State of Utah

SPENCER J. COX
Governor

DEIDRE HENDERSON
Lieutenant Governor

Department of
Environmental Quality

Kimberly D. Shelley
Executive Director

DIVISION OF WASTE MANAGEMENT
AND RADIATION CONTROL
Ty L. Howard
Director

A meeting of the Waste Management and Radiation Control Board has been scheduled for
April 8, 2021 at 1:30 p.m.
This is an electronic/telephonic meeting. No Anchor Location.
All Board members and any interested persons will participate electronically or telephonically,
Via the Internet:
meet.google.com/gad-sxsd-uvs
Join by phone: (US) +1 978-593-3748
PIN: 902 672 356#

This meeting is being held in accordance with House Bill 5002, effective July 1, 2020, which amended the Open and Public Meetings Act to address electronic meetings held without an anchor location. The Chair of the Waste Management and Radiation Control Board has determined that the presence of the COVID 19 virus in the community presents a substantial risk to the health and safety of those who might be present at an anchor location. Therefore, this meeting will be conducted without an anchor location. A member of the public may view this meeting and make comments via the electronic means outlined above.

AGENDA

I. Call to Order.

II. Public Comments on Agenda Items.

III. Declarations of Conflict of Interest.

IV. Approval of the Meeting Minutes for the March 11, 2021 Board Meeting..... Tab 1
(**Board Action Item**)

V. Underground Storage Tanks Update ..... Tab 2

VI. Administrative Rules.

A. Five-Year Review of R313-12, 14, 16, 17, 18, 19, 22, 25, 28, 32, 36, and 70 of the Utah Administrative Code (Information Item)..... Tab 3

VII. Low-Level Radioactive Waste Section.

A. Energy*Solutions'* request for a site-specific treatment variance from the Utah Hazardous Waste Management Rules. Energy*Solutions* seeks authorization to receive lithium and lithium-ion batteries for treatment and disposal (Information Item)..... Tab 4

(Over)

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B. Energy*Solutions'* request for a site-specific treatment variance from the Utah Hazardous Waste Management Rules. Energy*Solutions* seeks authorization to receive Cemented Uranium Extraction Process Residues for disposal (**Board Action Item**)..... Tab 5

VIII. Other Business.

A. Miscellaneous Information Items.
B. Scheduling of next Board meeting (May 13, 2021).

IX. Adjourn.

In compliance with the Americans with Disabilities Act, individuals with special needs (including auxiliary communicative aids and services) should contact Larene Wyss, Office of Human Resources at (801) 536-4284, Telecommunications Relay Service 711, or by email at "lwyss@utah.gov".

Waste Management and Radiation Control Board Meeting Minutes
Electronic/Telephonic Meeting
March 11, 2021
1:30 p.m.

No Anchor Location. All Board members participated electronically OR telephonically. Utah Department of Environmental Quality (UDEQ) employees and others from the public also participated either electronically or telephonically.

Board Members Participating (Electronically/Telephonically):
Brett Mickelson (Chair), Dennis Riding (Vice-Chair), Richard Codell, Danielle Endres, Mark Franc, Steve McIff, Nathan Rich, Vern Rogers and Shane Whitney

Board Members Excused: Kim Shelley

UDEQ Staff members participating (Electronically/Telephonically):
Ty Howard, Brent Everett, Arlene Lovato and Elisa Smith

I. Call to Order.

Chairman Mickelson called the meeting to order at 1:30 pm; roll call of Board members was conducted (see above).

Chairman Mickelson announced this meeting is being held in accordance with House Bill 5002, effective July 1, 2020, which amended the Open and Public Meetings Act to address electronic meetings held without an anchor location. The Chair of the Waste Management and Radiation Control Board has determined that the presence of the COVID 19 virus in the community presents a substantial risk to the health and safety of those who might be present at an anchor location. Therefore, this meeting is being conducted without an anchor location. A member of the public may participate/view this meeting via an electronic platform (Google Meet) or by Telephone call-in number by utilizing the electronic link/telephone number provided in the public notice of this meeting. Public notice of this meeting was posted on the Division of Waste Management and Radiation Control (DWMRC) web page and the Utah Public Notice website. Also, a member of the public may make a comment on any Agenda item during this Board meeting during the time allotted for "Public Comments on Agenda Items" listed on all Agendas.

II. Public Comments on Agenda Items. – None.

III. Declarations of Conflict of Interest. – None.

IV. Approval of Meeting Minutes for the February 11, 2021 Board Meeting (Board Action Item).

It was moved by Richard Codell and seconded by Steve McIff and UNANIMOUSLY CARRIED to approve the February 11, 2021 Board meeting minutes.

V. Underground Storage Tanks Update.

Brent Everett, Director of the Division of Environmental Response and Remediation (DERR) informed the Board that the cash balance of the Petroleum Storage Tank (PST) Trust Fund at the end of January 2020 was $19,484,534.00. The preliminary estimate of the cash balance of the PST Trust Fund for the end of February 2021 is $19,801,897.00. The DERR continues to watch the balance of the PST

Trust Fund closely to ensure sufficient cash is available to provide coverage of covered releases. Director Everett informed the Board that the annual PST Trust Fund actuarial report will be conducted later this year. Over the past few years, the PST Trust Fund has seen improvement in the negative equity balance due to legislation that was passed a few years ago.

Director Everett informed the Board that Senate Bill 40 was passed during the legislative session. There was an adjustment made to the bill regarding the size of tank that will be regulated. During the first year, aboveground storage tanks (ASTs) are required to be registered. During the second year, AST owners must provide financial assurance. This financial assurance can be met through either the PST Trust Fund or private insurance. Rules will be brought before the Board soon regarding the registration process for ASTs. There were no comments or questions.

VI. DWMRC Director's Report/Legislative Update.

Ty Howard, Director of DWMRC, provided an update on legislation passed from the 2021 General Session of the Utah State Legislature that impact the Division.

House Bill 30S04 Tax Modifications (Sponsored by Representative Barlow)
This bill amends the calculation of certain tax credits to match the applicable income tax rate – this modifies the tax credit for companies operating within a Recycling Market Development Zone (RMDZ). This bill also integrates the income tax code provisions from the 2020 Third Special Session, H.B. 3003, Income Tax Revisions, into the Utah Code and integrates the sales tax code provisions from the 2020 Fourth Special Session, H.B. 4002, Rail Fuel Sales Tax Amendments, into the Utah Code.

The attentiveness to this bill is because legislation passed in 2020 transferred the responsibility of administering the Recycling Market Development Zone Program from the Governor's Office of Economic Development to the Department.

STATUS: Passed

House Bill 217S01 Regulatory Sandbox Program Amendments (Sponsored by Representative Maloy)
This bill creates the Utah Office of Regulatory Relief within the Governor's Office of Economic Development (GOED) and creates the General Regulatory Sandbox Program which authorizes the office to waive laws or regulations applicable to a participant under certain circumstances.

The attentiveness to this bill is because it allows this regulatory relief office to waive laws or regulations applicable to a participant under certain circumstances. Those circumstances would not apply to a law that is required by a federal analog; most of UDEQ laws have a federal regulatory analog associated with them. Also, it is not applicable to laws that are part of a current statute or rule and it does not allow regulatory relief from a law/rule requirement that would create a health and safety issue.

STATUS: Passed

House Bill 236 Waste Tire Recycling Amendments (Sponsored by Representative Handy)
This bill authorizes state or local government owned landfills and transfer stations located within Class I and II counties to be reimbursed at 100% of their costs for removal and transfer of waste tires to a waste tire recycler.

STATUS: Passed

House Bill 346S02 Natural Resources Entities Amendments (Sponsored by Representative Snider)

This bill creates a coordination council comprised of the Department of Natural Resources, the DEQ, the Department of Agriculture and Food, the Public Lands Policy Coordination Office, and the Office of Energy Development, and moves the Office of Energy Development to within the Department of Natural Resources. It also divides the Division of Parks and Recreation into two divisions and transfers grants administered by the Utah Office of Outdoor Recreation to the new division.

The attentiveness to this bill is because this bill also includes a transition and study provision and repeal of that provision to evaluate and study combining the following into the Department of Natural Resources: the DEQ; the Division of Public Utilities; the Office of Consumer Services; and the Office of Rural Development.

STATUS: Passed

House Bill 399S01 Approval of Nonhazardous Solid or Hazardous Waste Facilities (Sponsored by Representative Hawkes)
This bill addresses the process of obtaining approval for nonhazardous solid or hazardous waste facilities. It addresses legislative approval and automatic revocation of that approval under certain circumstances, including if a facility withdraws its application after receiving legislative approval, and if after receiving legislative approval the facility does not receive approval of their application by DWMRC within five years from the date legislative approval is given.

The attentiveness to this bill is that nonhazardous solid or hazardous waste facilities that have submitted an application to become a Class V or Class VI facility are now required to have Legislature and Governor approval.

STATUS: Passed

Senate Joint Resolution 007 Approving Energy*Solutions* Constructing and Operating a Landfill for Nonhazardous Solid Waste (Sponsored by Representative Sandall)
This bill grants provisional legislative approval for the construction and operation of a Class VI commercial nonhazardous solid waste landfill and addresses the types of nonhazardous solid waste to be received by the landfill.

This bill specifically describes the proposed landfill; addresses the types of nonhazardous solid waste to be received and grants provisional legislative approval for the construction and operation of a Class VI commercial nonhazardous solid waste landfill at Energy*Solutions*.

STATUS: Passed

VII. Election of Board Chair and Vice Chair (Board Action Item).

Chairman Mickelson informed the Board that each year a Board Chairman and Board Vice-Chairman must be elected. Chairman Mickelson then conducted the elections.

Shane Whitney nominated Brett Mickelson to serve as Board Chairman. No other nominees were presented to serve as Board Chairman.

It was moved by Shane Whitney and seconded by Nathan Rich and UNANIMOUSLY CARRIED that Brett Mickelson be elected to serve as Board Chair.

Shane Whitney nominated Dennis Riding to serve as Board Vice-Chairman. No other nominees were presented to serve as Board Vice-Chairman.

It was moved by Shane Whitney and seconded by Nathan Rich and UNANIMOUSLY CARRIED that Dennis Riding continue to serve as Board Vice-Chair.

VIII. Other Business.

A. Miscellaneous Information Items.

DWMRC Director Howard expressed appreciation to the Board members for their dedicated service to the Board.

B. Schedule of Next Board Meeting.

The next meeting is scheduled for April 8, 2021 at 1:30 p.m. (electronic/telephonic meeting).

IX. Adjourn.

The meeting adjourned at 1:50 p.m.

DRAFT

UST STATISTICAL SUMMARY

March 1, 2020 -- February 28, 2021

PROGRAM

	March	April	May	June	July	August	September	October	November	December	January	February	(+/-) OR Total
Regulated Tanks	4,113	4,116	4,130	4,123	4,128	4,128	4,135	4,130	4,127	4,130	4,144	4,144	**31**
Tanks with Certificate of Compliance	3,988	4,000	4,006	4,009	4,033	4,029	4,027	4,027	4,039	4,044	4,051	4,051	**63**
Tanks without COC	125	116	124	114	95	99	108	103	88	86	93	93	**(32)**
Cumulative Facilitlies with Registered A Operators	1,291	1,290	1,289	1,289	1,255	1,250	1,084	1,104	1,108	1,111	1,252	1,252	**94.56%**
Cumulative Facilitlies with Registered B Operators	1,291	1,290	1,290	1,291	1,292	1,287	1,142	1,147	1,150	1,147	1,285	1,285	**97.05%**
New LUST Sites	5	2	6	4	3	11	5	8	8	8	5	5	**70**
Closed LUST Sites	7	5	3	4	2	6	3	7	2	6	4	4	**53**
Cumulative Closed LUST Sites	5281	5285	5291	5292	5295	5301	5302	5310	5315	5323	5329	5329	**48**

FINANCIAL

	March	April	May	June	July	August	September	October	November	December	January	February	(+/-)
Tanks on PST Fund	2,637	2,637	2,637	2,642	2,662	2,661	2,657	2,654	2,666	2,667	2,666	2,666	**29**
PST Claims (Cumulative)	675	675	681	684	685	685	687	688	688	688	688	688	**13**
Equity Balance	-$9,765,034	-$9,475,125	-$9,022,705	-$8,712,595	-$7,717,022	-$7,373,152	-$7,311,417	-$10,201,999	-$9,462,843	-$9,547,189	-$8,950,746	-$8,950,746	**$814,288**
Cash Balance	$16,353,246	$16,643,155	$17,095,575	$17,405,685	$18,401,258	$18,745,128	$18,806,863	$18,233,281	$18,972,437	$18,888,091	$19,484,534	$19,484,534	**$3,131,288**
Loans	0	0	0	0	0	0	0	0	0	0	0	0	**0**
Cumulative Loans	121	121	121	121	121	121	121	121	121	121	121	121	**0**
Cumulative Amount	$4,738,367	$4,738,367	$4,738,367	$4,738,367	$4,738,367	$4,738,367	$4,738,367	$4,738,367	$4,738,367	$4,738,367	$4,738,367	$4,738,367	**$0**
Defaults/Amount	1	1	1	2	2	2	2	2	2	2	2	2	**1**

	March	April	May	June	July	August	September	October	November	December	January	February	TOTAL
Speed Memos	27	54	32	50	7	38	95	72	73	42	48	48	**586**
Compliance Letters	8	8	7	5	15	18	32	30	9	14	15	15	**176**
Notice of Intent to Revoke	0	0	0	0	0	0	0	0	0	0	0	0	**0**
Orders	0	0	0	2	3	2	1	2	1	0	0	0	**11**

WASTE MANAGEMENT AND RADIATION CONTROL BOARD
Executive Summary
Five Year Review for Rules R313-12, 14, 16, 17, 18, 19, 22, 25, 28, 32, 36, and 70
April 8, 2021

What is the issue before the Board?	Rules R313-12, 14, 16, 17, 18, 19, 22, 25, 28, 32, 36, and 70 of the Utah Administrative Code are due for a five-year review. All these rules are Radiation Control rules. If these rules are to continue, a Notice of Continuation (Five-Year Review) must be filed prior to the anniversary of the last five-year review. The anniversary date for these rules is July 1, 2021.
What is the historical background or context for this issue?	The Utah Administrative Rulemaking Act (Utah Code §63G-3-305) requires state agencies to review each of their administrative rules within five years of the rule's original effective date or the last five-year review. The purpose of the review is to provide agencies with an opportunity to evaluate the rules to assess if the rules should be continued. In performing a five-year review, an agency may consider the need to amend or repeal rules that are archaic in form, are no longer used, are not based on existing statutory authority or are otherwise unnecessary. If an agency determines that a rule needs to be amended or repealed this is done in a separate action. To retain a rule as part of the Utah Administrative Code, a "Five-Year Notice of Review and Statement of Continuation" must be filed with the Office of Administrative Rules, before the rule's five-year anniversary date. The form provided by the Office of Administrative Rules requires the following information: 1. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize the rule; 2. A summary of written comments received during and since the last five-year review of the rule from interested persons supporting or opposing the rule; and, 3. A reasoned justification for continuation of the rule, including reasons why the agency disagrees with comments in opposition to the rule, if any. Completing the form provided by the Office of Administrative Rules and filing it before the five-year review date satisfies the provisions of the Administrative Rulemaking Act with respect to a five-year review. The completed forms and copies of the rules listed above follow this Executive Summary.

