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)(e)(ii) does not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.~~

~~_____ (A) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, and except as provided in R313-19-13(2)(c)(ii)(C), any person is exempt from the requirements for a license set forth in Section 274 b. of the Atomic Energy Act of 1954 and from the regulations in R313-15, R313-19, R313-32, R313-34, R313-36, R313-37, and R313-38 to the extent that such a person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, produced, or initially transferred in accordance with a specific license issued pursuant to 10 CFR 32.22 (2015), which license authorizes the initial transfer of the product for use.~~

~~_____ (B) Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under R313-19-13(2)(c)(ii)(A), should apply for a license under 10 CFR 32.22 (2015) and for a certificate of registration in accordance with 10 CFR 32.210 (2015).~~

~~_____ (C) The exemption in R313-19-13(2)(c)(ii)(A) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.~~

~~[(B)](D) 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.~~

~~_____ (A) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from the requirements for a license set forth in Section 274 b. of the Atomic Energy Act of 1954 and from the regulations in parts R313-18, R313-15, R313-19, R313-21, R313-22, R313-32, R313-34, R313-36, R313-37, and R313-38 to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect health, safety, or property, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CFR 32.26 (2015), which license authorizes the initial transfer of the product for use under this section. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by a State under comparable provisions to 10 CFR 32.26 (2015) authorizing distribution to persons exempt from regulatory requirements.~~

~~_____ (B) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use under paragraph (a) of this section, should apply for a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 32.26 (2015) and for a certificate of registration in accordance with R313-22-210 or equivalent regulations of an Agreement State.~~

~~(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) Certain industrial devices.~~

~~(A) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license set forth in Section 274 b. of the Atomic Energy Act of 1954 and from the regulations in parts R313-18, R313-15, R313-18, R313-15, R313-19, R313-21, R313-22, R313-32, R313-34, R313-36, R313-37, and R313-38 to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CFR 32.30 (2015), which license authorizes the initial transfer of the device for use under this rule. This exemption does not~~

cover sources not incorporated into a device, such as calibration and reference sources.

(B) Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under R313-19-13(2)(c)(v)(A), should apply for a license under 10 CFR 32.30 (2015) and for a certificate of registration in accordance with R313-22-210.

[(v)](vi) With respect to Subsections R313-19-13(2)(b)(iii), R313-19-13(2)(c)(i), (iii) and (iv), the authority to transfer possession or control by the manufacturer, processor, or producer of equipment, devices, commodities, or other products containing byproduct material whose subsequent possession, use, transfer, and disposal by other persons is exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

KEY: license, reciprocity, transportation, exemptions

Date of Enactment or Last Substantive Amendment: [~~February 17,~~]2015

Notice of Continuation: September 23, 2011

Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-3-108

Environmental Quality, Radiation Control **R313-19-34** Terms and Conditions of Licenses

NOTICE OF PROPOSED RULE

(Amendment)

DAR FILE NO.: 39274

FILED: 04/14/2015

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: This filing changes the requirements of general applicability to licensing of radioactive material.

SUMMARY OF THE RULE OR CHANGE: Subsection R313-19-34(5)(b) is revised to remove the reference "11 U.S.C. 101(14)" and add, in its place, the reference "11 U.S.C 101(15)."

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 is no anticipated cost or savings to the state budget. The proposed changes do not add or remove significant requirements that affect radiation. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause the state budget to incur any changes in compliance

costs beyond those identified by the Nuclear Regulatory Commission.

♦ **LOCAL GOVERNMENTS:** There is no anticipated cost or savings to the local government. The proposed changes do not add or remove significant requirements that affect radiation. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause local government to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

♦ **SMALL BUSINESSES:** Small businesses may hold a radioactive material license, but there is no anticipated cost or savings for small businesses. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause small businesses to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

♦ **PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES:** Small businesses and persons other than businesses may hold a radioactive material license, but there is no anticipated cost or savings for small businesses and persons other than businesses. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause local government to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

COMPLIANCE COSTS FOR AFFECTED PERSONS: There are no anticipated costs for affected persons since the proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause affected persons to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: The proposed changes to the rule are necessary for the Utah Radiation Control Rules to be compatible with NRC requirements, and to ensure that the Division's program activities are adequate to protect the public health and safety. The Division is not aware of any business that would be impacted fiscally due to the proposed rule changes.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:

ENVIRONMENTAL QUALITY

RADIATION CONTROL

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:

♦ Spencer Wickham by phone at 801-536-0082, by FAX at 801-533-4097, or by Internet E-mail at swickham@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 06/01/2015

THIS RULE MAY BECOME EFFECTIVE ON: 06/16/2015

AUTHORIZED BY: Rusty Lundberg, Director

R313. Environmental Quality, Radiation Control.**R313-19. Requirements of General Applicability to Licensing of Radioactive Material.****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 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 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 Director, and shall give his consent in writing.

(3) Persons licensed by the 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 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 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[(+4)] (15), 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 Director. The licensee may change the approved plan without the Director's approval only if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the 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 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).

KEY: license, reciprocity, transportation, exemptions

Date of Enactment or Last Substantive Amendment: [February 17,] 2015

Notice of Continuation: September 23, 2011

Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-3-108

**Environmental Quality, Radiation
Control
R313-21-22
General Licenses*--Radioactive
Material Other Than Source Material**

NOTICE OF PROPOSED RULE

(Amendment)

DAR FILE NO.: 39278

FILED: 04/14/2015

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: The State of Utah entered into an agreement with the U.S. Nuclear Regulatory Commission (NRC) to establish and maintain a compatible program for the control of radioactive material in Utah. To maintain compatibility with NRC requirements, the State of Utah is required to modify the Utah Radiation Control Rules in order to incorporate the appropriate regulations published by the NRC in 77 FR 43666.

SUMMARY OF THE RULE OR CHANGE: This rulemaking addresses the adoption of appropriate requirements found in 79 FR 43666. This rule change amends regulations in Section R313-21-22 to make requirements for distributors of radioactive material clearer, less prescriptive, and more risk-informed and up to date. This amendment also redefines categories of devices to be used under exemptions, adding explicit provisions regarding the sealed source and device registration process, and adding flexibility to the licensing of users of sealed sources and devices. This amendment is primarily intended to make the licensing process more efficient and effective.

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

ANTICIPATED COST OR SAVINGS TO:

♦ **THE STATE BUDGET:** There is no anticipated cost or savings to the state budget. The proposed changes do not add or remove significant requirements that affect radiation. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause the state budget to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

♦ **LOCAL GOVERNMENTS:** There is no anticipated cost or savings to the local government. The proposed changes do not add or remove significant requirements that affect radiation. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause local government to incur any changes in

compliance costs beyond those identified by the Nuclear Regulatory Commission.

♦ **SMALL BUSINESSES:** Small businesses may hold a radioactive material license, but there is no anticipated cost or savings for small businesses. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause small businesses to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

♦ **PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES:** Small businesses and persons other than businesses may hold a radioactive material license, but there is no anticipated cost or savings for small businesses and persons other than businesses. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause local government to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

COMPLIANCE COSTS FOR AFFECTED PERSONS: There are no anticipated costs for affected persons since the proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause affected persons to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: The proposed changes to the rule are necessary for the Utah Radiation Control Rules to be compatible with NRC requirements, and to ensure that the Division's program activities are adequate to protect the public health and safety. The Division is not aware of any business that would be impacted fiscally due to the proposed rule changes.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:

ENVIRONMENTAL QUALITY
RADIATION CONTROL
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:

♦ Spencer Wickham by phone at 801-536-0082, by FAX at 801-533-4097, or by Internet E-mail at swickham@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 06/01/2015

THIS RULE MAY BECOME EFFECTIVE ON: 06/16/2015

AUTHORIZED BY: Rusty Lundberg, Director

R313. Environmental Quality, Radiation Control.

R313-21. General Licenses.