What is the governing statutory or regulatory citation?	Utah Code §63G-3-305 and Utah Code §19-3-103.1, §19-6-105 and §19-6-106.
Is Board action required?	No. The Division is providing this information to keep the Board informed of Five-Year Reviews that have been conducted and are being submitted to the Office of Administrative Rules.
What is the Division Director's recommendation?	N/A
Where can more information be obtained?	Please contact Tom Ball by email at tball@utah.gov) or by phone at (801) 536-0251.

State of Utah
Administrative Rule Analysis
Revised December 2019

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION		
	Title No. - Rule No.	
Utah Admin. Code Ref (R no.):	**R313-12**	**Filing No. (Office Use Only)**

Agency Information

1. Department:	Department of Environmental Quality	
Agency:	Waste Management and Radiation Control	
Room no.:	Second Floor	
Building:	MASOB	
Street address:	195 North 1950 West	
City, state, zip:	Salt Lake City, Utah 84116	
Mailing address:	PO Box 144880	
City, state, zip:	Salt Lake City, Utah 84114-4880	
Contact person(s):		
Name:	**Phone:**	**Email:**
Tom Ball	801-536-0251	tball@utah.gov
Please address questions regarding information on this notice to the agency.		

General Information

2. Rule catchline:

General Provisions.

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Utah Code Subsection 19-3-104(4) allows the Waste Management and Radiation Control Board to make rules to meet the requirements of federal law relating to radiation control to ensure the radiation control program under this part is qualified to maintain primacy from the federal government. The subsection also allows the Board to make rules as necessary regarding the possession, use, transfer, or delivery of source and byproduct material and the disposal of byproduct material. As part of the state primacy of the radiation control program, the definitions and other general provisions in R313-12 have been reviewed by the U.S. Nuclear Regulatory Commission (NRC) and have been determined to be compatible with the corresponding federal radiation protection regulations.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

Since the last five-year review there have been no comments from interested persons specifically supporting or opposing this rule.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

This rule is necessary because it lays the foundation for establishing radiation safety and protection and, as an Agreement State, maintains the appropriate regulatory compatibility with the NRC. There have been no opposing comments to the rules since the last five-year review in 2016.

Agency Authorization Information

To the agency: Information requested on this form is required by Section 63G-3-305. Incomplete forms will be returned to the agency for completion, possibly delaying the effective date.

Agency head or designee, and title:		**Date** (mm/dd/yyyy)**:**	

Reminder: Text changes cannot be made with this type of rule filing. To change any text, please file an amendment or nonsubstantive change.

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

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

R313-12-2. Purpose and Scope.

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

R313-12-3. Definitions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include sources of radiation from radioactive materials regulated by the Division of Waste Management and Radiation Control 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 Waste Management and 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 x 10 to the tenth power 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 58-69-806, Dentist and Dental Hygienist Practice Act.

"Department" means the Utah 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 Waste Management and 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/cm^2).

"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 Director 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 58-17b-101 through 58-17b-806, 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 Director in accordance with the rules adopted by the Board.

"Regulations of the U.S. Department of Transportation" means 49 CFR 100 through 189 and 49 CFR 390 through 397, as referenced in 49 CFR 177.

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

"Research and development" means:

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

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

"Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but

excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of Rule R313-15.

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

"Roentgen" (R) means the special unit of EXPOSURE. One roentgen equals 2.58 x 10 to the -4 power 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 square centimeter).

"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 10 CFR 71.4 in effect on March 31, 1996, (see 10 CFR 71 revised January 1, 1983), and constructed before April 1, 1998, may continue to be used. Any other special form encapsulation must meet the specifications of this definition.

"Special nuclear material" means:

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

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

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

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

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

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

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

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

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

"U.S. Department of Energy" means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its

Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c), and (d) of Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, effective January 19, 1975 known as the Energy Reorganization Act of 1974, and retransferred to the Secretary of Energy pursuant to section 301(a) of Public Law 95-91, August 14, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977 known as the Department of Energy Organization Act.

"Unrefined and unprocessed ore" means ore in its natural form prior to processing, like grinding, roasting or beneficiating, or refining. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

"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.

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

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

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

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

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

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

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

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

TABLE 1

Quality Factors and Absorbed Dose Equivalencies

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

For the column in Table 1 labeled "Absorbed Dose Equal to

a Unit Dose Equivalent", the absorbed dose in rad is equal to one rem or the absorbed dose in gray is equal to one Sv.

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

TABLE 2

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

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

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

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

R313-12-40. Units of Radioactivity.

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

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

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

R313-12-51. Records.

(1) A person who receives source or byproduct material pursuant to a license issued pursuant to the regulations in this part shall

keep records showing the receipt, transfer, and disposal of this source or byproduct material as follows:

(a) The licensee shall retain each record of receipt of source or byproduct material as long as the material is possessed and for three years following transfer or disposition of the source or byproduct material.

(b) The licensee who transferred the material shall retain each record of transfer of source or byproduct material until the Director terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(c) The licensee shall retain each record of disposal of source or byproduct material until the Director terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(d) If source or byproduct material is combined or mixed with other licensed material and subsequently treated in a manner that makes direct correlation of a receipt record with a transfer, export, or disposition record impossible, the licensee may use evaluative techniques, such as first-in-first-out, to make the records that are required by Section R313-12-51 account for 100 percent of the material received.

(2) The licensee shall retain each record that is required by Section R313-12-51 or by license condition for the period specified by the appropriate rule or license condition. If a retention period is not otherwise specified by rule or license condition, each record must be maintained until the Director terminates the license that authorizes the activity that is subject to the recordkeeping requirement.

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

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

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

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

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

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

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

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

(6) Prior to license termination, each licensee may forward the records required by Subsection R313-22-35(7) to the Director.

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

R313-12-52. Inspections.

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

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

R313-12-53. Tests.

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

(a) sources of radiation;

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

(c) radiation detection and monitoring instruments; and

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

R313-12-54. Additional Requirements.

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

R313-12-55. Exemptions.

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

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

(a) prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or controlled sites, including the transportation of sources of radiation to or from the sites and the performance of contract services during temporary interruptions of the transportation;

(b) prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing or

transportation of, atomic weapons or components thereof;

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

(d) any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the state and the U.S. Nuclear Regulatory Commission jointly determine:

(i) that the exemption of the prime contractor or subcontractor is authorized by law; and

(ii) that under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

R313-12-70. Impounding.

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

R313-12-100. Prohibited Uses.

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

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

R313-12-110. Communications.

All communications and reports concerning these rules, and applications filed thereunder, should be addressed to the Director of the Division of Waste Management and Radiation Control, P.O. Box 144880, 195 North 1950 West, Salt Lake City, Utah 84114-4880.

R313-12-111. Submission of Electronic Copies.

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

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

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

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

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

(b) A Microsoft Word document.

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

(a) X-ray registration applications;

(b) Submissions shorter than 25 pages unless otherwise ordered by the Director;

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

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

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

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

(7) The Director may waive the requirements of R313-12-111(1) for good cause.

KEY: definitions, units, inspections, exemptions
Date of Enactment or Last Substantive Amendment: October 13, 2017
Notice of Continuation: July 1, 2016
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-104

State of Utah
Administrative Rule Analysis
Revised December 2019

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION		
	Title No. - Rule No.	
Utah Admin. Code Ref (R no.):	**R313-14**	**Filing No. (Office Use Only)**

Agency Information

1. Department:	Department of Environmental Quality	
Agency:	Waste Management and Radiation Control	
Room no.:	Second Floor	
Building:	MASOB	
Street address:	195 North 1950 West	
City, state, zip:	Salt Lake City, Utah 84116	
Mailing address:	PO Box 144880	
City, state, zip:	Salt Lake City, Utah 84114-4880	
Contact person(s):		
Name:	**Phone:**	**Email:**
Tom Ball	801-536-0251	tball@utah.gov
Please address questions regarding information on this notice to the agency.		

General Information

2. Rule catchline:

Violations and Escalated Enforcement.

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Utah Code Subsection 19-3-104(4) allows the Waste Management and Radiation Control Board to make rules to meet the requirements of federal law relating to radiation control to ensure the radiation control program under this part is qualified to maintain primacy from the federal government. Utah Code Subsection 19-3-109 allows the director to assess penalties and allows persons who violate provisions of the rules to appeal a penalty. Utah Code Subsection 19-3-111 allows the director to impound radioactive material. Utah Code Subsection 19-3-108.1 allows the director to issue orders, enforce orders and institute judicial proceedings in connection with rules adopted by the board. R313-14 contains the rules adopted by the board and as part of the state primacy of the radiation control program, the rules in R313-14 have been reviewed by the U.S. Nuclear Regulatory Commission (NRC) and have been determined to be compatible with the corresponding federal radiation protection regulations.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

Since the last five-year review there have been no comments from interested persons specifically supporting or opposing this rule.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

This rule is necessary because it establishes actions that may be taken for noncompliance with existing radiation control laws and rules and, as an Agreement State, maintains the appropriate regulatory compatibility with the NRC. This includes setting violation severity levels, enforcement sanctions, and assessment of civil penalties. There have been no opposing comments to the rules since the last five-year review in 2016.

Agency Authorization Information

To the agency: Information requested on this form is required by Section 63G-3-305. Incomplete forms will be returned to the agency for completion, possibly delaying the effective date.

Agency head or designee, and title:		**Date** (mm/dd/yyyy)**:**	

Reminder: Text changes cannot be made with this type of rule filing. To change any text, please file an amendment or nonsubstantive change.

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

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

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

(b) obtaining prompt correction of violations;

(c) deterring future violations; and

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

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

(3) The rules set forth herein are adopted pursuant to the provisions of Subsections 19-6-104(1)(a), 19-3-104(4) and 19-3-104(7), 19-6-107(2), 19-3-109, and 19-3-111.

R313-14-3. Definitions.

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

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

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

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

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

R313-14-10. Severity of Violations.

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

(a) electronically produced radiation operations; or

(b) radioactive materials operations.

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

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

(4) The severity of a violation shall be characterized at the level best suited to the significance of the particular violation. A severity level may be increased if circumstances surrounding the violation involve careless disregard of requirements, deception, or other indications of willfulness. In determining the specific severity level of a violation involving willfulness, relevant factors will be considered, including the position of the person involved in the violation, the significance of an underlying violation, the intent of the violator, and the economic advantage gained by the violation. The relative weight given to these factors in arriving at the appropriate severity level is dependent on the circumstances of the violation.

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

R313-14-15. Enforcement Actions.

This Section describes the enforcement sanctions available to the Director and specifies the conditions under which they are to be used.

(1) Notice of Violation

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

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

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

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

(b) The Director may require responses to Notices of Violation to be under oath.

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

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

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

(iii) it was reported, in writing, to the Director;

(iv) it was or will be corrected, including measures to prevent recurrence, within 90 days or other period approved by the Director; and

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

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

(2) Civil Penalty.

(a) A civil penalty is a monetary penalty that may be imposed for violation of Utah Radiation Control Rules or lawful orders issued by the Director. Civil penalties are designed to emphasize the need for lasting remedial action and to deter future violations. Generally, civil penalties are imposed for Severity Level I and Severity Level II violations. In the absence of mitigating circumstances, civil penalties are considered for Severity Level III violations. Penalties are not ordinarily imposed for Severity Level IV and V violations unless those violations are similar to previous violations for which the licensee, permittee, or registrant failed to take effective corrective action.

(b) The level of a civil penalty may not exceed $10,000 per violation. Except as modified by provision of the next paragraphs, the base civil penalties are as follows:

TABLE

Severity Level I Violations	$10,000
Severity Level II Violations	$ 8,000
Severity Level III Violations	$ 5,000
Severity Level IV Violations	$ 1,500
Severity Level V Violations	$ 500

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

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

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

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

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

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

(D) The civil penalty may be increased as much as 50%, up to the $10,000 maximum, for cases where the licensee, permittee, or registrant had prior knowledge of a problem as a result of an internal audit, or specific Director or industry notification, and had failed to take effective preventive steps.

(E) The civil penalty may be increased as much as 50%, up to the $10,000 maximum, where multiple examples of a particular violation are identified during the inspection period.

(c) A violation of a continuing nature shall, for the purposes of calculating the proposed civil penalty, be considered a separate violation for each day of its continuance. A continuing violation is not considered a repeat violation. In the event a violation is repeated within five years, the scheduled amount of the civil penalty may be increased 50%, up to the $10,000 maximum; and for repeat violations

of Severity Levels II and III, the penalty will not be avoided by compliance. Other rights and procedures are not affected by the repeat violation.

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

(3) Orders.

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

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

(c) Suspension Orders may be used:

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

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

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

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

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

(d) Revocation Orders may be used:

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

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

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

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

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

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

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

(4) Escalation of Enforcement Sanctions.

(a) In accordance with the provisions of Section 19-3-111 the radioactive material of a person may be impounded. Administrative procedures will be conducted as provided by Rule R305-7, prior to disposal of impounded radioactive materials.

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

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

(5) Related Administrative Actions.

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

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

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

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

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

Enforcement actions and responses are publicly available for inspection. In addition, press releases are generally issued for Notices of Proposed Imposition of a Civil Penalty and Orders. In the case of orders and civil penalties related to violations at Severity

Level I, II, or III, press releases may be issued at the time of the Order or the Notice of Proposed Imposition of the Civil Penalty. Press releases are not normally issued for Notices of Violation.

KEY: violations, penalties, enforcement
Date of Enactment or Last Substantive Amendment: April 3, 2014
Notice of Continuation: July 1, 2016
Authorizing, and Implemented or Interpreted Law: 19-3-109; 19-3-111

State of Utah
Administrative Rule Analysis
Revised December 2019

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION		
	Title No. - Rule No.	
Utah Admin. Code Ref (R no.):	**R313-16**	**Filing No. (Office Use Only)**

Agency Information

1. Department:	Department of Environmental Quality	
Agency:	Waste Management and Radiation Control	
Room no.:	Second Floor	
Building:	MASOB	
Street address:	195 North 1950 West	
City, state, zip:	Salt Lake City, Utah 84116	
Mailing address:	PO Box 144880	
City, state, zip:	Salt Lake City, Utah 84114-4880	
Contact person(s):		
Name:	**Phone:**	**Email:**
Tom Ball	801-536-0251	tball@utah.gov
Please address questions regarding information on this notice to the agency.		

General Information

2. Rule catchline:

General Requirements Applicable to the Installation, Registration, Inspection, and Use of Radiation Machines.

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Utah Code Subsection 19-3-104(4) allows the Waste Management and Radiation Control Board to make rules to meet the requirements of federal law relating to radiation control to ensure the radiation control program under this part is qualified to maintain primacy from the federal government. Utah Code Subsection 19-3-104 also allows the division to require registration or licensing of radiation sources that constitute a significant health hazard and requires all sources of ionizing radiation to be registered or licensed. This subsection also allows the board to make rules regarding the use radiation sources. Utah Code Subsection 19-3-108.1 allows the director to authorize inspections. R313-16 contains the rules adopted by the board and as part of the state primacy of the radiation control program, the rules in R313-16 have been reviewed by the U.S. Nuclear Regulatory Commission (NRC) and have been determined to be compatible with the corresponding federal radiation protection regulations.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

Since the last five-year review there have been no comments from interested persons specifically supporting or opposing this rule.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

This rule is necessary because it prescribes requirements governing the installation, registration, inspection, and use of sources of electronically produced ionizing radiation to protect human health and the environment. The prolific use of such machines is not only very common among the healing arts professions for critical diagnostic and therapeutic applications, they also provide key functions in veterinarian, academic, industrial, and other professional applications. There have been no opposing comments to the rules since the last five-year review in 2016.

Agency Authorization Information

To the agency: Information requested on this form is required by Section 63G-3-305. Incomplete forms will be returned to the agency for completion, possibly delaying the effective date.

Agency head or designee, and title:		**Date** (mm/dd/yyyy)**:**	

Reminder: Text changes cannot be made with this type of rule filing. To change any text, please file an amendment or nonsubstantive change.

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.
R313-16. General Requirements Applicable to the Installation, Registration, Inspection, and Use of Radiation Machines.
R313-16-200. Purpose and Authority.

(1) The purpose of this rule is to prescribe requirements governing the installation, registration, inspection, and use of sources of electronically produced ionizing radiation. This rule provides for the registration of individuals providing inspection services to a facility where one or more radiation machines are installed or located.

(2) The rules set forth herein are adopted pursuant to the provisions of Subsections 19-3-104(4) and 19-3-104(9).

R313-16-215. Definitions.

"Qualified expert" means an individual having the knowledge and training to measure regulatory parameters on radiation machines, to evaluate radiation safety programs, to evaluate radiation levels, and to give advice on radiation protection needs while conducting inspections of radiation machine facilities registered with the Division. Qualified experts are not considered employees or representatives of the Division of Waste Management and Radiation Control or the State.

"Sorting Center" means a facility in which radiation machines are in storage until they are shipped out of state.

"Storage" means a condition in which a radiation machine is not being used for an extended period of time, and has been made inoperable.

R313-16-220. Exemptions.

(1) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of Rule R313-16, providing the dose equivalent rate averaged over an area of ten square centimeters does not exceed 0.5 mrem (5.0 uSv) per hour at five centimeters from accessible surfaces of the equipment.

(2) Radiation machines while in transit are exempt from the requirements of Section R313-16-230. See Section R313-16-250 for other applicable requirements.

(3) Television receivers are exempt from the requirements of Rule R313-16.

(4) Radiation machines while in the possession of a manufacturer, assembler, or a sorting center are exempt from the requirements of Section R313-16-230.

(5) Radiation machines owned by an agency of the Federal Government are exempt from the requirements of Rule R313-16.

R313-16-225. Responsibility for Radiation Safety Program.

(1) The registrant shall be ultimately responsible for radiation safety, but may designate another person to implement the radiation safety program. When, in the Director's opinion, neither the registrant nor the registrant's designee is sufficiently qualified to insure safe use of the machine; the Director may order the registrant to designate another individual who has adequate qualifications.

(2) The registrant or the registrant's designee shall:

(a) develop a detailed program of radiation safety that assures compliance with the applicable requirements of these rules, including Section R313-15-101;

(b) have instructions given concerning radiation hazards and radiation safety practices to individuals who may be occupationally exposed;

(c) have surveys made and other procedures carried out as required by these rules; and

(d) keep a copy of all reports, records, and written policies and procedures required by these rules.

R313-16-230. Registration of Radiation Machines.

(1) Ionizing radiation producing machines not exempted by Section R313-16-220 shall be registered with the Director.

(2) Registration shall be required annually in accordance with a schedule established by the Director.

(3) Registration for the facility is achieved when the Director receives the following:

(a) a current and complete application form DWMRC-10 for registration of radiation machines; and

(b) annual registration fees.

(4) Registration for the current fiscal year shall be acknowledged by the Director through receipts for the remittance of the registration fee.

R313-16-231. Additional Requirements for the Issuance of a Registration for Particle Accelerators Excluding Therapeutic Radiation Machines (See Rule R313-30).

(1) In addition to the requirements of Section R313-16-230, a registrant who proposes to use a particle accelerator shall submit an application to the Director containing the following:

(a) information demonstrating that the applicant, by reason of training and experience, is qualified to use the accelerator in question for the purpose requested in a manner that will minimize danger to public health and safety or the environment;

(b) a discussion which demonstrates that the applicant's equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or the environment;

(c) the name and qualifications of the individual, appointed by the applicant, to serve as radiation safety officer pursuant to Section R313-35-140;

(d) a description of the applicant's or the staff's experience in the use of particle accelerators and radiation safety training; and

(e) a description of the radiation safety training the applicant will provide to particle accelerator operators.

R313-16-233. Notification of Intent to Provide Servicing and Services.

(1) Persons engaged in the business of installing or offering to install radiation machines or engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this State shall notify the Director of the intent to provide these services within 30 days following the effective date of this rule or, thereafter, prior to furnishing or offering to furnish these services.

(2) The notification shall specify:

(a) that the applicable requirements of these rules have been read and understood;

(b) the services which will be provided;

(c) the training and experience that qualify for the discharge of the services; and

(d) the type of measurement instrument to be used, frequency of calibration, and source of calibration.

(3) For the purpose of Section R313-16-233, services may include but shall not be limited to:

(a) installation or servicing of radiation machines and associated radiation machine components; and

(b) calibration of radiation machines or radiation measurement instruments or devices.

(4) Individuals shall not perform the services listed in Subsection R313-16-233(3) unless they are specifically stated for that individual on the notification of intent required in Subsection R313-16-233(1) and the complete information required by Subsection R313-16-233(2) has been received by the Director.

R313-16-235. Designation of Registrant.

The owner or lessee of a radiation machine is the registrant. The registrant shall be responsible for penalties imposed under the Director's escalated enforcement authority, see Rule R313-14.

R313-16-240. Reciprocal Recognition of Registration or License.

Radiation machines from jurisdictions other than the State of Utah may be operated in this state for a period of less than 30 days providing that the requirements of Section R313-16-280 have been met and providing they are properly registered or licensed with the State Agency having jurisdiction over the office directing the activities of the individuals operating the radiation machines. Radiation machines operating under reciprocity may be inspected pursuant to Section R313-16-290.

R313-16-250. Report of Changes.

The registrant shall send written notification within 14 working days to the Director when:

(1) there are changes in location or ownership of a radiation machine;

(2) radiation machines are retired from service;

(3) radiation machines are put in storage or returned to service from storage; or

(4) modifications in facility or equipment are made that might reasonably be expected to effect compliance under the terms of these rules.

R313-16-260. Approval Not Implied.

Registration does not constitute approval of activities performed under the registration and no person shall state or imply that activities under the registration have been approved by the Director.

R313-16-270. Transferor, Assembler, or Installer Obligation.

(1) Persons who sell, lease, transfer, lend, dispose, assemble, or install a radiation machine in this state shall notify the Director within 14 working days of the following:

(a) the name and address of the person who received the machine and also the name and address of the new registrant of the machine if not the same;

(b) the manufacturer, model, and serial number of the master control of the radiation machine and the number of x-ray tubes transferred; and

(c) the date of transfer of the radiation machine.

(2) Radiation machine equipment or accessories shall not be installed if the equipment will not meet the requirements of these rules when installation is completed.

(3) Reporting Compliance. Assemblers who install one or more components into a radiation machine system or subsystem, shall certify that the equipment meets the standards of these rules. A copy of this certification shall be transmitted to the purchaser and to the Director within 14 working days following the completion of the installation.

(4) Certification can be accomplished by providing the following in conjunction with the information required by Section R313-16-250 and Subsection R313-16-270(1):

(a) the full name and address of the assembler and the date of assembly or installation;

(b) a statement as to whether the equipment is a replacement for other equipment, in addition to other equipment, or new equipment in a new facility;

(c) an affirmation that the applicable rules have been met;

(d) a statement of the type and intended use of the radiation machine system or subsystem, for example "radiographic-stationary general purpose x-ray;" and

(e) a list of the components which were assembled or installed into the radiation machine system or subsystem, identifying the components by type, manufacturer, model number, and serial number.

R313-16-275. Obligation of Equipment Registrant or Recipient of New Equipment.

The registrant of a radiation machine shall not allow the equipment to be put into operation until it has been determined that the facility in which it is installed meets the shielding and design requirements of Rule R313-28; see Sections R313-28-32, R313-28-200 and R313-28-450.

R313-16-280. Out-of-State Radiation Machines.

(1) Whenever a radiation machine is to be brought into the state, for either temporary or extended use, the person proposing to bring the machine into the state shall give written notice to the Director at least three working days before the machine is to be used in the state. The notice shall include the type of radiation machine; the manufacturer model and serial number of the master control; the nature, duration, and scope of use; and the exact location where the radiation machine is to be used. If, for a specific case, the three working-day period would impose an undue hardship, the person may, upon application to the Director, obtain permission to proceed sooner.

(2) In addition, the out-of-state person shall:

(a) comply with the applicable portions of these rules;

(b) supply the Director other information as the Director requests.

R313-16-290. Inspection of Radiation Machines and Facilities.

(1) Registrants shall assure that radiation machines registered pursuant to Section R313-16-230 are compliant with these rules. Radiation machines, facilities, and radiation safety programs are subject to inspection to assure compliance with these rules and to assist in lowering radiation exposure to as low as reasonably achievable levels, see Section R313-15-101. Inspections may be performed by representatives of the Director or by independent qualified experts.

(2) Inspections may, at the Director's discretion, be done after the installation of equipment, or after a change in the facility or equipment which might cause a significant change in radiation output or hazards. Inspections may be completed in accordance with the schedule as defined in Table I.

TABLE I

FACILITY TYPE	MAXIMUM TIME BETWEEN INSPECTIONS
Hospital or Radiation Therapy Facility	one year
Medical Facility using Fluoroscopic or Computed Tomography (CT) Units	one year
Medical Facility Using General Radiographic Devices	two years
Chiropractic	two years
Dental	five years
Podiatry	five years
Veterinary	five years
Industrial Facility with High or Very High Radiation Areas Accessible to Individuals	one year
Industrial Facility Using Cabinet X-Ray Units or Units Designed for Other Industrial Purposes	five years
Other	one to five years

(3) The registrant, in a timely manner, shall pay the appropriate inspection fee after completion of the inspection.

(4) Ionizing radiation producing machines which have been officially placed in storage are exempt from inspection fees but are subject to visual verification of their status by representatives of the Director.

R313-16-291. Inspection Services.

Registrants shall only utilize qualified experts who have been registered by the Director in accordance with Section R313-16-293. Registrants may also utilize inspectors from the Division of Waste Management and Radiation Control in lieu of registered qualified experts.

R313-16-292. Minimum Qualifications for Registration of Inspection Services.

A qualified expert who is engaged in the business of furnishing or offering to furnish inspection services at facilities shall meet the training and experience criteria developed by the Director. At a minimum, the training and experience shall include:

(1) Bachelor's degree in health physics, chemistry, biology, physical or environmental science plus one year full-time paid professional related experience, such as performing radiation safety evaluations in a hospital.

(a) An advanced degree in a related field may be substituted for one year of required experience; or

(2) Five years full-time paid professional, directly related work experience.

R313-16-293. Application for Registration of Inspection Services.

(1) Each qualified expert who is providing or offering to provide inspection services at facilities registered with the Director shall complete an application for registration on a form prescribed by the Director and shall submit all information required by the Director as indicated on the form. A qualified expert must complete the registration process prior to providing services.

(2) Individuals applying for registration under Section R313-16-293 shall personally sign and submit to the Director an attestation statement:

(a) that they have read and understand the requirements of these rules; and

(b) that they will document inspection items defined by the Director on a form prescribed by the Director; and

(c) that they will follow guidelines for the evaluation of x-ray equipment defined by the Director; and

(d) that, except for those facilities where a registered qualified expert is a full-time employee, they will limit inspections to facilities with which they have no direct conflict of interest; and

(e) that radiation exposure measurements and peak tube potential measurements will be made with instruments which have been calibrated biennially by the manufacturer of the instrument or by a calibration laboratory accredited in x-ray calibration procedures by the American Association of Physicians in Medicine, American Association for Laboratory Accreditation, Conference of Radiation Control Program Directors, Health Physics Society or the National Voluntary Laboratory Accreditation Program; and

(f) that the calibration of radiation exposure measuring and peak tube potential measuring instruments used to evaluate compliance of x-ray systems with the requirements of these rules will include at least secondary level traceability to a National Institute of Standards and Technology, or similar international agency, transfer standard instrument or transfer standard source; and

(g) that they will make available to representatives of the Director documents concerning the calibration of any radiation exposure measuring or peak tube potential measuring instrument used to evaluate compliance of x-ray systems; and

(h) that they will submit to the Director, within 30 calendar days after completion of an inspection, a written report of compliance or noncompliance; and

(i) that reports of items of noncompliance will include:

(i) the name of the facility inspected, and

(ii) the date of the inspection, and

(iii) the manufacturer, model number, and serial number or Utah identification number of the control unit for the radiation machine, and

(iv) the requirements of the rule where compliance was not achieved, and

(v) the manner in which the facility or radiation machine failed to meet the requirements, and

(vi) a signed commitment from the registrant of the radiation machine facility that the problem will be fixed within 30 days of the date the written report of noncompliance is submitted to the Director; and

(vii) that all reports of compliance or noncompliance will contain a statement signed by the qualified expert acknowledging under penalties of law that all information contained in the report is truthful, accurate, and complete; and

(viii) that they acknowledge that they are subject to the provisions of Section R313-16-300.

(3) Individuals applying for registration under Section R313-16-293 shall attach to their application a copy of two inspection reports that demonstrate their work product follows the evaluation guidelines defined by the Director pursuant to Subsection R313-16-293(2)(c). The inspection reports shall pertain to inspections performed within the last two years.

R313-16-294. Issuance of Registration Certificate for Inspection Services.

Upon a determination that an applicant meets the requirements of these rules, the Director shall issue a registration certificate for inspection services.

R313-16-295. Expiration of Registration Certificates for Inspection Services.

A registration certificate for inspection services shall expire at the end of the day on the date stated therein.

R313-16-296. Renewal of Registration Certificate for Inspection Services.

(1) Timely renewal of a registration certificate for inspection services is possible when:

(a) the qualified expert files an application for renewal of a registration certificate for inspection services 30 days in advance of the registration certificate expiration date and in accordance with Section R313-16-293, and

(b) the qualified expert attaches to the application documentation that they performed a minimum of two inspections in Utah under these rules each year the previous registration certificate was in effect. An applicant who did not complete the minimum number of inspections in Utah may, as an alternative, attach to the application documentation that they performed four inspections at facilities in other states. These four inspections shall demonstrate their work product follows the evaluation guidelines defined by the Director pursuant to Subsection R313-16-293(2)(c).

(2) A registered qualified expert who allows a registration certificate to expire is no longer a qualified expert and may not perform inspection services that will be accepted by the Director. Reapplication may be accomplished pursuant to Section R313-16-293.