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

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

(1) ~~[Certain devices and equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the Director, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State for use pursuant to 10 CFR 31.3. This general license is subject to the provisions of R313-12-51 through R313-12-70, R313-14, R313-15, R313-18 and R313-19 as applicable.]Reserved.~~

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

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

(2) Certain items and self-luminous products containing radium-226.

(a) A general license is hereby issued to a person to acquire, receive, possess, use, or transfer, in accordance with the provisions of Subsections R313-21-22(2)(b), R313-21-22(2)(c), and R313-21-22(2)(d), radium-226 contained in the following products manufactured prior to November 30, 2007.

(i) Antiquities originally intended for use by the general public. For the purposes of Subsection R313-21-22(2)(a), antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

(ii) Intact timepieces containing greater than 37 kilobecquerels (1 uCi), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

(iii) Luminous items installed in air, marine, or land vehicles.

(iv) All other luminous products provided that no more than 100 items are used or stored at the same location at one time.

(v) Small radium sources containing no more than 37 kilobecquerels (1 uCi) of radium-226. For the purposes of Subsection R313-21-22(2)(a), "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations such as cloud chambers and spinthariscopes, electron tubes, static eliminators, or as designated by the Director.

(b) Persons who acquire, receive, possess, use, or transfer radioactive material under the general license issued in Subsection R313-21-22(2)(a) are exempt from the provisions of Rules R313-15, R313-18, and Sections R313-12-51 and R313-19-50, to the extent that

the receipt, possession, use, or transfers of radioactive material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to a person specifically licensed under Rule R313-22.

(c) A person who acquires, receives, possesses, uses, or transfers radioactive material in accordance with the general license in Subsection R313-21-22(2)(a):

(i) Shall notify the Director should there be an indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Director within 30 days.

(ii) Shall not abandon products containing radium-226. The product, and radioactive material from the product, may only be disposed of according to Section R313-15-1008 or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the Director.

(iii) Shall not export products containing radium-226 except in accordance with 10 CFR Part 110.

(iv) Shall dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with Federal or State solid or hazardous waste laws, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 under Rule R313-22 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State or as otherwise approved by the Director.

(v) Shall respond to written requests from the Director to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Director a written justification using the method stated in Section R313-12-110.

(d) The general license in R313-21-22(2)(a) does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

(3) RESERVED.

(4) Certain detecting, measuring, gauging or controlling devices and certain devices for producing light or an ionized atmosphere.*

NOTE: *Persons possessing radioactive material in devices under a general license in R313-21-22(4) before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of R313-21-22(4) in effect on January 14, 1975.

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

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

manufactured or initially transferred and labeled in accordance with the specifications contained in:

(A) a specific license issued by the Director pursuant to R313-22-75(4); or

(B) an equivalent specific license issued by the Nuclear Regulatory Commission or an Agreement State; or

(C) An equivalent specific license issued by a State with provisions comparable to R313-22-75.*

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

(ii) The devices must have been received from one of the specific licensees described in R313-21-22(4)(b)(i) or through a transfer made under R313-21-22(4)(c)(ix).

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

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

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

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

(B) Devices containing only tritium or not more than 3.7 megabecquerel (100 uCi) of other beta, gamma, or both, emitting material or 0.37 megabecquerel (10 uCi) of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(iii) shall assure that other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

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

(B) by a person holding a specific license pursuant to R313-22 or from the Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform such activities;

(iv) shall maintain records showing compliance with the requirements of R313-21-22(4)(c)(ii) and (iii). The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from the installation the radioactive material and its shielding or containment. The licensee shall retain these records as follows:

(A) Each record of a test for leakage of radioactive material required by R313-21-22(4)(c)(ii) shall be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of;

(B) Each record of a test of the on-off mechanism and indicator required by R313-21-22(4)(c)(ii) shall be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of;

(C) Each record that is required by R313-21-22(4)(c)(iii) shall be retained for three years from the date of the recorded event or until the device is transferred or disposed of;

(v) shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 185 becquerel (0.005 uCi) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair the device that was issued by the Director, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the Director, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 185 becquerel (0.005 uCi) or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the Director within 30 days. Under these circumstances, the criteria set out in R313-15-402 may be applicable, as determined by the Director on a case-by-case basis;

(vi) shall not abandon the device containing radioactive material;

(vii) shall not export the device containing radioactive materials except in accordance with 10 CFR 110;

(viii)(A) shall transfer or dispose of the device containing radioactive material only by export as provided by R313-21-22(4)(c)(vii) by transfer to another general licensee as authorized in R313-21-22(4)(c)(ix), to a person authorized to receive the device by a specific license issued under R313-22, to an authorized waste collector under R313-25, or equivalent regulations of the Nuclear Regulatory Commission, an Agreement State, or a Licensing State, or as otherwise approved under R313-21-22(4)(c)(viii)(C);

(B) shall furnish a report to the Director within 30 days after transfer of a device to a specific licensee or export. The report must contain:

(I) the identification of the device by manufacturer's or initial transferor's name, model number, and serial number;

(II) the name, address, and license number of the person receiving the device, the license number is not applicable if exported; and

(III) the date of the transfer;

(C) shall obtain written approval from the Director before transferring the device to any other specific licensee not specifically identified in R313-21-22(4)(c)(viii)(A); however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if the holder:

(I) verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(II) removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by R313-21-22(4)(c)(i)) so that the device is labeled in compliance with R313-15-904; however, the manufacturer, model number, and serial number must be retained;

(III) obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and

(IV) reports the transfer under R313-21-22(4)(c)(viii)(B);
 (ix) shall transfer the device to another general licensee only if:

(A) the device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of R313-21-22(4), R313-12-51, R313-15-1201, and R313-15-1202, and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to the Director:

(I) the manufacturer's or initial transferor's name;
 (II) the model number and serial number of the device transferred;

(III) the transferee's name and mailing address for the location of use; and

(IV) the name, title, and phone number of the responsible individual identified by the transferee in accordance with R313-21-22(4)(c)(xii) to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

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

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

(xi) shall respond to written requests from the Director to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by submitting a letter to the Director and provide written justification as to why it cannot comply;

(xii) shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard;

(xiii)(A) shall register, in accordance with R313-21-22(4)(c)(xiii)(B) and (C), devices containing at least 370 megabecquerel (ten mCi) of cesium-137, 3.7 megabecquerel (0.1 mCi) of strontium-90, 37 megabecquerel (one mCi) of cobalt-60, 3.7 megabecquerel (0.1 mCi) of radium-226, or 37 megabecquerel (one mCi) of americium-241 or any other transuranic, (elements with atomic number greater than uranium-92), based on the activity indicated on the label. Each address for a location of use, as described under R313-21-22(4)(c)(xiii)(C)(IV) represents a separate general licensee and requires a separate registration and fee;

(B) if in possession of a device meeting the criteria of R313-21-22(4)(c)(xiii)(A), shall register these devices annually with the Director and shall pay the fee required by R313-70. Registration shall include verifying, correcting, or adding, as appropriate, to the information provided in a request for registration received from the Director. The registration information must be submitted to the Director within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of R313-21-22(4)(c)(xiii)(A) is

subject to the bankruptcy notification requirement in R313-19-34(5) and (6);

(C) in registering devices, the general licensee shall furnish the following information and any other information specifically requested by the Director:

(I) name and mailing address of the general licensee;
 (II) information about each device: the manufacturer or initial transferor, model number, serial number, the radioisotope and activity as indicated on the label;

(III) name, title, and telephone number of the responsible person designated as a representative of the general licensee under R313-21-22(4)(c)(xii);

(IV) address or location at which the device(s) are used, stored, or both. For portable devices, the address of the primary place of storage;

(V) certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information; and

(VI) certification by the responsible representative of the general licensee that they are aware of the requirements of the general license; and

(D) persons generally licensed by the Nuclear Regulatory Commission, an Agreement State, or Licensing State with respect to devices meeting the criteria in R313-21-22(4)(c)(xiii)(A) are not subject to registration requirements if the devices are used in areas subject to Division jurisdiction for a period less than 180 days in any calendar year. The Director will not request registration information from such licensees;

(xiv) shall report changes to the mailing address for the location of use, including changes in the name of a general licensee, to the Director within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage; and

(xv) may not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by R313-21-22(4)(c)(ii) need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

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

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

(5) Luminous safety devices for aircraft.

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

(i) each device contains not more than 370.0 gigabecquerel (10 Ci) of tritium or 11.1 gigabecquerel (300 mCi) of promethium-147; and

(ii) each device has been manufactured, assembled or initially transferred in accordance with a specific license issued by the Nuclear Regulatory Commission or an Agreement State, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the Director or an Agreement State to the manufacturer or assembler of the device pursuant to licensing requirements equivalent to those in R313-22-75(5).

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

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

(d) This general license does not authorize the export of luminous safety devices containing tritium or promethium-147.

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

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

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

(7) Calibration and reference sources.

(a) A general license is hereby issued to own, receive, acquire, possess, use and transfer, in the form of calibration or reference sources, americium-241, plutonium or radium-226 in accordance with the provisions of Subsections R313-21-22(7)(b) and (c), to a person who holds a specific license issued by the Director which authorizes that person to receive, possess, use and transfer radioactive material.

(b) The general license in Subsection R313-21-22(7)(a) applies only to calibration or reference sources which have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued by the Nuclear Regulatory Commission pursuant to 10 CFR 32.57 or 10 CFR 70.39 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Director, or an Agreement State which authorizes manufacture of the sources for distribution to persons generally licensed, or in accordance with a specific license issued by a State with requirements equivalent to 10 CFR 32.57 or 10 CFR 70.39.

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

(i) shall not possess at any one time, at any one location of storage or use, more than 185.0 kilobecquerel (5 uCi) of americium-

241, 185.0 kilobecquerel (5 uCi) of plutonium, or 185.0 kilobecquerel (5 uCi) of radium-226 in such sources;

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

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

CAUTION - RADIOACTIVE MATERIAL
THIS SOURCE CONTAINS (AMERICIUM-241)
(PLUTONIUM)(RADIUM-226)*
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

.....
Typed or printed name of the manufacturer or initial transferor

NOTE: *Show the name of the appropriate material.

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

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

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

(d) A general license issued pursuant to Subsection R313-21-22(7)(a) does not authorize the manufacture, import, or export of calibration or reference sources containing americium-241, plutonium, or radium-226.

(8) RESERVED.

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

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

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

(i) iodine-125, in units not exceeding 370.0 kilobecquerel (10 uCi) each;

(ii) iodine-131, in units not exceeding 370.0 kilobecquerel (10 uCi) each;

(iii) carbon-14, in units not exceeding 370.0 kilobecquerel (10 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 370.0 kilobecquerel (10 uCi) each;

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

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

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

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

(ii) the location of use; and

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

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

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

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

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

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

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

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

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

(i) Except as prepackaged units which are labeled in accordance with the provision of a specific license issued pursuant to R313-22-75(7) or in accordance with the provisions of a specific license issued by the Nuclear Regulatory Commission, or an

Agreement State, or before November 30, 2007, in accordance with the provisions of a specific license issued by a State with comparable provisions to 10 CFR 32.71 (2010) which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under Subsection R313-21-22(9) or its equivalent, and

(ii) Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

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

.....
Name of Manufacturer"

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

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

(10) Ice Detection Devices.

(a) A general license is hereby issued to own, receive, acquire, possess, use and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 1.85 megabecquerel (50 uCi) of strontium-90 and each device has been manufactured or initially transferred in accordance with a specific license issued by the Nuclear Regulatory Commission, or each device has been manufactured in accordance with the specifications contained in a specific license issued by the Director, an Agreement State, or a Licensing State to the manufacturer of the device pursuant to licensing requirements equivalent to those in 10 CFR 32.61.

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

(i) shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from over-heating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the Director, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State to manufacture or service the device; or shall dispose of the device pursuant to the provisions of Section R313-15-1001;

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

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

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

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

KEY: radioactive materials, general licenses, source materials

Date of Enactment or Last Substantive Amendment: [~~October 13, 2010~~2015]

Notice of Continuation: October 4, 2013

Authorizing, and Implemented or Interpreted Law: 19-3-104

Environmental Quality, Radiation Control **R313-22** Specific Licenses

NOTICE OF PROPOSED RULE

(Amendment)

DAR FILE NO.: 39279

FILED: 04/14/2015

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: The State of Utah entered into an agreement with the U.S. Nuclear Regulatory Commission (NRC) to establish and maintain a compatible program for the control of radioactive material in Utah. To maintain compatibility with NRC requirements, the State of Utah is required to modify the Utah Radiation Control Rules in order to incorporate the appropriate regulations published by the NRC in 77 FR 43666.

SUMMARY OF THE RULE OR CHANGE: This rulemaking addresses the adoption of appropriate requirements found in 79 FR 43666. This rule change amends regulations in Rule R313-22 to make requirements for distributors of radioactive material clearer, less prescriptive, and more risk-informed and up to date. This amendment also redefines categories of devices to be used under exemptions, adding explicit provisions regarding the sealed source and device registration process, and adding flexibility to the licensing of users of sealed sources and devices. This amendment is primarily intended to make the licensing process more efficient and effective.

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 is no anticipated cost or savings to the state budget. The proposed changes do not add or remove significant requirements that affect radiation. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause the state budget to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

◆ **LOCAL GOVERNMENTS:** There is no anticipated cost or savings to the local government. The proposed changes do not add or remove significant requirements that affect radiation. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause local government to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

◆ **SMALL BUSINESSES:** Small businesses may hold a radioactive material license, but there is no anticipated cost or savings for small businesses. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause small businesses to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

◆ **PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES:** Small businesses and persons other than businesses may hold a radioactive material license, but there is no anticipated cost or savings for small businesses and persons other than businesses. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause local government to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

COMPLIANCE COSTS FOR AFFECTED PERSONS: There are no anticipated costs for affected persons since the proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause affected persons to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: The proposed changes to the rule are necessary for the Utah Radiation Control Rules to be compatible with NRC requirements, and to ensure that the Division's program activities are adequate to protect the public health and safety.

The Division is not aware of any business that would be impacted fiscally due to the proposed rule changes.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:

ENVIRONMENTAL QUALITY
RADIATION CONTROL
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:

♦ Spencer Wickham by phone at 801-536-0082, by FAX at 801-533-4097, or by Internet E-mail at swickham@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 06/01/2015

THIS RULE MAY BECOME EFFECTIVE ON: 06/16/2015

AUTHORIZED BY: Rusty Lundberg, Director

R313. Environmental Quality, Radiation Control.

R313-22. Specific Licenses.

R313-22-32. Filing Application for Specific Licenses.

(1) Applications for specific licenses shall be filed on a form prescribed by the Director.

(2) The Director may, after the filing of the original application, and before the expiration of the license, require further statements in order to enable the 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 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.~~

_____ (6)(i) Except as provided in paragraphs (g)(2), (3), and (4) of this section, an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either--

_____ (A) Identify the source or device by manufacturer and model number as registered with the sealed source and device registry under R313-22-210; or

_____ (B) Contain the information identified in R313-22-210.

_____ (ii) For sources or devices manufactured before October 23, 2012 that are not registered with sealed source and device registry under R313-22-210 and for which the applicant is unable to provide all categories of information specified in R313-22-210, the application must include:

_____ (A) All available information identified in R313-22-210 concerning the source, and, if applicable, the device; and

_____ (B) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

_____ (iii) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 CFR 32.210(g)(1) (2015), the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

_____ (iv) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

(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 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 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 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 Director. The licensee shall provide any comments received within the 60 days to the Director with the emergency plan.

(9) An application from a medical facility, educational institution, or Federal facility to produce Positron Emission 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.