R313-16-297. Revocation of Registration Certificate for Inspection Services.

A registration certificate for inspection services may be revoked by the Director for any matter of deliberate misconduct pursuant to Section R313-16-300 or for misfeasance, malfeasance or nonfeasance.

R313-16-300. Deliberate Misconduct.

(1) Any registrant, applicant for registration, employee of a registrant or applicant; or any contractor, including a supplier or consultant, subcontractor, employee of a contractor or subcontractor of any registrant or applicant for registration, who knowingly provides to any registrant, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a registrant's, or applicant's activities in these rules, may not:

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

(b) Deliberately submit to the Director, a registrant, an applicant, or a registrant's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Director.

(2) A person who violates Subsections R313-16-300(1)(a) or (b) may be subject to enforcement action in accordance with Rule R313-14.

(3) For the purposes of Subsection R313-16-300(1)(a), deliberate misconduct by a person means an intentional act or omission that the person knows:

(a) Would cause a registrant or applicant to be in violation of any rule or order; or any term, condition, or limitation, of any registration issued by the Director; or

(b) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a registrant, applicant, contractor, or subcontractor.

KEY: x-rays, inspections
Date of Enactment or Last Substantive Amendment: April 13, 2020
Notice of Continuation: July 1, 2016
Authorizing, and Implemented or Interpreted Law: 19-3-104

State of Utah
Administrative Rule Analysis
Revised December 2019

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION		
	Title No. - Rule No.	
Utah Admin. Code Ref (R no.):	**R313-17**	**Filing No. (Office Use Only)**

Agency Information

1. Department:	Department of Environmental Quality	
Agency:	Waste Management and Radiation Control	
Room no.:	Second Floor	
Building:	MASOB	
Street address:	195 North 1950 West	
City, state, zip:	Salt Lake City, Utah 84116	
Mailing address:	PO Box 144880	
City, state, zip:	Salt Lake City, Utah 84114-4880	
Contact person(s):		
Name:	**Phone:**	**Email:**
Tom Ball	801-536-0251	tball@utah.gov
Please address questions regarding information on this notice to the agency.		

General Information

2. Rule catchline:

Administative Procedures

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Utah Code Subsection 19-3-104(4) allows the Waste Management and Radiation Control Board to make rules to meet the requirements of federal law relating to radiation control to ensure the radiation control program under this part is qualified to maintain primacy from the federal government. Utah Code Subsections 19-1-301 and 19-1-301.5 govern adjudicative proceedings and the actions that may be taken by the department and its boards. R313-17 contains the rules adopted by the board and as part of the state primacy of the radiation control program, the rules in R313-17 have been reviewed by the U.S. Nuclear Regulatory Commission (NRC) and have been determined to be compatible with the corresponding federal radiation protection regulations.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

Since the last five-year review there have been no comments from interested persons specifically supporting or opposing this rule.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

This rule is necessary because it establishes the requirements for conducting public hearings for various radioactive materials licensing actions and for conducting adjudicative proceedings. As an Agreement State the rule is necessary for maintaining the appropriate regulatory compatibility with the NRC. There have been no opposing comments to the rules since the last five-year review in 2016.

Agency Authorization Information

To the agency: Information requested on this form is required by Section 63G-3-305. Incomplete forms will be returned to the agency for completion, possibly delaying the effective date.

Agency head or designee, and title:		**Date** (mm/dd/yyyy)**:**	

Reminder: Text changes cannot be made with this type of rule filing. To change any text, please file an amendment or nonsubstantive change.

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.
R313-17. Administrative Procedures.
R313-17-1. Authority.

The rules set forth herein are adopted pursuant to the provision of Subsection 19-3-104(4) and Sections 19-1-301 and 19-1-301.5.

R313-17-2. Public Notice and Public Comment Period.

(1) The Director shall give public notice of and provide an opportunity to comment on the following:

(a) A proposed major licensing action for license categories 2b and c, 4a, b, c, d and 6 identified in Section R313-70-7.

(i) Major licensing actions include:

(A) Pending issuance of a new license,

(B) Pending issuance of a license renewal,

(C) Pending approval of a license termination,

(D) An increase in process, storage, or disposal capacity,

(E) A geographic expansion,

(F) A change in engineering design, construction, or process controls that will more than likely cause an individual to receive a higher total effective dose equivalent or increase the annual quantity of radioactive effluents released to the environment,

(G) A decrease in environmental monitoring or sampling frequency,

(H) Pending approval of reclamation, decontamination or decommissioning plans,

(I) Pending approval of corrective actions to control or remediate existing radioactive material contamination, not already authorized by a license,

(J) A licensing issue the Director deems is of significant public interest.

(b) The initial proposed registration of an ionizing radiation producing machine which operates at a kilovoltage potential (kVp) greater than 200 in an open beam configuration. R313-17-2(1)(b) does not apply to ionizing radiation producing machines used in the healing arts.

(c) Board activities that may have significant public interest and the Board requests the Director to take public comment on those proposed activities.

(2) The Director may elect to give public notice of and provide an opportunity to comment on licensing actions that do not include the actions in Subsection R313-17-2(1)(a)(i), for all license categories identified in Section R313-70-7.

(3) Public notice shall allow at least 30 days for public comment.

(4) Public notice may describe more than one action listed in Subsection R313-17-2(1) and may combine notice of a public hearing with notice of the proposed action.

(5) Public notice shall be given by one or more of the following methods:

(a) Publication in a newspaper of general circulation in the area affected by the proposed action,

(b) Publication on the Division of Waste Management and Radiation Control website, or

(c) Distribution by an electronic mail server.

R313-17-3. Administrative Procedures.

Administrative proceedings under the Radiation Control Act are governed by Rule R305-7.

R313-17-4. Special Procedures for Decisions Associated with Licenses for Uranium Mills and Disposal of Byproduct Material.

(1) Definitions. For purposes of this rule:

(a) "Byproduct material" has the same meaning as defined in 42 U.S.C. Section 2014(e)(2);

(b) "License" means a radioactive materials license for a uranium mill or disposal of byproduct material, including any ground water discharge permit incorporated in a license; and

(c) "Question and answer hearing" means the informal hearing described in paragraphs (3) through (5) held for the purpose of responding to questions from the public.

(2) Scope. This rule R313-17-4 applies only to licensing activities that meet both of the following criteria:

(a) they are licensing activities described in R313-17-2(a)(i)(A) through (I); and

(b) they are for licenses or license amendments for uranium mills and disposal of byproduct materials.

(3) Opportunity for Question and Answer Hearing Prior to Director's Decision.

(a) For licensing actions that are subject to the scope of this rule, the Director may, at the Director's discretion, schedule a question and answer hearing at the time it proposes the action.

(b) If the Director does not choose to schedule a question and answer hearing at the time it proposes a licensing action, the Director shall provide notice to the public of an opportunity to request a question and answer hearing, and it shall schedule and hold a hearing if there is a request from a member of the public.

(c) Notice of a hearing or an opportunity to request a hearing under this rule shall be made as provided in R313-17-3(5). Members of the public shall be given at least ten days to request a hearing.

(d) The Director may combine the question and answer hearing with a licensing hearing held for the purpose of taking public comment on a proposed licensing action.

(4) Procedures Prior to Question and Answer Hearing.

(a) The Director shall provide a notice of the question and answer hearing at least 30 days before the hearing. The notice shall also summarize the applicable procedures, including the obligation to provide questions in advance of the hearing.

(b) Any person who proposes to ask questions during the question and answer hearing shall submit the questions to the Director. Questions must be received by the Director by the deadline specified in the public notice, which shall be no fewer than 15 days after the notice of the question and answer hearing is posted. If a question relies on information that is not included in the licensing record, that information shall be submitted with the questions. The relevance of and the relevant portions of any supporting materials shall be described with reasonable specificity. Information submitted in accordance with this paragraph will become part of the record.

(c) If the Director determines that any of the questions submitted will not be answered during the question and answer hearing, as provided in paragraph (5)(f), the Director shall notify the person who submitted the questions prior to the hearing. Notification shall include a statement about the Director's reasons for the determination.

(5) Procedures for Question and Answer Hearing.

(a) The question and answer hearing shall ordinarily be held in the Department of Environmental Quality offices. Unless the question and answer hearing is held in a place near the proposed facility, the Director shall provide an opportunity for the public to participate by telephone or other electronic means.

(b) The question and answer hearing will not ordinarily be scheduled for longer than three hours. The Director may allocate time to those who have submitted questions after considering the number and nature of the questions submitted.

(c) A hearing officer who is not the director or a member of the director's staff shall manage the question and answer hearing. Representatives of the licensee and Director's staff shall attend the hearing.

(d) The question and answer hearing shall be recorded and transcribed. Alternatively, the Director may elect to have a court reporter record and transcribe the hearing.

(e) The Director shall determine whether the initial and follow-up question will be answered by the applicant, by the Director's staff, or by both. Notwithstanding the Director's decision, the applicant may choose to respond to any question. After the response to a question, the person who submitted the question shall be allowed to follow up with additional questions based on the response provided.

(f) Appropriate questions are those that seek specific factual information about the license application, or about other documents created during the licensing process. The following kinds of questions do not require a response during a question and answer hearing:

(i) Questions that are not relevant to the licensing action;

(ii) Questions that are based on information that is not in the record;

(iii) Questions that are vague;

(iv) Questions that require speculation;

(v) Questions that seek legal conclusions;

(vi) Questions that have been previously answered;

(vii) Questions that are more appropriately characterized as comments; and

(viii) Questions that would not have to be answered during a trial-type hearing.

(g) Either the Director or the applicant may elect to answer a question even if it is a question that does not require a response under paragraph (f). No waiver will result from answering a question that does not require a response.

(h) Questions requesting information that is clear in the record may be answered by referring the questioner to the record.

(i) In the event that a questioner or the applicant disagrees with the Director's determinations under paragraphs (4)(c), (5)(b), or (5)(e), it may request a determination by the hearing officer. If the hearing officer disagrees with the Director's determination, the Director or, as appropriate, the applicant may then:

(i) comply with the hearing officer's determination during the question and answer hearing;

(ii) comply with the hearing officer's determination by responding to the question in writing no fewer than 10 days before the end of the comment period; or

(iii) notify the questioner or applicant that it contests the determination, and provide information to the questioner about the procedures available to it under paragraph (5)(j).

(j) If a decision of the hearing officer is contested as described in paragraph (5)(i)(iii), the person who asked the question may challenge that failure to comply with the hearing officer's decision on appeal. If the hearing officer's determination is upheld on appeal, the record on appeal shall be supplemented as described in paragraph (6) and R305-7-607.

(6) Formal Questioning During Appeal.

If no opportunity for a question and answer hearing is provided, or if an opportunity that was provided is found by the Administrative Law Judge to have been deficient, an opportunity for questions and answers shall be provided on appeal as described in R305-7-607. This opportunity for questions and answers on appeal shall be available only to a petitioner who has exhausted procedures and remedies available under paragraphs R313-17-4(1) through R313-17-4(5). The scope of questions and answers on appeal shall be limited by the scope of the deficiency.

KEY: administrative procedures, comment, hearings, adjudicative proceedings
Date of Enactment or Last Substantive Amendment: February 17, 2015
Notice of Continuation: July 1, 2016
Authorizing, and Implemented or Interpreted Law: 19-3-104(4); 19-1-301 and 19-1-301.5

State of Utah
Administrative Rule Analysis
Revised December 2019

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION		
	Title No. - Rule No.	
Utah Admin. Code Ref (R no.):	**R313-18**	**Filing No. (Office Use Only)**

Agency Information

1. Department:	Department of Environmental Quality	
Agency:	Waste Management and Radiation Control	
Room no.:	Second Floor	
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Mailing address:	PO Box 144880	
City, state, zip:	Salt Lake City, Utah 84114-4880	
Contact person(s):		
Name:	**Phone:**	**Email:**
Tom Ball	801-536-0251	tball@utah.gov
Please address questions regarding information on this notice to the agency.		

General Information

2. Rule catchline:

Notices, Instructions and Reports to Workers by Licensees or Registrants--Inspections.

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Utah Code Subsection 19-3-104(4) allows the Waste Management and Radiation Control Board to make rules to meet the requirements of federal law relating to radiation control to ensure the radiation control program under this part is qualified to maintain primacy from the federal government. Utah Code Subsections 19-6-107 and 19-6-109 authorize the Director of the division to authorize employees or representatives of the department to conducted inspections. R313-18 contains the rules adopted by the board and as part of the state primacy of the radiation control program, the rules in R313-18 have been reviewed by the U.S. Nuclear Regulatory Commission (NRC) and have been determined to be compatible with the corresponding federal radiation protection regulations.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

Since the last five-year review there have been no comments from interested persons specifically supporting or opposing this rule.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

This rule is necessary because it specifies the training and notification requirements by employers for workers that use radioactive materials. The rule also provides the basis for worker protection and safety requirements and inspections by the division. As an Agreement State the rule is necessary for maintaining the appropriate regulatory compatibility with the NRC. There have been no opposing comments to the rules since the last five-year review in 2016.

Agency Authorization Information

To the agency: Information requested on this form is required by Section 63G-3-305. Incomplete forms will be returned to the agency for completion, possibly delaying the effective date.

Agency head or designee, and title:		**Date** (mm/dd/yyyy)**:**	

Reminder: Text changes cannot be made with this type of rule filing. To change any text, please file an amendment or nonsubstantive change.

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.
R313-18. Notices, Instructions and Reports to Workers by Licensees or Registrants--Inspections.
R313-18-1. Purpose and Authority.

(1) The purpose of this rule is to establish requirements for notices, instructions and reports by licensees or registrants to individuals engaged in work under a license or registration and options available to such individuals in connection with inspections of licensees or registrants.

(2) The rules set forth herein are adopted pursuant to the provisions of Sections 19-3-104(4) and 19-3-104(7).

R313-18-2. General.

The rules of R313-18 shall apply to all persons who receive, possess, use, own or transfer a source of radiation licensed by or registered with the Director pursuant to the rules in R313-16, R313-19 or R313-22.

R313-18-11. Posting of Notices to Workers.

(1) Licensees or registrants shall post current copies of the following documents:

(a) the rules in R313-15 and R313-18;

(b) the license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;

(c) the operating procedures applicable to work under the license or registration; and

(d) a notice of violation involving radiological working conditions, proposed imposition of civil penalty, order issued pursuant to R313-14, or any response from the licensee or registrant.

(2) If posting of a document specified in R313-18-11(1)(a), (b), or (c) is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

(3) DWMRC-04 "Notice to Employees," shall be posted by licensees or registrants wherever individuals work in or frequent a portion of a restricted area.

(4) Documents from the Director which are posted pursuant to R313-18-11(1)(d) shall be posted within five working days after receipt of the documents from the Director; the licensee's or registrant's response, if there is one, shall be posted for a minimum of five working days after dispatch from the licensee or registrant. The documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

(5) Documents, notices or forms posted pursuant to R313-18-11 shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

R313-18-12. Instructions to Workers.

(1) All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 1.0 mSv (100 mrem):

(a) shall be kept informed of the storage, transfer, or use of sources of radiation in the licensee's or registrant's workplace;

(b) shall be instructed in the health protection considerations associated with exposure to radiation or radioactive material to the individual and potential offspring, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

(c) shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of these rules and licenses for the protection of personnel from exposure to radiation or radioactive material;

(d) shall be instructed as to their responsibility to report promptly to the licensee or registrant a condition which may constitute, lead to, or cause a violation of the Act, these rules, or a condition of the licensee's license or unnecessary exposure to radiation or radioactive material;

(e) shall be instructed in the appropriate response to warnings made in the event of an unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and

(f) shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to R313-18-13.

(2) In determining those individuals subject to the requirements of R313-18-12(1), licensees must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation or radioactive material which can reasonably be expected to occur during the life of a licensed facility. The extent of these instructions shall be commensurate with potential radiological health protection considerations for the workplace.

R313-18-13. Notifications and Reports to Individuals.

(1) Radiation exposure data for an individual and the results of measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in R313-18-13. The information reported shall include data and results obtained pursuant to these rules, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to R313-15-1107. Notifications and reports shall:

(a) be in writing;

(b) include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number, preferably social security number;

(c) include the individual's exposure information; and

(d) contain the following statement:

"This report is furnished to you under the provisions of the Utah Administrative Code Section R313-18-13. You should preserve this report for further reference."

(2) Licensees or registrants shall make dose information available to workers as shown in records maintained by the licensee or registrant pursuant to R313-15-1107. The licensee shall provide an annual report to each individual monitored under R313-15-502 of the dose received in that monitoring year if:

(a) The individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue; or

(b) The individual requests his or her annual dose report.

(3) Licensees or registrants shall furnish a written report of the worker's exposure to sources of radiation at the request of a worker formerly engaged in activities controlled by the licensee or registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to R313-15-502. The report shall be furnished within 30 days from the date of the request, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

(4) When a licensee or registrant is required pursuant to R313-15-1202, R313-15-1203, or R313-15-1204 to report to the Director an exposure of an individual to sources of radiation, the licensee or registrant shall also provide the individual a written report on the exposure data included in the report to the Director. This report shall be transmitted at a time no later than the transmittal to the Director.

(5) At the request of a worker who is terminating employment with the licensee or registrant in work involving exposure to radiation or radioactive material, during the current year, the licensee or registrant shall provide at termination to the worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

R313-18-14. Presence of Representatives of Licensees or Registrants and Workers During Inspection.

(1) Licensees or registrants shall afford representatives of the Director, at reasonable times, the opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these rules.

(2) During an inspection, representatives of the Director may consult privately with workers as specified in R313-18-15. The licensee or registrant may accompany representatives during other phases of an inspection.

(3) If, at the time of inspection, an individual has been authorized by the workers to represent them during inspections, the licensee or registrant shall notify the representatives of the Director of the authorization and shall give the workers' representative an opportunity to accompany the representatives during the inspection of physical working conditions.

(4) The workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in R313-18-12.

(5) Different representatives of licensees or registrants and workers may accompany the representatives of the Director during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the representatives of the Director.

(6) With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany representatives of the Director during the inspection of physical working conditions.

(7) Notwithstanding the other provisions of R313-18-14, representatives of the Director are authorized to refuse to permit accompaniment by an individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an Agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to areas containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

R313-18-15. Consultation with Workers During Inspections.

(1) Representatives of the Director may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of these rules and licenses to the extent the representatives deem necessary for the conduct of an effective and thorough inspection.

(2) During the course of an inspection, workers may bring privately to the attention of the representatives of the Director, either orally or in writing, a past or present condition which the worker has reason to believe may have contributed to or caused a violation of the Act, these rules, or license condition, or an unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. A notice in writing shall comply with the requirements of R313-18-16(1).

(3) The provisions of R313-18-15(2) shall not be interpreted as authorization to disregard instructions pursuant to R313-18-12.

R313-18-16. Request by Workers for Inspections.

(1) A worker or representative of workers believing that a violation of the Act, these rules, or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged, may request

an inspection by giving notice of the alleged violation to the Director. The notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by representatives of the Director no later than at the time of inspection except that, upon the request of the worker giving the notice, his name and the name of individuals referred to therein shall not appear in a copy or on a record published, released, or made available by the Director except for good cause shown.

(2) If, upon receipt of the notice, representatives of the Director determine that the complaint meets the requirements set forth in R313-18-16(1), and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if the alleged violation exists or has occurred. Inspections pursuant to R313-18-16 need not be limited to matters referred to in the complaint.

(3) A licensee, registrant or contractor or subcontractor of a licensee or registrant shall not discharge or discriminate against a worker because that worker has filed a complaint or instituted or caused to be instituted a proceeding under these rules or has testified or is about to testify in a proceeding or because of the exercise by the worker on behalf of the worker or others of an option afforded by R313-18.

R313-18-17. Inspections Not Warranted -- Informal Review.

(1)(a) If the Director determines, with respect to a complaint under Section R313-18-16, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Director shall notify the complainant in writing of that determination. The complainant may obtain review of the determination by submitting a written statement of position with the Director. The Director will provide the licensee or registrant with a copy of the statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the Director. The Director will provide the complainant with a copy of the statement by certified mail.

(b) Upon the request of the complainant, the Director may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering written and oral views presented, the Director shall affirm, modify, or reverse the determination of the representatives of the Director and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefor.

(2) If the Director determines that an inspection is not warranted because the requirements of R313-18-16(1) have not been met, the complainant shall be notified in writing of the determination. The determination shall be without prejudice to the filing of a new complaint meeting the requirements of R313-18-16(1).

KEY: radioactive materials, inspections, radiation safety, licensing
Date of Enactment or Last Substantive Amendment: March 19, 2013
Notice of Continuation: July 1, 2016
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-107

State of Utah
Administrative Rule Analysis
Revised December 2019

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION		
	Title No. - Rule No.	
Utah Admin. Code Ref (R no.):	**R313-19**	**Filing No. (Office Use Only)**

Agency Information

1. Department:	Department of Environmental Quality	
Agency:	Waste Management and Radiation Control	
Room no.:	Second Floor	
Building:	MASOB	
Street address:	195 North 1950 West	
City, state, zip:	Salt Lake City, Utah 84116	
Mailing address:	PO Box 144880	
City, state, zip:	Salt Lake City, Utah 84114-4880	
Contact person(s):		
Name:	**Phone:**	**Email:**
Tom Ball	801-536-0251	tball@utah.gov
Please address questions regarding information on this notice to the agency.		

General Information

2. Rule catchline:

Requirements of General Applicability to Licensing of Radioactive Material.

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Utah Code Subsection 19-3-104(4) allows the Waste Management and Radiation Control Board to make rules to meet the requirements of federal law relating to radiation control to ensure the radiation control program under this part is qualified to maintain primacy from the federal government. R313-19 contains the rules adopted by the board and as part of the state primacy of the radiation control program, the rules in R313-19 have been reviewed by the U.S. Nuclear Regulatory Commission (NRC) and have been determined to be compatible with the corresponding federal radiation protection regulations.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

Since the last five-year review there have been no comments from interested persons specifically supporting or opposing this rule.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

This rule is necessary because it prescribes requirements governing the licensing of radioactive material. This rule also needs to be continued to ensure that the state's rules are adequate to protect public health and safety. The rule identifies certain concentrations or quantities of radioactive material, provides for reciprocal recognition of out-of-state licenses, and identifies terms and conditions of licenses. As an Agreement State the rule is necessary for maintaining the appropriate regulatory compatibility with the NRC. There have been no opposing comments to the rules since the last five-year review in 2016.

Agency Authorization Information

To the agency: Information requested on this form is required by Section 63G-3-305. Incomplete forms will be returned to the agency for completion, possibly delaying the effective date.

Agency head or designee, and title:		**Date** (mm/dd/yyyy)**:**	

Reminder: Text changes cannot be made with this type of rule filing. To change any text, please file an amendment or nonsubstantive change.

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.
R313-19. Requirements of General Applicability to Licensing of Radioactive Material.
R313-19-1. Purpose and Authority.

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

(2) The rules set forth herein are adopted pursuant to the provisions of Subsections 19-3-104(4) and 19-3-104(7).

R313-19-2. General.

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

(2) In addition to the requirements of Rules R313-19, R313-21 or R313-22, all licensees are subject to the requirements of Rules R313-12, R313-15, and R313-18. Licensees engaged in source material milling operations, authorized to possess byproduct material, as defined in Section R313-12-3 (see definition (b)) from source material milling operations, authorized to possess and maintain a source material milling facility in standby mode, authorized to receive byproduct material from other persons for disposal, or authorized to possess and dispose of byproduct material generated by source material milling operations are subject to the requirements of Rule R313-24. Licensees engaged in land disposal of radioactive material are subject to the requirements of Rule R313-25. Licensees using radioactive material in the healing arts are subject to the requirements of Rule R313-32. Licensees authorized to use sealed sources containing radioactive materials in panoramic irradiators with dry or wet storage of radioactive sealed sources, underwater irradiators, or irradiators with high dose rates from radioactive sealed sources are subject to the requirements of Rule R313-34. Licensees engaged in industrial radiographic operations are subject to the requirements of Rule R313-36. Licensees possessing category 1 or category 2 quantities of radioactive material, as defined in Section R313-37-3 (incorporating 10 CFR 37.5 by reference), are subject to the physical protection requirements of Rule R313-37. Licensees engaged in wireline and subsurface tracer studies are subject to the requirements of Rule R313-38.

R313-19-5. Deliberate Misconduct.

(1) Any licensee, certificate of registration holder, applicant for a license or certificate of registration, employee of a licensee, certificate of registration holder or applicant; or any contractor, including a supplier or consultant, subcontractor, employee of a contractor or subcontractor of any licensee or certificate of registration holder or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, certificate holder, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's or applicant's activities in these rules, may not:

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

(b) Deliberately submit to the Director, a licensee, certificate of registration holder, an applicant, or a licensee's, certificate holder's or applicant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Director.

(2) A person who violates Subsections R313-19-5(1)(a) or (b) may be subject to enforcement action in accordance with Rule R313-14.

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

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

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

R313-19-7. Carriers.

Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from the regulations in Rules R313-19, R313-21, R313-22, R313-32, R313-34, R313-36, R313-37, and R313-38 and the requirements for a license set forth in Subsection 19-3-104(3) to the extent that they transport or store radioactive material in the regular course of carriage for another or storage incident thereto.

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 the requirements in Rules R313-15, R313-18, 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 manufactured before October 16, 2017, 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 two percent by weight source material or, for glassware manufactured before October 16, 2017, 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) each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM",

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

(C) The requirements specified in Subsections R313-19-13(1)(c)(v)(A) and (B) need not be met by counterweights manufactured prior to December 31, 1969, provided that such counterweights were manufactured under a specific license issued by the Atomic Energy Commission and were impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM", as previously required by the rules in effect on June 30, 1969, 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 any such 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 or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain more than 10 percent by weight thorium or uranium or, for lenses manufactured before October 16, 2017, 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) 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.

(ix) No person may initially transfer for sale or distribution a product containing source material to persons exempt under Subsection R313-19-13(1)(c), or equivalent regulations of an Agreement State, unless authorized by a license issued under 10 CFR 40.52 to initially transfer such products for sale or distribution.

(A) A person initially distributing source material in products covered by the exemptions in this Subsection R313-19-13(1)(c) before (Utah effective date to be set by the Board), without specific authorization may continue such distribution for one year beyond this date. Initial distribution may also be continued until the director takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than one year beyond this date.

(B) A person authorized to manufacture, process, or produce these materials or products containing source material by an Agreement State, and a person who imports finished products or parts, for sale or distribution must be authorized by a license issued under 10 CFR 40.52 for distribution only and are exempt from the requirements of Rules R313-15 and R313-18 and Subsections R313-22-33(1)(a) and (b).

(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 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.

(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.

(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.

(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.

(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.

(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)(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) 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 regulations in R313-15, R313-19, R313-21, R313-22, R313-32, R313-34, R313-36, 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.

(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, any person is exempt from the regulations in parts R313-18, R313-15, R313-19, R313-21, R313-22, R313-32, R313-34, R313-36, 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 regulations in parts R313-18, R313-15, R313-18, R313-15, R313-19, R313-21, R313-22, R313-32, R313-34, R313-36, 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) With respect to Subsections R313-19-13(2)(b)(iii), R313-19-13(2)(c)(i), (iii) and (iv), the authority to transfer possession or control by the manufacturer, processor, or producer of equipment, devices, commodities, or other products containing byproduct material whose subsequent possession, use, transfer, and disposal by other persons is exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

R313-19-20. Types of Licenses.

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

(1) General licenses provided in Rule R313-21 are effective without the filing of applications with the Director or the issuance of licensing documents to the particular persons, although the filing of a registration certificate with the Director may be required by the particular general license. The general licensee is subject to the other applicable portions of these rules and limitations of the general license.

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

R313-19-25. Prelicensing Inspection.

The Director may verify information contained in applications and secure additional information deemed necessary to make a reasonable determination as to whether to issue a license and whether special conditions should be attached thereto by visiting the facility or location where radioactive materials would be possessed or used, and by discussing details of the proposed possession or use of the radioactive materials with the applicant or representatives designated by the applicant. Such visits may be made by representatives of the Director.

R313-19-30. Reciprocal Recognition of Licenses.

(1) Subject to these rules, a person who holds a specific license from the U.S. Nuclear Regulatory Commission, an Agreement State, or Licensing State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in the licensing document within this state, except in areas of exclusive federal jurisdiction, for a period not in excess of 180 days in a calendar year provided that:

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

(b) the out-of-state licensee notifies the Director in writing at least three days prior to engaging in such activity. Notifications shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Director, obtain permission to proceed sooner. The Director may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in Subsection R313-19-30(1);

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

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

(e) the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in Subsection R313-19-30(1) except by transfer to a person specifically licensed by the Director or by the U.S. Nuclear Regulatory Commission, a Licensing State, or an Agreement State to receive the material.

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

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

(b) the device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific

license issued to the person by the Nuclear Regulatory Commission, a Licensing State, or an Agreement State;

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

(d) the holder of the specific license shall furnish to the general licensee to whom the device is transferred or on whose premises a device is installed a copy of the general license contained in Subsection R313-21-22(4) or in equivalent rules of the agency having jurisdiction over the manufacture and distribution of the device.

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

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

(1) Licenses issued pursuant to Rule R313-19 shall be subject to provisions of the Act, now or hereafter in effect, and to all rules, and orders of the Director.

(2)(a) 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.

(b) An application for transfer of license shall include:

(i) The identity, technical and financial qualifications of the proposed transferee; and

(ii) Financial assurance for decommissioning information required by R313-22-35.

(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(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. The licensee shall report the results of each test that exceeds the permissible concentration listed in R313-32 (incorporating 10 CFR 35.204(a)) at the time of generator elution, in accordance with R313-32 (incorporating 10 CFR 35.3204).

(9) Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(10)(a) Authorization under Subsection R313-22-32(9) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(b) A licensee authorized under Subsection R313-22-32(9) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(i) Satisfy the labeling requirements in Subsection R313-22-75(9)(a)(iv) for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(ii) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in Subsection R313-22-75(9)(c).