R313-22-75. 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:

(iii) the device has been registered in the Sealed Source and Device Registry.

(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:

.....

(iii) each device bears a durable, legible, clearly visible label or labels approved by the 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 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 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 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 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 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)~~](2015) 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)~~](2015), 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~~]2015 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 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 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] the source or device has been registered in the Sealed Source and Device Registry.~~

(e) 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)](f)~~ in determining the acceptable interval for test of leakage of radioactive material, the 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 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 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 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 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).

R313-22-210. 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)~~](2015) or equivalent regulations of an Agreement State.

R313-22-211. Inactivation of Certificates of Registration of Sealed Sources and Devices.

Licensees who no longer manufacture or initially transfer any of the sealed sources or devices covered by a particular certificate issued in accordance with the requirements of R313-22-210 shall request inactivation of the registration certificate in accordance with 10 CFR 32.211 (2015) or equivalent regulations of an Agreement State.

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

Date of Enactment or Last Substantive Amendment: [~~October 21, 2014~~]**2015**

Notice of Continuation: September 23, 2011

Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-3-108

**Environmental Quality, Radiation
Control
R313-24-4
Clarifications or Exceptions**

**NOTICE OF PROPOSED RULE
(Amendment)**

DAR FILE NO.: 39275
FILED: 04/14/2015

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: This filing changes the uranium mills and source material mill tailings disposal facility requirements.

SUMMARY OF THE RULE OR CHANGE: The proposed changes to Section R313-24-4 would: update the incorporation of the outdated 2002 version of Title 10, Code of Federal Regulations (CFR) Part 40, with the current 2015 version of 10 CFR 40.

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: 10 CFR 40 and Section 19-3-104 and Section 19-3-108

ANTICIPATED COST OR SAVINGS TO:

♦ **THE STATE BUDGET:** There is no anticipated cost or savings to the state budget. The proposed changes do not add or remove significant requirements that affect radiation. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause the state budget to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

♦ **LOCAL GOVERNMENTS:** There is no anticipated cost or savings to the local government. The proposed changes do not add or remove significant requirements that affect radiation. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause local government to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

♦ **SMALL BUSINESSES:** Small businesses may hold a radioactive material license, but there is no anticipated cost or savings for small businesses. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause small businesses to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

♦ **PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES:** Small businesses and persons other than businesses may hold a radioactive material license, but there is no anticipated cost or savings for small businesses and persons other than businesses. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause local government to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

COMPLIANCE COSTS FOR AFFECTED PERSONS: There are no anticipated costs for affected persons since the proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause affected persons to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: The proposed changes to the rule are necessary for the Utah Radiation Control Rules to be compatible with NRC requirements, and to ensure that the Division's program activities are adequate to protect the public health and safety. The Division is not aware of any business that would be impacted fiscally due to the proposed rule changes.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED,
DURING REGULAR BUSINESS HOURS, AT:

ENVIRONMENTAL QUALITY
RADIATION CONTROL
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:

◆ Spencer Wickham by phone at 801-536-0082, by FAX at 801-533-4097, or by Internet E-mail at swickham@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON
THIS RULE BY SUBMITTING WRITTEN COMMENTS NO
LATER THAN AT 5:00 PM ON 06/01/2015

THIS RULE MAY BECOME EFFECTIVE ON: 06/16/2015

AUTHORIZED BY: Rusty Lundberg, Director

R313. Environmental Quality, Radiation Control.

R313-24. Uranium Mills and Source Material Mill Tailings Disposal Facility Requirements.

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_(20[02]15) 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) "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) "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) "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) "Director" for reference to "Commission" in the definition of "closure plan", in paragraph five of the introduction, and in Criteria 6(2), 6(4), 6(6), 6A(2), 6A(3), 9, and 10 of Appendix A;

(v) "license issued by the Director" for reference to "Commission license" in the definition of "licensed site," in the introduction to Appendix A;

(vi) "Director" for reference to "NRC" in Criterion 4D;

(vii) "representatives of the Director" for reference to "NRC staff" in Criterion 6(6);

(viii) "Director-approved" for reference to "Commission-approved" in Criterion 6A(1) and Criterion 9;

(ix) "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) "Director" for reference to "the Commission or the State regulatory agency" in Criterion 9, paragraph 2.

KEY: environmental analysis, uranium mills, tailings, byproduct material

Date of Enactment or Last Substantive Amendment: ~~March 19, 2013~~ 2015

Notice of Continuation: May 24, 2012

Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-3-108

**Environmental Quality, Radiation
Control
R313-27
Medical Use Advisory Committee**

NOTICE OF PROPOSED RULE

(New Rule)
DAR FILE NO.: 39283
FILED: 04/15/2015

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: Creation of a new Medical Use Advisory Committee will ensure that, before initiating rulemaking relating to the medical use of radiation, the Radiation Control Board and its successor the Waste Management and Radiation Control Board will have appropriate technical advice from individuals representing areas of medical use affected by the rulemaking action.

SUMMARY OF THE RULE OR CHANGE: The proposed rule would require the board to create a new Medical Use Advisory Committee that will provide recommendations to the board before the board takes action on any rule or other policy matter that affects the medical use of radiation. The proposed rule adds this procedural step but does not in any other way change the board's authority to make a rule. There is an exception in the proposed rule for emergency rulemaking.

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Section 19-3-103.5 and Subsection 19-3-104(4)

ANTICIPATED COST OR SAVINGS TO:

- ◆ **THE STATE BUDGET:** Any costs would be insignificant and will be managed within existing budgets.
- ◆ **LOCAL GOVERNMENTS:** The proposed rule does not govern or regulate local government in any way, so there will be no impact on local government.
- ◆ **SMALL BUSINESSES:** The proposed rule does not govern or regulate small business in any way, so there will be no impact on small business.
- ◆ **PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES:** The proposed rule does not govern or regulate other persons in any way, so there will be no impact on other persons.

COMPLIANCE COSTS FOR AFFECTED PERSONS: The proposed rule does not impose any compliance requirements on any person, so there will be no compliance costs for any person.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: The proposed rule does not govern or regulate any business in any way, so there will be no impact on businesses.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:
ENVIRONMENTAL QUALITY
RADIATION CONTROL
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:

- ◆ Laura Lockhart by phone at 801-536-0283, by FAX at 801-366-0292, or by Internet E-mail at llockhart@utah.gov
- ◆ Philip Griffin by phone at 801-536-4261, by FAX at 801-533-4097, or by Internet E-mail at pgriffin@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 06/01/2015

THIS RULE MAY BECOME EFFECTIVE ON: 06/09/2015

AUTHORIZED BY: Amanda Smith, Executive Director

**R313. Environmental Quality, Radiation Control.
R313-27. Medical Use Advisory Committee.
R313-27-1. Formation and Role of Medical Use Advisory Committee.**

(1) The board shall appoint a Medical Use Advisory Committee to review and make recommendations prior to a board action for any rule or other policy matter that affects the medical use of radiation. Committee members shall be appointed after considering recommendations from affected groups or individuals.

(2) The Medical Use Advisory Committee shall consist of at least three members, with the majority of members from an area of medical use affected by the rulemaking action.

(3) Members may include non-physician professionals if the member's professional credentials are applicable to the scope of the matter being considered.

(4) Members may include board members.

(5) The Medical Use Advisory Committee shall, by majority vote, provide recommendations and, as appropriate, suggested rule language to the board. Minority recommendations and suggested rule language, if any, shall also be provided to the board.

(6) This rule shall not apply to emergency rulemaking under Section 63G-3-304.

**KEY: medical use advisory committee, medical use of radiation
Date of Enactment or Last Substantive Amendment: 2015
Authorizing, and Implemented or Interpreted Law: 19-3-103.5;
19-3-104(4)**

**Environmental Quality, Radiation
Control
R313-36-3
Clarifications or Exceptions**

NOTICE OF PROPOSED RULE

(Amendment)

DAR FILE NO.: 39276

FILED: 04/14/2015

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: This filing changes the requirements for industrial radiographic operations.