(c) A licensee that is a pharmacy authorized under Subsection R313-22-32(9) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(i) an authorized nuclear pharmacist that meets the requirements in Subsection R313-22-75(9)(b)(ii); or

(ii) an individual under the supervision of an authorized nuclear pharmacist as specified in Rule R313-32 (incorporating 10 CFR 35.27 by reference).

(d) A pharmacy authorized under Subsection R313-22-32(9) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of Subsection R313-22-75(9)(b)(v).

R313-19-41. Transfer of Material.

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

(2) Except as otherwise provided in the license and subject to the provisions of Subsections R313-19-41(3) and (4), licensees may transfer radioactive material:

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

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

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

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

(e) as otherwise authorized by the Director in writing.

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

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

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

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

(c) for emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date, provided that the oral certification is confirmed in writing within ten days;

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

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

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

R313-19-50. Reporting Requirements.

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

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

(a) an unplanned contamination event that:

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

(ii) involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of 10 CFR 20.1001 through 20.2402 (2017), which is incorporated by reference, for the material; and

(iii) has access to the area restricted for a reason other than to allow radionuclides with a half-life of less than 24 hours to decay prior to decontamination; or

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

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

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

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

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

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

(i) the quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of 10

CFR 20.1001 through 20.2402 (2017), which is incorporated by reference, for the material; and

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

(3) Preparation and submission of reports. Reports made by licensees in response to the requirements of Section R313-19-50 must be made as follows:

(a) For radioactive materials, other than special nuclear material, licensees shall make reports required by Subsections R313-19-50(1) and (2) by telephone to the Director. To the extent that the information is available at the time of notification, the information provided in these reports must include:

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

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

(iii) the exact location of the event;

(iv) the radionuclides, quantities, and chemical and physical form of the licensed material involved; and

(v) available personnel radiation exposure data.

(b) For special nuclear materials, licensees shall make reports required by Subsections R313-19-50(1) and (2) by telephone to the Director. To the extent that the information is available at the time of notification, the information provided in these reports must include:

(i) the caller's name, position title, and call-back telephone number;

(ii) the date, time, and exact location of the event; and

(iii) a description of the event, including:

(A) radiological or chemical hazards involved, including isotopes, quantities, and chemical and physical form of any material released; and

(B) actual or potential health and safety consequences to the workers, the public, and the environment, including relevant chemical and radiation data for actual personnel exposures to radiation or radioactive materials or hazardous chemicals produced from radioactive materials (e.g., level of radiation exposure, concentration of chemicals, and duration of exposure).

(c) Written report for materials other than special nuclear materials. A licensee who makes a report required by Subsections R313-19-50(1) or (2) shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other rules may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports shall be sent to the Director. The report shall include the following:

(i) A description of the event, including the probable cause and the manufacturer and model number, if applicable, of equipment that failed or malfunctioned;

(ii) the exact location of the event;

(iii) the radionuclides, quantities, and chemical and physical form of the licensed material involved;

(iv) date and time of the event;

(v) corrective actions taken or planned and results of evaluations or assessments; and

(vi) the extent of exposure of individuals to radiation or radioactive materials without identification of individuals by name.

(d) Written report for special nuclear material. A licensee who makes a report required by Subsections R313-19-50(1) or (2) shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other rules may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports shall be sent to the Director. The report shall include the following:

(i) the complete applicable information required by Subsection R313-19-50(3)(b);

(ii) the probable cause of the event, including all factors that contributed to the event and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned; and

(iii) corrective actions taken or planned to prevent occurrence of similar or identical events in the future and the results of any evaluations or assessments.

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

(1) The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Act, or by reason of rules, and orders issued by the Director.

(2) Licenses may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act, or because of conditions revealed by the application or statement of fact or any report, record, or inspection or other means which would warrant the Director to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rule, or order of the Director.

(3) Administrative reviews, modifications, revocations or terminations of licenses will be in accordance with Title 19, Chapter 3.

(4) The Director may terminate a specific license upon written request submitted by the licensee to the Director.

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

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

TABLE

	Column I		
	Concentration	Column II	
Element	Material	Concentration	
(Atomic	Normally Used	Liquid (uCi/ml)	
Number)	Radionuclide	As Gas (uCi/ml)	Solid (uCi/g)
Antimony (51)	Sb-122	3 E-4	

	Sb-124	2 E-4	
	Sb-125	1 E-3	
Argon (18)	Ar-37	1 E-3	
	Ar-41	4 E-7	
Arsenic (33)	As-73	5 E-3	
	As-74	5 E-4	
	As-76	2 E-4	
	As-77	8 E-4	
Barium (56)	Ba-131	2 E-3	
	Ba-140	3 E-4	
Beryllium (4)	Be-7	2 E-2	
Bismuth (83)	Bi-206	4 E-4	
Bromine (35)	Br-82	4 E-7	3 E-3
Cadmium (48)	Cd-109	2 E-3	
	Cd-115m	3 E-4	
	Cd-115	3 E-4	
Calcium (20)	Ca-45	9 E-5	
	Ca-47	5 E-4	
Carbon (6)	C-14	1 E-6	8 E-3
Cerium (58)	Ce-141	9 E-4	
	Ce-143	4 E-4	
	Ce-144	1 E-4	
Cesium (55)	Cs-131	2 E-2	
	Cs-134m	6 E-2	
	Cs-134	9 E-5	
Chlorine (17)	Cl-38	9 E-7	4 E-3
Chromium (24)	Cr-51	2 E-2	
Cobalt (27)	Co-57	5 E-3	
	Co-58	1 E-3	
	Co-60	5 E-4	
Copper (29)	Cu-64	3 E-3	
Dysprosium (66)	Dy-165	4 E-3	
	Dy-166	4 E-4	
Erbium (68)	Er-169	9 E-4	
	Er-171	1 E-3	
Europium (63)	Eu-152 (T = 9.2 h)	6 E-4	
	Eu-155	2 E-3	
Fluorine (9)	F-18	2 E-6	8 E-3
Gadolinium (64)	Gd-153	2 E-3	
	Gd-159	8 E-4	
Gallium (31)	Ga-72	4 E-4	
Germanium (32)	Ge-71	2 E-2	
Gold (79)	Au-196	2 E-3	
	Au-198	5 E-4	
	Au-199	2 E-3	
Hafnium (72)	Hf-181	7 E-4	
Hydrogen (1)	H-3	5 E-6	3 E-2
Indium (49)	In-113m	1 E-2	
	In-114m	2 E-4	
Iodine (53)	I-126	3 E-9	2 E-5
	I-131	3 E-9	2 E-5
	I-132	8 E-8	6 E-4
	I-133	1 E-8	7 E-5
	I-134	2 E-7	1 E-3
Iridium (77)	Ir-190	2 E-3	
	Ir-192	4 E-4	
	Ir-194	3 E-4	
Iron (26)	Fe-55	8 E-3	
	Fe-59	6 E-4	
Krypton (36)	Kr-85m	1 E-6	
	Kr-85	3 E-6	
Lanthanum (57)	La-140	2 E-4	
Lead (82)	Pb-203	4 E-3	
Lutetium (71)	Lu-177	1 E-3	
Manganese (25)	Mn-52	3 E-4	
	Mn-54	1 E-3	
	Mn-56	1 E-3	
Mercury (80)	Hg-197m	2 E-3	
	Hg-197	3 E-3	
	Hg-203	2 E-4	
Molybdenum (42)	Mo-99	2 E-3	
Neodymium (60)	Nd-147	6 E-4	
	Nd-149	3 E-3	
Nickel (28)	Ni-65	1 E-3	
Niobium (Columbium)(41)	Nb-95	1 E-3	
	Nb-97	9 E-3	
Osmium (76)	Os-185	7 E-4	
	Os-191m	3 E-2	
	Os-191	2 E-3	
	Os-193	6 E-4	
Palladium (46)	Pd-103	3 E-3	
	Pd-109	9 E-4	
Phosphorus (15)	P-32	2 E-4	

Platinum (78)	Pt-191	1 E-3	
	Pt-193m	1 E-2	
	Pt-197m	1 E-2	
	Pt-197	1 E-3	
Potassium (19)	K-42	3 E-3	
Praseodymium (59)	Pr-142	3 E-4	
	Pr-143	5 E-4	
Promethium (61)	Pm-147	2 E-3	
	Pm-149	4 E-3	
Rhenium (75)	Re-183	6 E-4	
	Re-186	9 E-3	
	Re-188	6 E-4	
Rhodium (45)	Rh-103m	1 E-1	
	Rh-105	1 E-3	
Rubidium (37)	Rb-86	7 E-4	
Ruthenium (44)	Ru-97	4 E-4	
	Ru-103	8 E-4	
	Ru-105	1 E-3	
	Ru-106	1 E-4	
Samarium (62)	Sm-153	8 E-4	
Scandium (21)	Sc-46	4 E-4	
	Sc-47	9 E-4	
	Sc-48	3 E-4	
Selenium (34)	Se-75	3 E-3	
Silicon (14)	Si-31	9 E-3	
Silver (47)	Ag-105	1 E-3	
	Ag-110m	3 E-4	
	Ag-111	4 E-4	
Sodium (11)	Na-24	2 E-3	
Strontium (38)	Sr-85	1 E-4	
	Sr-89	1 E-4	
	Sr-91	7 E-4	
	Sr-92	7 E-4	
Sulfur (16)	S-35	9 E-8	6 E-4
Tantalum (73)	Ta-182	4 E-4	
Technetium (43)	Tc-96m	1 E-1	
	Tc-96	1 E-3	
Tellurium (52)	Te-125m	2 E-3	
	Te-127m	6 E-4	
	Te-127	3 E-3	
	Te-129m	3 E-4	
	Te-131m	6 E-4	
	Te-132	3 E-4	
Terbium (65)	Tb-160	4 E-4	
Thallium (81)	Tl-200	4 E-3	
	Tl-201	3 E-3	
	Tl-202	1 E-3	
	Tl-204	1 E-3	
Thulium (69)	Tm-170	5 E-4	
	Tm-171	5 E-3	
Tin (50)	Sn-113	9 E-4	
	Sn-125	2 E-4	
Tungsten (Wolfram)(74)	W-181	4 E-3	
	W-187	7 E-4	
Vanadium (23)	V-48	3 E-4	
Xenon (54)	Xe-131m	4 E-6	
	Xe-133	3 E-6	
	Xe-135	1 E-6	
Ytterbium (70)	Yb-175	1 E-3	
Yttrium (39)	Y-90	2 E-4	
	Y-91m	3 E-2	
	Y-91	3 E-4	
	Y-92	6 E-4	
	Y-93	3 E-4	
Zinc (30)	Zn-65	1 E-3	
	Zn-69m	7 E-4	
	Zn-69	2 E-2	
Zirconium (40)	Zr-95	6 E-4	
	Zr-97	2 E-4	
Beta or gamma emitting radioactive material not listed above with half-life less than 3 years		1 E-10	1 E-6

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

(2) For purposes of Subsection R313-19-13(2)(a) where there is involved a combination of radionuclides, the limit for

the combination should be derived as follows: Determine for each radionuclide in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in Section R313-19-70 for the specific radionuclide when not in combination. The sum of the ratios may not exceed one or unity.

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

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

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

TABLE

RADIOACTIVE MATERIAL	MICROCURIES
Antimony-122 (Sb-122)	100
Antimony-124 (Sb-124)	10
Antimony-125 (Sb-125)	10
Arsenic-73 (As-73)	100
Arsenic-74 (As-74)	10
Arsenic-76 (As-76)	10
Arsenic-77 (As-77)	100
Barium-131 (Ba-131)	10
Barium-133 (Ba-133)	10
Barium-140 (Ba-140)	10
Bismuth-210 (Bi-210)	1
Bromine-82 (Br-82)	10
Cadmium-109 (Cd-109)	10
Cadmium-115m (Cd-115m)	10
Cadmium-115 (Cd-115)	100
Calcium-45 (Ca-45)	10
Calcium-47 (Ca-47)	10
Carbon-14 (C-14)	100
Cerium-141 (Ce-141)	100
Cerium-143 (Ce-143)	100
Cerium-144 (Ce-144)	1
Cesium-129 (Cs-129)	100
Cesium-131 (Cs-131)	1,000
Cesium-134m (Cs-134m)	100
Cesium-134 (Cs-134)	1
Cesium-135 (Cs-135)	10
Cesium-136 (Cs-136)	10
Cesium-137 (Cs-137)	10
Chlorine-36 (Cl-36)	10
Chlorine-38 (Cl-38)	10
Chromium-51 (Cr-51)	1,000
Cobalt-57 (Co-57)	100
Cobalt-58m (Co-58m)	10
Cobalt-58 (Co-58)	10
Cobalt-60 (Co-60)	1
Copper-64 (Cu-64)	100
Dysprosium-165 (Dy-165)	10
Dysprosium-166 (Dy-166)	100
Erbium-169 (Er-169)	100
Erbium-171 (Er-171)	100
Europium-152 (Eu-152) 9.2h	100
Europium-152 (Eu-152) 13 yr	1
Europium-154 (Eu-154)	1
Europium-155 (Eu-155)	10
Fluorine-18 (F-18)	1,000
Gadolinium-153 (Gd-153)	10
Gadolinium-159 (Gd-159)	100
Gallium-67 (Ga-67)	100
Gallium-72 (Ga-72)	10
Germanium-68 (Ge-68)	10
Germanium-71 (Ge-71)	100
Gold-195 (Au 195)	10
Gold-198 (Au-198)	100
Gold-199 (Au-199)	100
Hafnium-181 (Hf-181)	10
Holmium-166 (Ho-166)	100
Hydrogen-3 (H-3)	1,000
Indium-111 (In-111)	100
Indium-113m (In-113m)	100
Indium-114m (In-114m)	10
Indium-115m (In-115m)	100
Indium-115 (In-115)	10
Iodine-123 (I-123)	100
Iodine-125 (I-125)	1
Iodine-126 (I-126)	1
Iodine-129 (I-129)	0.1

Iodine-131 (I-131) 1
Iodine-132 (I-132) 10
Iodine-133 (I-133) 1
Iodine-134 (I-134) 10
Iodine-135 (I-135) 10
Iridium-192 (Ir-192) 10
Iridium-194 (Ir-194) 100
Iron-52 (Fe-52) 10
Iron-55 (Fe-55) 100
Iron-59 (Fe-59) 10
Krypton-85 (Kr-85) 100
Krypton-87 (Kr-87) 10
Lanthanum-140 (La-140) 10
Lutetium-177 (Lu-177) 100
Manganese-52 (Mn-52) 10
Manganese-54 (Mn-54) 10
Manganese-56 (Mn-56) 10
Mercury-197m (Hg-197m) 100
Mercury-197 (Hg-197) 100
Mercury-203 (Hg-203) 10
Molybdenum-99 (Mo-99) 100
Neodymium-147 (Nd-147) 100
Neodymium-149 (Nd-149) 100
Nickel-59 (Ni-59) 100
Nickel-63 (Ni-63) 10
Nickel-65 (Ni-65) 100
Niobium-93m (Nb-93m) 10
Niobium-95 (Nb-95) 10
Niobium-97 (Nb-97) 10
Osmium-185 (Os-185) 10
Osmium-191m (Os-191m) 100
Osmium-191 (Os-191) 100
Osmium-193 (Os-193) 100
Palladium-103 (Pd-103) 100
Palladium-109 (Pd-109) 100
Phosphorus-32 (P-32) 10
Platinum-191 (Pt-191) 100
Platinum-193m (Pt-193m) 100
Platinum-193 (Pt-193) 100
Platinum-197m (Pt-197m) 100
Platinum-197 (Pt-197) 100
Polonium-210 (Po-210) 0.1
Potassium-42 (K-42) 10
Potassium-43 (K-43) 10
Praseodymium-142 (Pr-142) 100
Praseodymium-143 (Pr-143) 100
Promethium-147 (Pm-147) 10
Promethium-149 (Pm-149) 10
Rhenium-186 (Re-186) 100
Rhenium-188 (Re-188) 100
Rhodium-103m (Rh-103m) 100
Rhodium-105 (Rh-105) 100
Rubidium-81 (Rb-81) 10
Rubidium-86 (Rb-86) 10
Rubidium-87 (Rb-87) 10
Ruthenium-97 (Ru-97) 100
Ruthenium-103 (Ru-103) 10
Ruthenium-105 (Ru-105) 10
Ruthenium-106 (Ru-106) 1
Samarium-151 (Sm-151) 10
Samarium-153 (Sm-153) 100
Scandium-46 (Sc-46) 10
Scandium-47 (Sc-47) 100
Scandium-48 (Sc-48) 10
Selenium-75 (Se-75) 10
Silicon-31 (Si-31) 100
Silver-105 (Ag-105) 10
Silver-110m (Ag-110m) 1
Silver-111 (Ag-111) 100
Sodium-22 (Na-22) 10
Sodium-24 (Na-24) 10
Strontium-85 (Sr-85) 10
Strontium-89 (Sr-89) 1
Strontium-90 (Sr-90) 0.1
Strontium-91 (Sr-91) 10
Strontium-92 (Sr-92) 10
Sulfur-35 (S-35) 100
Tantalum-182 (Ta-182) 10
Technetium-96 (Tc-96) 10
Technetium-97m (Tc-97m) 100
Technetium-97 (Tc-97) 100
Technetium-99m (Tc-99m) 100
Technetium-99 (Tc-99) 10
Tellurium-125m (Te-125m) 10

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

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

R313-19-100. Transportation.

For purposes of Section R313-19-100, 10 CFR 71.0(c), 71.1(a), 71.3, 71.4, 71.13, 71.14(a), 71.15, 71.17, 71.19(a), 71.19(b), 71.19(c), 71.20 through 71.23, 71.47, 71.83 through 71.89, 71.97, 71.101(a), 71.101(b), 71.101(c)(1), 71.101(g), 71.105, 71.127 through 71.137, and Appendix A to Part 71 (2019) are incorporated by reference with the following clarifications or exceptions:

(1) The exclusion of the following:

(a) In 10 CFR 71.4 the following definitions:

(i) "close reflection by water";

(ii) "licensed material";

(iii) "optimum interspersed hydrogenous moderation";

(iv) "spent nuclear fuel or spent fuel"; and

(v) "state."

(2) The substitution of the following date reference:

(a) "October 1, 2011" for "October 1, 2008".

(3) The substitution of the following rule references:

(a) "R313-36 (incorporating 10 CFR 34.31(b) by reference)" for "Sec. 34.31(b) of this chapter" as found in 10 CFR 71.101(g);

(b) "R313-15-502" for reference to "10 CFR 20.1502";

(c) "R313-14" for reference to "10 CFR Part 2 Subpart B";

(d) "Rule R313-32, 10 CFR Part 35," for reference to "10 CFR part 35";

(e) "R313-15-906(5)" for reference to "10 CFR 20.1906(e)";

(f) "R313-19-100(5)" for "Sec.71.5";

(g) "10 CFR 71.101(a), 71.101(b), 71.101(c)(1), 71.101(g), 71.105, and 71.127 through 71.137" for "subpart H of this part" or for "subpart H" except in 10 CFR 71.17(b), 71.20(b), 71.21(b), 71.22(b), 71.23(b);

(h) "10 CFR 71.0(c), 71.1(a), 71.3, 71.4, 71.17(c)(2), 71.20(c)(2), 71.21(d)(2), 71.83 through 71.89, 71.97, 71.101(a), 71.101(b), 71.101(c)(1), 71.101(g), 71.105, and 71.127 through 71.137" for "subparts A, G, and H of this part";

(i) "10 CFR 71.47" for "subparts E and F of this part"; and

(j) "10 CFR 71.101(a), 71.101(b), 71.101(c)(1), 71.101(g), 71.105, and 71.127 through 71.137" for "Sec. Sec. 71.101 through 71.137."

(4) The substitution of the following terms:

(a) "Director" for:

(i) "Commission" in 10 CFR 71.0(c), 71.17(a), 71.20(a), 71.21(a), 71.22(a), 71.23(a), and 71.101(c)(1);

(ii) "Director, Division of Nuclear Safety, Office of Nuclear Security and Incident Response" in 10 CFR 71.97(c)(1), and 71.97(f)(1);

(iii) "Director, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001" in 10 CFR 71.97(c)(3)(iii);

(iv) "NRC" in 10 CFR 71.101(f);

(b) "Director, the U.S. Nuclear Regulatory Commission, or an Agreement State" for "Commission" in 10 CFR 71.3;

(c) "The Governor of Utah" for:

(i) "the governor of a State" in 71.97(a);

(ii) "each appropriate governor" in 10 CFR 71.97(c)(1);

(iii) "the governor" in 10 CFR 71.97(c)(3);

(iv) "the governor of the state" in 10 CFR 71.97(e);

(v) "the governor of each state" in 10 CFR 71.97(f)(1);

(vi) "a governor" in 10 CFR 71.97(e);

(d) "State of Utah" for "State" in 71.97(a), 71.97(b)(2), and 71.97(d)(4);

(e) "the Governor of Utah's" for:

(i) "the governor's" in 10 CFR 71.97(a), 71.97(c)(3), 71.97(c)(3)(iii), 71.97(e), and 71.97(f)(1);

(ii) "governor's" in 10 CFR 71.97(c)(1), and 71.97(e);

(f) "Specific or general" for "NRC" in 10 CFR 71.0(c);

(g) "The Director at the address specified in R313-12-110" for reference to "ATTN: Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards" in 10 CFR 71.101(c)(1);

(h) "Each" for "Using an appropriate method listed in Sec. 71.1(a), each" in 10 CFR 71.101(c)(1);

(i) "The material must be contained in a Type A package meeting the requirements of 49 CFR 173.417(a)." for "The fissile material need not be contained in a package which meets the standards of subparts E and F of this part; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a)." as found in 10 CFR 71.22(a) and 71.23(a);

(j) "Licensee" for "licensee, certificate holder, and applicant for a COC"; and

(k) "Licensee is" for reference to "licensee, certificate holder, and applicant for a COC are."

(5) Transportation of licensed material

(a) Each licensee who transports licensed material outside the site of usage, as specified in the license issued by the Director, the U.S. Nuclear Regulatory Commission or an Agreement State, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the U.S. Department of Transportation regulations in 49 CFR parts 107, 171 through 180, and 390 through 397 (2009), appropriate to the mode of transport.

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

(A) Packaging--49 CFR part 173: subparts A (49 CFR 173.1 through 49 CFR 173.13), B (49 CFR 173.21 through 49 CFR 173.40), and I (49 CFR 173.401 through 49 CFR 173.477).

(B) Marking and labeling--49 CFR part 172: subpart D (49 CFR 172.300 through 49 CFR 172.338); and 49 CFR 172.400 through 49 CFR 172.407 and 49 CFR 172.436 through 49 CFR 172.441 of subpart E.

(C) Placarding--49 CFR part 172: subpart F (49 CFR 172.500 through 49 CFR 172.560), especially 49 CFR 172.500 through 49 CFR 172.519 and 49 CFR 172.556; and appendices B and C.

(D) Accident reporting--49 CFR part 171: 49 CFR 171.15 and 171.16.

(E) Shipping papers and emergency information--49 CFR part 172: subparts C (49 CFR 172.200 through 49 CFR 172.205) and G (49 CFR 172.600 through 49 CFR 172.606).

(F) Hazardous material employee training--49 CFR part 172: subpart H (49 CFR 172.700 through 49 CFR 172.704).

(G) Security plans--49 CFR part 172: subpart I (49 CFR 172.800 through 49 CFR 172.804).

(H) Hazardous material shipper/carrier registration--49 CFR part 107: subpart G (49 CFR 107.600 through 49 CFR 107.606).

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

(A) Rail--49 CFR part 174: subparts A through D (49 CFR 174.1 through 49 CFR 174.86) and K (49 CFR 174.700 through 49 CFR 174.750).

(B) Air--49 CFR part 175.

(C) Vessel--49 CFR part 176: subparts A through F (49 CFR 176.1 through 49 CFR 176.99) and M (49 CFR 176.700 through 49 CFR 107.720).

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

(b) If DOT regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the DOT specified in paragraph (a) of this section to the same extent as if the shipment or transportation were subject to DOT regulations. A request for modification, waiver, or exemption from those requirements, and any notification referred to in those requirements, must be filed with, or made to, the Director, P.O. Box 144850, Salt Lake City, Utah 84114-4850.

KEY: licenses, reciprocity, transportation, exemptions
Date of Enactment or Last Substantive Amendment: February 14, 2020
Notice of Continuation: July 1, 2016
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-104

State of Utah
Administrative Rule Analysis
Revised December 2019

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION		
	Title No. - Rule No.	
Utah Admin. Code Ref (R no.):	**R313-22**	**Filing No. (Office Use Only)**

Agency Information

1. Department:	Department of Environmental Quality	
Agency:	Waste Management and Radiation Control	
Room no.:	Second Floor	
Building:	MASOB	
Street address:	195 North 1950 West	
City, state, zip:	Salt Lake City, Utah 84116	
Mailing address:	PO Box 144880	
City, state, zip:	Salt Lake City, Utah 84114-4880	
Contact person(s):		
Name:	**Phone:**	**Email:**
Tom Ball	801-536-0251	tball@utah.gov
Please address questions regarding information on this notice to the agency.		

General Information

2. Rule catchline:

Specific Licenses.

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Utah Code Subsection 19-3-104(4) allows the Waste Management and Radiation Control Board to make rules to meet the requirements of federal law relating to radiation control to ensure the radiation control program under this part is qualified to maintain primacy from the federal government. R313-22 contains the rules adopted by the board and as part of the state primacy of the radiation control program, the rules in R313-22 have been reviewed by the U.S. Nuclear Regulatory Commission (NRC) and have been determined to be compatible with the corresponding federal radiation protection regulations.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

Since the last five-year review there have been no comments from interested persons specifically supporting or opposing this rule.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

This rule is necessary because it prescribes requirements for the issuance of "specific licenses" for control of radioactive material. This rule also needs to be continued to ensure that the state's rules are adequate to protect public health and safety. The rule prescribes procedures for filing an application, assuring financial surety for decommissioning facilities where radioactive materials are used, and requirements for "specific licenses" of broad scope. As an Agreement State the rule is necessary for maintaining the appropriate regulatory compatibility with the NRC. There have been no opposing comments to the rules since the last five-year review in 2016.

Agency Authorization Information

To the agency: Information requested on this form is required by Section 63G-3-305. Incomplete forms will be returned to the agency for completion, possibly delaying the effective date.

Agency head or designee, and title:		**Date** (mm/dd/yyyy)**:**	

Reminder: Text changes cannot be made with this type of rule filing. To change any text, please file an amendment or nonsubstantive change.

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.
R313-22. Specific Licenses.
R313-22-1. Purpose and Authority.

(1) The purpose of this rule is to prescribe the requirements for the issuance of specific licenses.

(2) The rules set forth herein are adopted pursuant to the provisions of Subsections 19-3-104(4) and 19-3-104(7).

R313-22-2. General.

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

R313-22-4. Definitions.

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

"Nationally tracked source" is a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix E of 10 CFR 20.1001 to 20.2402 (2017), which is incorporated by reference. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

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

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

R313-22-30. Specific License by Rule.

A license by rule is issued in the following circumstances, without the necessity of filing an application for a specific license as required by Subsection R313-22-32(1), and the licensee shall be subject to the applicable provisions of Sections R313-22-33, R313-22-34, R313-22-35, R313-22-36 and R313-22-37:

(1) When a site must be timely remediated of contamination by radioactive materials that are subject to licensing under these rules but are unlicensed;

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

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

(1) Applications for specific licenses shall be filed on a form prescribed by the 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)(i) Except as provided in R313-22 (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 10 CFR 32.210(c) (January 1, 2015).

(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 10 CFR 32.210(c) (January 1, 2015), the application must include:

(A) All available information identified in 10 CFR 32.210(c) (January 1, 2015) 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 Emmission Tomography (PET) radioactive drugs for non-commercial transfer to licensees in its consortium authorized for medical use under Rule R313-32 shall include:

(a) A request for authorization for the production of PET radionuclides or evidence of an existing license issued pursuant to 10 CFR Part 30 or equivalent Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(b) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in Subsection R313-22-75(9)(a)(ii).

(c) Identification of the individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in Rule R313-32.

(d) Information identified in Subsection R313-22-75(9)(a)(iii) on the PET drugs to be noncommercially transferred to members of its consortium.

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

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

(a) the applicant and all personnel who will be handling the radioactive material are qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these rules in a manner as to minimize danger to public health and safety or the environment;

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

(c) the applicant's facilities are permanently located in Utah, otherwise the applicant shall seek reciprocal recognition as required by Section R313-19-30;

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

(e) the applicant satisfies applicable special requirements in Sections R313-22-50, R313-22-54, and R313-22-75, and Rules R313-24, R313-25, R313-32, R313-34, R313-36, or R313-38; and

(f) in the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, or for the conduct of other activities which the Director determines will significantly affect the quality of the environment, the Director, before commencement of construction of the plant or facility in which the activity will be conducted, has concluded, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. The Director shall respond to the application within 60 days. Commencement of construction prior to a response and conclusion shall be grounds for denial of a license to receive and possess radioactive material in the plant or facility.

R313-22-34. Issuance of Specific Licenses.

(1) Upon a determination that an application meets the requirements of the Act and the rules of the Board, the Director will issue a specific license authorizing the proposed activity in a form and containing conditions and limitations as the Director deems appropriate or necessary.

(a) Specific licenses for a new license application shall have an expiration date five years from the end of the month in which it is issued.

(b) Specific licenses for a renewed license shall expire ten years after the expiration date of the previous version of the license.

(c) Notwithstanding R313-22-34(1)(b), if during the review of the license renewal application, the Director determines issues that need to be reassessed sooner than the ten year renewal interval, the Director may shorten the renewal interval on a case by case basis. Examples of issues that may result in a shortened renewal interval includes new technologies, new company management, poor regulatory compliance, or other situations that would warrant increased attention.