SUMMARY OF THE RULE OR CHANGE: The proposed changes to Section R313-36-3 would: update the incorporation of the outdated 2011 version of Title 10, Code of Federal Regulations (CFR) Part 34, with the current 2015 version of 10 CFR 34.

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: 10 CFR 34 and Section 19-3-104 and Section 19-3-108

ANTICIPATED COST OR SAVINGS TO:

◆ **THE STATE BUDGET:** There is no anticipated cost or savings to the state budget. The proposed changes do not add or remove significant requirements that affect radiation. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause the state budget to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

◆ **LOCAL GOVERNMENTS:** There is no anticipated cost or savings to the local government. The proposed changes do not add or remove significant requirements that affect radiation. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause local government to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

◆ **SMALL BUSINESSES:** Small businesses may hold a radioactive material license, but there is no anticipated cost or savings for small businesses. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause small businesses to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

◆ **PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES:** Small businesses and persons other than businesses may hold a radioactive material license, but there is no anticipated

cost or savings for small businesses and persons other than businesses. The proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause local government to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

COMPLIANCE COSTS FOR AFFECTED PERSONS: There are no anticipated costs for affected persons since the proposed rule changes are adopting required federal regulations to maintain compatibility as an agreement state. These changes do not add new requirements that would cause affected persons to incur any changes in compliance costs beyond those identified by the Nuclear Regulatory Commission.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: The proposed changes to the rule are necessary for the Utah Radiation Control Rules to be compatible with NRC requirements, and to ensure that the Division's program activities are adequate to protect the public health and safety. The Division is not aware of any business that would be impacted fiscally due to the proposed rule changes.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:

ENVIRONMENTAL QUALITY
RADIATION CONTROL
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:

◆ Spencer Wickham by phone at 801-536-0082, by FAX at 801-533-4097, or by Internet E-mail at swickham@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 06/01/2015

THIS RULE MAY BECOME EFFECTIVE ON: 06/16/2015

AUTHORIZED BY: Rusty Lundberg, Director

R313. Environmental Quality, Radiation Control.

R313-36. Special Requirements for Industrial Radiographic Operations.

R313-36-3. Clarifications or Exceptions.

For purposes of R313-36, 10 CFR 34.3; 34.13; 34.20(a)(1); 34.20(b) through 34.41(b); 34.42(a) through 34.42(c); 34.43(a)(1); 34.43(b) through 34.45(a)(8); 34.45(a)(10) through 34.101 (20[+][15]), are incorporated by reference with the following clarifications or exceptions:

- (1) The exclusion of the following:
- (a) In 10 CFR 34.3, exclude definitions for "Lay-barge radiography," "Offshore platform radiography," and "Underwater radiography";
 - (b) In 10 CFR 34.27(d), exclude "A copy of the report must be sent to the Administrator of the appropriate Nuclear Regulatory Commission's Regional Office listed in appendix D of 10 CFR part 20 of this chapter "Standards for Protection Against Radiation."; and
 - (c) In 10 CFR 34.27(e), exclude "Licensees will have until June 27, 1998, to comply with the DU leak-testing requirements of this paragraph."
- (2) The substitution of the following wording:
- (a) "radioactive materials" for references to "byproduct materials";
 - (b) "Utah Radiation Control Rules" for references to:
 - (i) "Commission's regulations";
 - (ii) "Federal regulations";
 - (iii) "NRC regulations"; and
 - (iv) "Commission regulations.";
 - (c) "Director" for references to:
 - (i) "Commission";
 - (ii) "appropriate NRC regional office listed in Section 30.6(a)(2)";
 - (iii) "Director, Office of Federal and State Materials and Environmental Management Programs" except as used in 10 CFR 34.43(a)(1); and
 - (iv) "NRC's Office of Federal and State Materials and Environmental Management Programs";
 - (d) "Director, the U.S. Nuclear Regulatory Commission, or an Agreement State" for references to:
 - (i) "NRC or an Agreement State"; and
 - (ii) "Commission or an Agreement State";
 - (e) "Director, the U.S. Nuclear Regulatory Commission, or by an Agreement State" for references to "Commission or by an Agreement State";
 - (f) "License(s)" for references to "NRC license(s)";
 - (g) "NRC or Agreement State License" for references to "Agreement State license"; and
 - (h) "the Utah Radiation Control Rules" for references to "this chapter, such as Section 21.21."
- (3) The substitution of the following rule references:
- (a) In 10 CFR 34.51, "R313-12" for references to "10 CFR part 20 of this chapter";
 - (b) "R313-15" for references to "10 CFR part 20" and "10 CFR part 20 of this chapter" except as found in 10 CFR 34.51;
 - (c) "R313-15-601(1)(a)" for references to "Section 20.1601(a)(1) of this chapter";
 - (d) "R313-15-902(1) and (2)" for references to "10 CFR 20.1902(a) and (b) of this chapter";
 - (e) "R313-15-903" for references to "Section 20.1903 of this chapter";
 - (f) "R313-15-1203" for references to "10 CFR 20.2203" and "Section 20.2203 of this chapter";
 - (g) "R313-12-110" for references to "Section 30.6(a) of this chapter" except as used in 10 CFR 34.43(a)(1);
 - (h) "R313-19-30" for references to "Section 150.20 of this chapter";
 - (i) "R313-19-50" for references to "Section 30.50";

- (j) "R313-19-100" for references to "10 CFR part 71", and "49 CFR parts 171 - 173";
- (k) "R313-22-33" for references to "Section 30.33 of this chapter";
- (l) "R313-36" for references to "NRC regulations contained in this part";
- (m) "R313-19-100(5)" for references to "Section 71.5 of this chapter"
- (n) "R313-19-5" for references to "Sections 30.7, 30.9, and 30.10 of this chapter."

KEY: industry, radioactive material, licensing, surveys**Date of Enactment or Last Substantive Amendment: ~~January 16, 2012~~ 2015****Notice of Continuation: September 23, 2011****Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-3-108**

SUPERSEDES PREVIOUS VERSION

**UTAH RADIATION CONTROL BOARD
BOARD ACTION ITEM
June 9, 2015**

**PROPOSED RULE AMENDMENTS – FINAL ADOPTION
for**

R313-12-3, GENERAL PROVISIONS, DEFINITIONS

**CHANGE IN PROPOSED RULE
for**

**R313-19-13, REQUIREMENTS OF GENERAL
APPLICABILITY TO LICENSING OF
RADIOACTIVE MATERIAL, EXEMPTIONS**

**R313-21-22, GENERAL LICENSES, GENERAL
LICENSES*--RADIOACTIVE MATERIAL
OTHER THAN SOURCE MATERIAL**

**R313-22-32, SPECIFIC LICENSES, FILING
APPLICATION FOR SPECIFIC LICENSES**

Background

On July 25, 2012, the Nuclear Regulatory Commission (NRC) promulgated revisions to selected portions of the federal radiation control regulations found in Title 10 Code of Federal Regulations (10 CFR). All Agreement States (including Utah) are required to maintain rules compatible with NRC regulations. As a means to assist Agreement States in preparing and performing the necessary rulemaking changes, the NRC prepares a compatibility action table (RATS ID 2012-4) that lists each change and its corresponding compatibility category.

The NRC notified the Utah Division of Radiation Control (DRC) that the revised regulations need to be adopted by Agreement States before October 23, 2015. The DRC proposes to revise the existing rules by incorporating the federal rules found in 10 CFR Parts 30, 31, 32, 40, and 70 and as published in the July 25, 2012 Federal Register (77 FR 43666).

During the April 14, 2015, Board meeting, Notice of Proposed Rule Amendments for Sections R313-12-3, R313-19-13, R313-21-22, and R313-22-32 were discussed. The Board approved the proposed changes and directed staff to file the proposed changes with the Division of Administrative Rules for publication in the Utah State Bulletin. A thirty day public comment period began on May 01, 2015. The Director received no comments from the public during the comment period.

After the formal comment period ended, the Division received comments that raised

compatibility issues pertaining to some citations for the proposed rules. To resolve the comments, changes to the proposed rules (R313-19-13, R313-21-22, and R313-22-32) are required to meet Compatibility Requirements. The filing of a change in Proposed Rule is the appropriate mechanism to address the comments.

Recommendation

The Director recommends that the Board approve the proposed changes as published in the May 01, 2015, issue of the Utah State Bulletin and set an effective date of June 16, 2015, for the rule amendments to R313-12-3.

The Director recommends that the Board approve the filing of the Change in Proposed Rule to R313-19-13, R313-21-22 and R313-22-32 with the Division of Administrative rules. The proposed changes will be published in the July 01, 2015, issue of the *Utah State Bulletin* notifying interested stake holders of the approved changes and setting an effective date of August 7, 2015.

R313. Environmental Quality, Radiation Control.

R313-19. Requirements of General Applicability to Licensing of Radioactive Material.

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 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)(I) Static elimination devices which contain, as sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 uCi) of polonium-210 per device.~~

~~(II) Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 uCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.~~

~~(III) Such devices authorized before October 23, 2012 for use under the general license then provided in [\[R313-21-22\(1\)\(a\)\] 10 CFR 31.3 \(January 1, 2012\)](#) or equivalent regulations of the Commission or an Agreement State and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Commission or Agreement State.~~

~~(B)(C) Precision balances containing not more than one millicurie (37.0 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part manufactured before June 9, 2010.~~

~~(C)(D) 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)(E) 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)(F) 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)(G) 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)(G), 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.~~

~~(A) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, and except as provided in R313-19-13(2)(c)(ii)(C), any person is exempt from the requirements for a license set forth in Section 274 b. of the Atomic Energy Act of 1954 and from the regulations in R313-15, R313-19, R313-32, R313-34, R313-36, R313-37, and R313-38 to the extent that such a person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, produced, or initially transferred in accordance with a specific license issued pursuant to 10 CFR 32.22 (2015), which license authorizes the initial transfer of the product for use.~~

~~(B) Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under R313-19-13(2)(c)(ii)(A), should apply for a license under 10 CFR 32.22 (2015) and for a certificate of registration in accordance with 10 CFR 32.210 (2015).~~

~~(C) The exemption in R313-19-13(2)(c)(ii)(A) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.~~

~~(B)~~(D) 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.~~

(A) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from the requirements for a license set forth in Section 274 b. of the Atomic Energy Act of 1954 and from the regulations in parts R313-18, R313-15, R313-19, R313-21, R313-22, R313-32, R313-34, R313-36, R313-37, and R313-38 to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect health, safety, or property, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CFR 32.26 (2015), which license authorizes the initial transfer of the product for use under this section. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by a State under comparable provisions to 10 CFR 32.26 (2015) authorizing distribution to persons exempt from regulatory requirements.

(B) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use under paragraph (a) of this section, should apply for a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 32.26 (2015) and for a certificate of registration in accordance with R313-22-210 or equivalent regulations of an Agreement State.

(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) Certain industrial devices.

(A) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license set forth in Section 274 b. of the Atomic Energy Act of 1954 and from the regulations in parts R313-18, R313-15, R313-18, R313-15, R313-19, R313-21, R313-22, R313-32, R313-34, R313-36, R313-37, and R313-38 to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CFR 32.30 (2015), which license authorizes the initial transfer of the device for use under this rule. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

(B) Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under R313-19-13(2)(c)(v)(A), should apply for a license under 10 CFR 32.30 (2015) and for a certificate of registration in accordance with R313-22-210.

~~(vi)~~(vi) With respect to Subsections R313-19-13(2)(b)(iii), R313-19-13(2)(c)(i), (iii) and (iv), the authority to transfer possession or control by the manufacturer, processor, or producer of equipment, devices, commodities, or other products containing byproduct material whose subsequent possession, use, transfer, and disposal by other persons is exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

KEY: license, reciprocity, transportation, exemptions

Date of Enactment or Last Substantive Amendment: ~~February 17,~~ 2015

Notice of Continuation: September 23, 2011

Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-3-108

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R313. Environmental Quality, Radiation Control.

R313-21. General Licenses.

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

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

(1) ~~[Certain devices and equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the Director, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State for use pursuant to 10 CFR 31.3. This general license is subject to the provisions of R313-12-51 through R313-12-70, R313-14, R313-15, R313-18 and R313-19 as applicable.]RESERVED.~~

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

~~—(b) Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 megabecquerel (500 uCi) of polonium-210 per device or a total of not more than 1.85 gigabecquerel (50 mCi) of hydrogen-3 (tritium) per device.]~~

(2) Certain items and self-luminous products containing radium-226.

(a) A general license is hereby issued to a person to acquire, receive, possess, use, or transfer, in accordance with the provisions of Subsections R313-21-22(2)(b), R313-21-22(2)(c), and R313-21-22(2)(d), radium-226 contained in the following products manufactured prior to November 30, 2007.

(i) Antiquities originally intended for use by the general public. For the purposes of Subsection R313-21-22(2)(a), antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

(ii) Intact timepieces containing greater than 37 kilobecquerels (1 uCi), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

(iii) Luminous items installed in air, marine, or land vehicles.

(iv) All other luminous products provided that no more than 100 items are used or stored at the same location at one time.

(v) Small radium sources containing no more than 37 kilobecquerels (1 uCi) of radium-226. For the purposes of Subsection R313-21-22(2)(a), "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations such as cloud chambers and spinthariscopes, electron tubes, static eliminators, or as designated by the Director.

(b) Persons who acquire, receive, possess, use, or transfer radioactive material under the general license issued in Subsection R313-21-22(2)(a) are exempt from the provisions of Rules R313-15, R313-18, and Sections R313-12-51 and R313-19-50, to the extent that the receipt, possession, use, or transfers of radioactive material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to a person specifically licensed under Rule R313-22.

(c) A person who acquires, receives, possesses, uses, or transfers radioactive material in accordance with the general license in Subsection R313-21-22(2)(a):

(i) Shall notify the Director should there be an indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Director within 30 days.

(ii) Shall not abandon products containing radium-226. The product, and radioactive material from the product, may only be disposed of according to Section R313-15-1008 or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the Director.

(iii) Shall not export products containing radium-226 except in accordance with 10 CFR Part 110.

(iv) Shall dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with Federal or State solid or hazardous waste laws, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 under Rule R313-22 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State or as otherwise approved by the Director.

(v) Shall respond to written requests from the Director to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Director a written justification using the method stated in Section R313-12-110.

(d) The general license in R313-21-22(2)(a) does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

(3) RESERVED.

(4) Certain detecting, measuring, gauging or controlling devices and certain devices for producing light or an ionized atmosphere.*

NOTE: *Persons possessing radioactive material in devices under a general license in R313-21-22(4) before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of R313-21-22(4) in effect on January 14, 1975.

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

(b)(i) The general license in R313-21-22(4)(a) applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in:

- (A) a specific license issued by the Director pursuant to R313-22-75(4); or
- (B) an equivalent specific license issued by the Nuclear Regulatory Commission or an Agreement State; or
- (C) An equivalent specific license issued by a State with provisions comparable to R313-22-75.*

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

(ii) The devices must have been received from one of the specific licensees described in R313-21-22(4)(b)(i) or through a transfer made under R313-21-22(4)(c)(ix).

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

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

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

- (A) Devices containing only krypton need not be tested for leakage of radioactive material, and
- (B) Devices containing only tritium or not more than 3.7 megabecquerel (100 uCi) of other beta, gamma, or both, emitting material or 0.37 megabecquerel (10 uCi) of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(iii) shall assure that other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

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

(B) by a person holding a specific license pursuant to R313-22 or from the Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform such activities;

(iv) shall maintain records showing compliance with the requirements of R313-21-22(4)(c)(ii) and (iii). The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from the installation the radioactive material and its shielding or containment. The licensee shall retain these records as follows:

(A) Each record of a test for leakage of radioactive material required by R313-21-22(4)(c)(ii) shall be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of;

(B) Each record of a test of the on-off mechanism and indicator required by R313-21-22(4)(c)(ii) shall be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of;

(C) Each record that is required by R313-21-22(4)(c)(iii) shall be retained for three years from the date of the recorded event or until the device is transferred or disposed of;

(v) shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 185 becquerel (0.005 uCi) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair the device that was issued by the Director, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the Director, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 185 becquerel (0.005 uCi) or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the Director within 30 days. Under these circumstances, the criteria set out in R313-15-402 may be applicable, as determined by the Director on a case-by-case basis;

(vi) shall not abandon the device containing radioactive material;

(vii) shall not export the device containing radioactive materials except in accordance with 10 CFR 110;

(viii)(A) shall transfer or dispose of the device containing radioactive material only by export as provided by R313-21-22(4)(c)(vii), by transfer to another general licensee as authorized in R313-21-22(4)(c)(ix), to a person authorized to receive the device by a specific license issued under R313-22, to an authorized waste collector under R313-25, or equivalent regulations of the Nuclear Regulatory Commission, an Agreement State, or a Licensing State, or as otherwise approved under R313-21-22(4)(c)(viii)(C);

(B) shall furnish a report to the Director within 30 days after transfer of a device to a specific licensee or export. The report must contain:

(I) the identification of the device by manufacturer's or initial transferor's name, model number, and serial number;
(II) the name, address, and license number of the person receiving the device, the license number is not applicable if exported; and

(III) the date of the transfer;

(C) shall obtain written approval from the Director before transferring the device to any other specific licensee not specifically identified in R313-21-22(4)(c)(viii)(A); however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if the holder:

(I) verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(II) removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by R313-21-22(4)(c)(i)) so that the device is labeled in compliance with R313-15-904; however, the manufacturer, model number, and serial number must be retained;

(III) obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and

(IV) reports the transfer under R313-21-22(4)(c)(viii)(B);

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

(A) the device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of R313-21-22(4), R313-12-51, R313-15-1201, and R313-15-1202, and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to the Director:

(I) the manufacturer's or initial transferor's name;

(II) the model number and serial number of the device transferred;

(III) the transferee's name and mailing address for the location of use; and

(IV) the name, title, and phone number of the responsible individual identified by the transferee in accordance with R313-21-22(4)(c)(xii) to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

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

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

(xi) shall respond to written requests from the Director to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by submitting a letter to the Director and provide written justification as to why it cannot comply;

(xii) shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard;

(xiii)(A) shall register, in accordance with R313-21-22(4)(c)(xiii)(B) and (C), devices containing at least 370 megabecquerel (ten mCi) of cesium-137, 3.7 megabecquerel (0.1 mCi) of strontium-90, 37 megabecquerel (one mCi) of cobalt-60, 3.7 megabecquerel (0.1 mCi) of radium-226, or 37 megabecquerel (one mCi) of americium-241 or any other transuranic, (elements with atomic number greater than uranium-92), based on the activity indicated on the label. Each address for a location of use, as described under R313-21-22(4)(c)(xiii)(C)(IV) represents a separate general licensee and requires a separate registration and fee;

(B) if in possession of a device meeting the criteria of R313-21-22(4)(c)(xiii)(A), shall register these devices annually with the Director and shall pay the fee required by R313-70. Registration shall include verifying, correcting, or adding, as appropriate, to the information provided in a request for registration received from the Director. The registration information must be submitted to the Director within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of R313-21-22(4)(c)(xiii)(A) is subject to the bankruptcy notification requirement in R313-19-34(5) and (6);

(C) in registering devices, the general licensee shall furnish the following information and any other information specifically requested by the Director:

(I) name and mailing address of the general licensee;

(II) information about each device: the manufacturer or initial transferor, model number, serial number, the radioisotope and activity as indicated on the label;

(III) name, title, and telephone number of the responsible person designated as a representative of the general licensee under R313-21-22(4)(c)(xii);

(IV) address or location at which the device(s) are used, stored, or both. For portable devices, the address of the primary place of storage;

(V) certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information; and

(VI) certification by the responsible representative of the general licensee that they are aware of the requirements of the general license; and

(D) persons generally licensed by the Nuclear Regulatory Commission, an Agreement State, or Licensing State with respect to devices meeting the criteria in R313-21-22(4)(c)(xiii)(A) are not subject to registration requirements if the devices are used in areas subject to Division jurisdiction for a period less than 180 days in any calendar year. The Director will not request registration information from such licensees;

(xiv) shall report changes to the mailing address for the location of use, including changes in the name of a general licensee, to the Director within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage; and

(xv) may not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by R313-21-22(4)(c)(ii) need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

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

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

(5) Luminous safety devices for aircraft.

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

(i) each device contains not more than 370.0 gigabecquerel (10 Ci) of tritium or 11.1 gigabecquerel (300 mCi) of promethium-147; and

(ii) each device has been manufactured, assembled or initially transferred in accordance with a specific license issued by the Nuclear Regulatory Commission or an Agreement State, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the Director or an Agreement State to the manufacturer or assembler of the device pursuant to licensing requirements equivalent to those in R313-22-75(5).

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

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

(d) This general license does not authorize the export of luminous safety devices containing tritium or promethium-147.

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

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

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

(7) Calibration and reference sources.

(a) A general license is hereby issued to own, receive, acquire, possess, use and transfer, in the form of calibration or reference sources, americium-241, plutonium or radium-226 in accordance with the provisions of Subsections R313-21-22(7)(b) and (c), to a person who holds a specific license issued by the Director which authorizes that person to receive, possess, use and transfer radioactive material.

(b) The general license in Subsection R313-21-22(7)(a) applies only to calibration or reference sources which have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued by the Nuclear Regulatory Commission pursuant to 10 CFR 32.57 or 10 CFR 70.39 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Director, or an Agreement State which authorizes manufacture of the sources for distribution to persons generally licensed, or in accordance with a specific license issued by a State with requirements equivalent to 10 CFR 32.57 or 10 CFR 70.39.

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

(i) shall not possess at any one time, at any one location of storage or use, more than 185.0 kilobecquerel (5 uCi) of americium-241, 185.0 kilobecquerel (5 uCi) of plutonium, or 185.0 kilobecquerel (5 uCi) of radium-226 in such sources;

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

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

CAUTION - RADIOACTIVE MATERIAL

THIS SOURCE CONTAINS (AMERICIUM-241)(PLUTONIUM)(RADIUM-226)*

DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

.....

Typed or printed name of the manufacturer or initial transferor

NOTE: *Show the name of the appropriate material.

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

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

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

(d) A general license issued pursuant to Subsection R313-21-22(7)(a) does not authorize the manufacture, import, or export of calibration or reference sources containing americium-241, plutonium, or radium-226.

(8) RESERVED.

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

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

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

(i) iodine-125, in units not exceeding 370.0 kilobecquerel (10 uCi) each;

(ii) iodine-131, in units not exceeding 370.0 kilobecquerel (10 uCi) each;

(iii) carbon-14, in units not exceeding 370.0 kilobecquerel (10 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 370.0 kilobecquerel (10 uCi) each;

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

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

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

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

(ii) the location of use; and

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

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

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

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

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

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

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

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

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

(i) Except as prepackaged units which are labeled in accordance with the provision of a specific license issued pursuant to R313-22-75(7) or in accordance with the provisions of a specific license issued by the Nuclear Regulatory Commission, or an Agreement State, or before November 30, 2007, in accordance with the provisions of a specific license issued by a State with comparable provisions to 10 CFR 32.71 (2010) which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3(tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under Subsection R313-21-22(9) or its equivalent, and

(ii) Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

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

.....
Name of Manufacturer"

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

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

(10) Ice Detection Devices.

(a) A general license is hereby issued to own, receive, acquire, possess, use and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 1.85 megabecquerel (50 uCi) of strontium-90 and each device has been manufactured or initially transferred in accordance with a specific license issued by the Nuclear Regulatory Commission, or each device has been manufactured in accordance with the specifications contained in a specific license issued by the Director, an Agreement State, or a Licensing State to the manufacturer of the device pursuant to licensing requirements equivalent to those in 10 CFR 32.61.

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

(i) shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from over-heating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the Director, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State to manufacture or service the device; or shall dispose of the device pursuant to the provisions of Section R313-15-1001;

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

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

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

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

KEY: radioactive materials, general licenses, source materials

Date of Enactment or Last Substantive Amendment: ~~October 13, 2010~~2015

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R313. Environmental Quality, Radiation Control.

R313-22. Specific Licenses.

R313-22-32. Filing Application for Specific Licenses.

- (1) Applications for specific licenses shall be filed on a form prescribed by the Director.
- (2) The Director may, after the filing of the original application, and before the expiration of the license, require further statements in order to enable the 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 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.~~
- ~~(6)(i) Except as provided in ~~paragraphs (g)(2), (3), and (4)~~ R313-22-32 (6)(ii), (iii) or (iv) of this section, an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either---~~
 - ~~(A) Identify the source or device by manufacturer and model number as registered with the sealed source and device registry under R313-22-210; or~~
 - ~~(B) Contain the information identified in R313-22-210.~~
- ~~(ii) For sources or devices manufactured before October 23, 2012 that are not registered with sealed source and device registry under R313-22-210 and for which the applicant is unable to provide all categories of information specified in R313-22-210, the application must include:~~
 - ~~(A) All available information identified in R313-22-210 concerning the source, and, if applicable, the device; and~~
 - ~~(B) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.~~
- ~~(iii) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 CFR 32.210(g)(1) (2015), the applicant may supply only the manufacturer, model number, and radionuclide and quantity.~~
- ~~(iv) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.~~
- (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 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 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 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 Director. The licensee shall provide any comments received within the 60 days to the Director with the emergency plan.

(9) An application from a medical facility, educational institution, or Federal facility to produce Positron Emission 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.

R313-22-75. 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:

(iii) the device has been registered in the Sealed Source and Device Registry.

(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:

.....

(iii) each device bears a durable, legible, clearly visible label or labels approved by the 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 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 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 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 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 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 32.401 (2010)~~](2015) 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, [~~32.402~~] and 10 CFR 70.39 [~~(2010)~~](2015), 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~~](2015) 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 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 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]the source or device has been registered in the Sealed Source and Device Registry.~~

~~(e) 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~~

~~(f)~~ in determining the acceptable interval for test of leakage of radioactive material, the 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 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 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 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 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).

R313-22-210. 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)~~(2015) or equivalent regulations of an Agreement State.

R313-22-211. Inactivation of Certificates of Registration of Sealed Sources and Devices.

Licensees who no longer manufacture or initially transfer any of the sealed sources or devices covered by a particular certificate issued in accordance with the requirements of R313-22-210 shall request inactivation of the registration certificate in accordance with 10 CFR 32.211 (2015) or equivalent regulations of an Agreement State.

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

Date of Enactment or Last Substantive Amendment: [~~October 21, 2014~~2015

Notice of Continuation: September 23, 2011

Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-3-108

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MEETING NOTICE INFORMATION

Project Manager: Stephen Dembek

Is Bridgeline Information (phone number/passcode) to be in meeting notice? Yes (See below)

Meeting Title: Public Meeting on Proposed 10 CFR Part 61 Rulemaking

Purpose: The purpose of the meeting is to initiate a discussion on this technical rulemaking, answer questions and solicit comments from the public, and encourage the submittal of formal comments from stakeholders.

Date(s) and Time(s): June 10, 2015, 6:00 pm – 9:00 pm

Location: Hilton Garden Inn Salt Lake City Downtown, 250 West 600 South, Salt Lake City, UT 84101, Tel: 801-364-5200

Category 3

Bridgeline: 1- 888-469-5450

Participant passcode: 4779467

Participants: Andrew Persinko, Christopher McKenney, David Esh, Stephen Dembek, and Chip Cameron (facilitator)

Docket Numbers: NRC–2015–0003 and NRC-2011-0012

Comments: Webinar information:

<https://attendee.gotowebinar.com/register/2044567526801942786>

Agenda

6:00 pm Opening remarks and NRC staff introductions-Chip Cameron

6:10 pm Discussion of background and need for rulemaking –Andrew Persinko

6:30 pm Discussion on process for submitting comments-Stephen Dembek

6:45 pm NRC presentations on proposed rule language (questions and comments from the public after each discussion topic)-David Esh

8:50 pm Summation and closing remarks-Andrew Persinko

10 CFR Part 61 Proposed Rule and Guidance

WHAT IS IN THE PROPOSED RULE FOR 10 CFR PART 61?

The NRC is proposing to amend its regulations that govern low-level radioactive waste (LLRW) disposal facilities to:

- Require new and revised site-specific technical analyses
- Permit the development of site-specific criteria for LLRW acceptance based on the results of these analyses
- Facilitate implementation and to better align the requirements with current health and safety standards.

This proposed rule would affect LLRW disposal licensees or license applicants that are regulated by the NRC or the Agreement States.

WHAT IS IN THE GUIDANCE DOCUMENT?

The Guidance for Conducting Technical Analyses for 10 CFR Part 61 (NUREG-2175) provides:

- Flowcharts, NRC staff recommendations, and examples for how licensees can develop high-quality technical analyses
- Guidelines for what licensees or applicants should include and what regulators should review for each type of analysis
- Suggested references, screening tools, and case studies
- Recommendations on how to risk-inform each technical analysis

WHERE CAN I GET A COPY OF THE PROPOSED RULE AND GUIDANCE?



Redlined versions of the proposed changes, the complete Guidance document, and the Proposed Rule and Guidance Federal Register Notices are available at the Public NRC website.

Both documents are also available at www.regulations.gov
Docket ID NRC-2011-0012 (Rule)
Docket ID NRC-2015-0003 (NUREG-2175)

In NRC's Agencywide Document Access and Management System (ADAMS)
ML14289A152 (Rule)
ML15056A516 (NUREG-2175)

10 CFR Part 61 Proposed Rule and Guidance

HOW DO I SUBMIT COMMENTS ON THE PROPOSED RULE?

Please include Docket ID NRC-2011-0012 in the subject line of your comments.

- **Federal Rulemaking Website:** Go to <http://www.regulations.gov> and search for documents filed under Docket ID NRC-2011-0012.
- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.
- **E-mail comments to:** Rulemaking.Comments@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at 301-415-1677.
- **Hand-deliver comments to:** 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays. (Telephone 301-415-1677)
- **Fax comments to:** Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.

Priya Yadav, Project Manager
Priya.Yadav@nrc.gov
301-415-6667

Stephen Dembek, Senior Project Manager
Stephen.Dembek@nrc.gov
301-415-2342

Gary Comfort, Senior Project Manager
Gary.Comfort@nrc.gov
301-415-8106

HOW DO I SUBMIT COMMENTS ON THE GUIDANCE?

Please include Docket ID NRC-2015-0003 in the subject line of your comments.

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for documents filed under Docket ID NRC-2015-0003. Click on the comment icon and complete the Web form.
- **Mail comments to:** Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: 3WFN-06-A44M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

WHEN ARE THE PUBLIC MEETINGS?

Public Meetings/Events	Dates
Issued Proposed Rule/Guidance	March 26, 2015
Rockville, MD	April 28, 2015
Austin, TX	May 12, 2015
Columbia, SC	June 2, 2015
Richland, WA	June 9, 2015
Salt Lake City, UT	June 10, 2015
Close of Public Comment Period	July 24, 2015