(2) The Director may incorporate in licenses at the time of issuance, or thereafter, additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to Rule R313-22 as the Director deems appropriate or necessary in order to:

(a) minimize danger to public health and safety or the environment;

(b) require reports and the keeping of records, and to provide for inspections of activities under the license as may be appropriate or necessary; and

(c) prevent loss or theft of material subject to Rule R313-22.

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

(1)(a) Applicants for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than

120 days and in quantities exceeding 10^5 times the applicable quantities set forth in Appendix B of 10 CFR 30.1 through 30.72, 2010, which is incorporated by reference, shall submit a decommissioning funding plan as described in Subsection R313-22-35(5). The decommissioning funding plan shall also be submitted when a combination of radionuclides is involved if R divided by 10^5 is greater than one, where R is defined here as the sum of the ratios of the quantity of each radionuclide to the applicable value in Appendix B of 10 CFR 30.1 through 30.72, 2010, which is incorporated by reference.

(b) Holders of, or applicants for, a specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding 10^{12} times the applicable quantities set forth in Appendix B of 10 CFR 30.1 through 30.72, 2010, which is incorporated by reference, or when a combination of isotopes is involved if R, as defined in Subsection R313-22-35(1)(a), divided by 10^{12} is greater than one, shall submit a decommissioning funding plan as described in Subsection R313-22-35(5).

(c) Applicants for a specific license authorizing the possession and use of more than 100 mCi of source material in a readily dispersible form shall submit a decommissioning funding plan as described in Subsection R313-22-35(5).

(2) Applicants for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in Subsection R313-22-35(4), or authorizing the possession and use of source material greater than 10 mCi but less than or equal to 100 mCi in a readily dispersible form shall either:

(a) submit a decommissioning funding plan as described in Subsection R313-22-35(5); or

(b) submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by Subsection R313-22-35(4) using one of the methods described in Subsection R313-22-35(6). Applicants for a specific license authorizing the possession and use of source material in a readily dispersible form shall submit a certification that financial assurance for decommissioning has been provided in the amount of $225,000 by October 20, 2007. For an applicant subject to this subsection, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but before the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of Subsection R313-22-35(6) shall be submitted to the Director before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the Director, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements in Subsection R313-22-35(6).

(3)(a) Holders of a specific license issued on or after October 20, 2006, which is of a type described in Subsections R313-22-35(1) or (2), shall provide financial assurance for decommissioning in accordance with the criteria set forth in Section R313-22-35.

(b) Holders of a specific license issued before October 20, 2006, and of a type described in Subsection R313-22-35(1), shall submit by October 20, 2007, a decommissioning funding plan as described in Subsection R313-22-35(5) or a certification of financial assurance for decommissioning in an amount at least equal to $1,125,000 in accordance with the criteria set forth in Section R313-22-35. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan, the licensee shall include a decommissioning funding plan in any application for license renewal.

(c) Holders of a specific license issued before October 20, 2006, and of a type described in Subsection R313-22-35(2), shall submit by October 20, 2007, a decommissioning funding plan as described in Subsection R313-22-35(5) or a certification of financial assurance for decommissioning in accordance with the criteria set forth in Section R313-22-35.

(d) A licensee who has submitted an application before October 20, 2006, for renewal of license in accordance with Section R313-22-37, shall provide financial assurance for decommissioning in accordance with Subsections R313-22-35(1) and (2).

(e) Waste collectors and waste processors, as defined in Appendix G of 10 CFR 20.1001 to 20.2402, 2015, which is incorporated by reference, shall provide financial assurance in an amount based on a decommissioning funding plan as described in Subsection R313-22-35(5). The decommissioning funding plan shall include the cost of disposal of the maximum amount (curies) of radioactive material permitted by the license, and the cost of disposal of the maximum quantity, by volume, of radioactive material which could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of Rule R313-15.

(f) If, in surveys made under R313-15-501(1), residual radioactivity in the facility and environment, including the subsurface, is detected at levels that would, if left uncorrected, prevent the site from meeting the R313-15-402 criteria for unrestricted use, the licensee shall submit a decommissioning funding plan within one year of when the survey is completed.

(g) Holders of a specific license issued prior to October 20, 2006, which is of a type described in Subsections R313-22-35(1), (2), or (3)(h), shall submit a decommissioning funding plan to the Director on or before October 20, 2007. Holders of a specific license issued on or after October 20, 2006, which is of a type described in Subsections R313-22-35(1), (2), or (3)(h), shall submit a decommissioning funding plan to the Director as a part of the license application.

(h) Applicants for a specific license authorizing the possession and use of radioactive materials in sufficient quantities that require financial assurance and recordkeeping for decommissioning under Section R313-22-35 shall assure that all documents submitted to the Director for the purpose of demonstrating compliance with financial assurance and recordkeeping requirements meet the applicable criteria contained in the Nuclear Regulatory Commission's document NUREG-1757, Volume 3, "Consolidated NMSS Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness" (9/2003).

(i) Documents provided to the Director under Subsection R313-22-35(3)(h) shall provide that legal remedies be sought in a court of appropriate jurisdiction within Utah.

(4) Table of required amounts of financial assurance for decommissioning by quantity of material. Licensees required to submit an amount of financial assurance listed in this table must do so during a license application or as part of an amendment to an existing license. Licensees having possession limits exceeding the upper bounds of this table must base financial assurance on a decommissioning funding plan.

TABLE

Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of radioactive material, as defined in Appendix B of 10 CFR 30.1 through 30.72 (2010) which is incorporated by reference, in unsealed form. For a combination of radionuclides, if R, as defined in Subsection R313-22-35(1)(a) divided by 10^4 is greater than one but R divided by 10^5 is less than or equal to one:	$1,125,000
Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of radioactive material, as defined in Appendix B of 10 CFR 30.1 through 30.72 (2010) which is incorporated by reference, in unsealed form. For a combination of radionuclides, if R, as defined in Subsection R313-22-35(1)(a) divided by 10^3 is greater than one but R divided by 10^4 is less than or equal to one:	$225,000
Greater than 10^{10} but less than or equal to 10^{12} times the applicable quantities of radioactive material, as defined in Appendix B of 10 CFR 30.1 through 30.72 (2010) which is incorporated by reference, in sealed sources or plated foils. For combination of radionuclides, if R, as defined in R313-22-35(1)(a), divided by 10^{10} is greater than one, but R divided by 10^{12} is less than or equal to one:	$113,000

(5)(a) Each decommissioning funding plan shall be submitted for review and approval and shall contain-

(i) A detailed cost estimate for decommissioning, in an amount reflecting:

(A) The cost of an independent contractor to perform all decommissioning activities;

(B) The cost of meeting the R313-15-402 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of R313-15-403, the cost estimate may be based on meeting the R313-15-403 criteria;

(C) The volume of onsite subsurface material containing residual radioactivity that will require remediation; and

(D) An adequate contingency factor.

(ii) Identification of and justification for using the key assumptions contained in the decommissioning cost estimate;

(iii) A description of the method of assuring funds for decommissioning from R313-22-35(6), including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

(iv) A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

(v) A signed original of the financial instrument obtained to satisfy the requirements of R313-22-35(6) (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

(b) At the time of license renewal and at intervals not to exceed 3 years, the decommissioning funding plan shall be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this cannot be done until the updated decommissioning funding plan is approved. The decommissioning funding plan shall update the information submitted with the original or prior approved plan, and shall specifically consider the effect of the following events on decommissioning costs:

(i) Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;

(ii) Waste inventory increasing above the amount previously estimated;

(iii) Waste disposal costs increasing above the amount previously estimated;

(iv) Facility modifications;

(v) Changes in authorized possession limits;

(vi) Actual remediation costs that exceed the previous cost estimate;

(vii) Onsite disposal; and

(viii) Use of a settling pond.

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

(a) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets so that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities;

(b) A surety method, insurance, or other guarantee method. These methods shall guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Subsection R313-22-35(8). A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of Section R313-22-35. A guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Subsection R313-22-35(9). A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of Section R313-22-35 or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. A surety method or insurance used to provide financial assurance for decommissioning shall contain the following conditions:

(i) the surety method or insurance shall be open-ended or, if written for a specified term, such as five years, shall be renewed automatically unless 90 days or more prior to the renewal date the issuer notifies the Director, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance shall also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Director within 30 days after receipt of notification of cancellation,

(ii) the surety method or insurance shall be payable to a trust established for decommissioning costs. The trustee and trust shall be acceptable to the Director. An acceptable trustee includes an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency, and

(iii) the surety method or insurance shall remain in effect until the Director has terminated the license;

(c) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions shall be as stated in Subsection R313-22-35(6)(b);

(d) In the case of Federal, State or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in Subsection R313-22-35(4) and indicating that funds for decommissioning will be obtained when necessary; or

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

(7) Persons licensed under Rule R313-22 shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with Subsection R313-19-34(2), licensees shall transfer all records described in Subsections R313-22-35(7)(a) through (d) to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the Director considers important to decommissioning consists of the following:

(a) records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records shall include any known information on identification of involved nuclides, quantities, forms, and concentrations;

(b) as-built drawings and modification of structures and equipment in restricted areas where radioactive materials are used or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations;

(c) except for areas containing only sealed sources, provided the sources have not leaked or no contamination remains after a leak, or radioactive materials having only half-lives of less than 65 days, a list contained in a single document and updated every two years, including all of the following:

(i) all areas designated and formerly designated as restricted areas as defined under Section R313-12-3;

(ii) all areas outside of restricted areas that require documentation under Subsection R313-22-35(7)(a);

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

(iv) all areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in Sections R313-15-401 through R313-15-406, or apply for

approval for disposal under Section R313-15-1002; and

(d) records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

(8) Criteria relating to use of financial tests and parent company guarantees for providing reasonable assurance of funds for decommissioning.

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

(i) The parent company shall have all of the following:

(A) Two of the following three ratios: a ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5;

(B) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates, or prescribed amount if a certification is used;

(C) Tangible net worth of at least $10 million; and

(D) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates, or prescribed amount if a certification is used; or

(ii) The parent company shall have all of the following:

(A) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or Aaa, Aa, A or Baa as issued by Moody's;

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

(C) Tangible net worth of at least $10 million; and

(D) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates, or prescribed amount if certification is used.

(b) The parent company's independent certified public accountant shall have compared the data used by the parent company in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform the Director within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(c)(i) After the initial financial test, the parent company shall repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

(ii) If the parent company no longer meets the requirements of Subsection R313-22-35(8)(a) the licensee shall send notice to the Director of intent to establish alternative financial assurance as specified in Section R313-22-35. The notice shall be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee shall provide alternate financial assurance within 120 days after the end of such fiscal year.

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

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

(ii) If the licensee fails to provide alternate financial assurance as specified in Section R313-22-35 within 90 days after receipt by the licensee and Director of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

(iii) The parent company guarantee and financial test provisions shall remain in effect until the Director has terminated the license.

(iv) If a trust is established for decommissioning costs, the trustee and trust shall be acceptable to the Director. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(9) Criteria relating to use of financial tests and self guarantees for providing reasonable assurance of funds for decommissioning.

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

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

(ii) Assets located in the United States amounting to at least 90 percent of total assets or at least ten times the total current decommissioning cost estimate, or the current amount required if certification is used, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor; and

(iii) A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poor's, or Aaa, Aa, or A as issued by Moody's.

(b) To pass the financial test, a company shall meet all of the following additional requirements:

(i) The company shall have at least one class of equity securities registered under the Securities Exchange Act of 1934;

(ii) The company's independent certified public accountant shall have compared the data used by the company in the financial test

which is derived from the independently audited, yearend financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Director within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test; and

(iii) After the initial financial test, the company shall repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(c) If the licensee no longer meets the requirements of Subsection R313-22-35(9)(a), the licensee shall send immediate notice to the Director of its intent to establish alternate financial assurance as specified in Section R313-22-35 within 120 days of such notice.

(d) The terms of a self-guarantee which an applicant or licensee furnishes shall provide that:

(i) The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Director. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Director, as evidenced by the return receipt.

(ii) The licensee shall provide alternative financial assurance as specified in Section R313-22-35 within 90 days following receipt by the Director of a notice of a cancellation of the guarantee.

(iii) The guarantee and financial test provisions shall remain in effect until the Director has terminated the license or until another financial assurance method acceptable to the Director has been put in effect by the licensee.

(iv) The licensee shall promptly forward to the Director and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

(v) If, at any time, the licensee's most recent bond issuance ceases to be rated in a category of "A" or above by either Standard and Poor's or Moody's, the licensee shall provide notice in writing of such fact to the Director within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poor's and Moody's, the licensee no longer meets the requirements of Subsection R313-22-35(9)(a).

(vi) The applicant or licensee shall provide to the Director a written guarantee, a written commitment by a corporate officer, which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Director, the licensee shall set up and fund a trust in the amount of the current cost estimates for decommissioning.

R313-22-36. Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas.

(1) A specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under Section R313-22-37 no less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days prior to the expiration date stated in the existing license, the existing license expires at the end of the day on which the Director makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(2) A specific license revoked by the Director expires at the end of the day on the date of the Director's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by an Order issued by the Director.

(3) A specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the Director notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

(a) limit actions involving radioactive material to those related to decommissioning; and

(b) continue to control entry to restricted areas until they are suitable for release so that there is not an undue hazard to public health and safety or the environment.

(4) Within 60 days of the occurrence of any of the following, a licensee shall provide notification to the Director in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release so that there is not an undue hazard to public health and safety or the environment, or submit within 12 months of notification a decommissioning plan, if required by Subsection R313-22-36(7), and begin decommissioning upon approval of that plan if:

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

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

(c) no principal activities under the license have been conducted for a period of 24 months; or

(d) no principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release because of an undue hazard to public health and safety or the environment.

(5) Coincident with the notification required by Subsection R313-22-36(4), the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to Section R313-22-35 in conjunction with a license issuance or renewal or as required by Section R313-22-36. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to Subsection R313-22-36(7)(d)(v).

(a) A licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so on or before August 15, 1997.

(b) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as

decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Director.

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

(7)(a) A decommissioning plan shall be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Director and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(i) procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(ii) workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(iii) procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(iv) procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(b) The Director may approve an alternate schedule for submittal of a decommissioning plan required pursuant to Subsection R313-22-36(4) if the Director determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(c) Procedures such as those listed in Subsection R313-22-36(7)(a) with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(d) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(i) a description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(ii) a description of planned decommissioning activities;

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

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

(v) an updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(vi) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in Subsection R313-22-36(8).

(e) The proposed decommissioning plan will be approved by the Director if the information therein demonstrates that the decommissioning will be completed as soon as practical and that the health and safety of workers and the public will be adequately protected.

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

(b) Except as provided in Subsection R313-22-36(9), when decommissioning involves the entire site, the licensee shall request license termination as soon as practical but no later than 24 months following the initiation of decommissioning.

(9) The Director may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Director determines that the alternative is warranted by consideration of the following:

(a) whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(b) whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(c) whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(d) whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(e) other site-specific factors which the Director may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

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

(a) certify the disposition of all licensed material, including accumulated wastes, by submitting a completed Form DWMRC-14 or equivalent information; and

(b) conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in Sections R313-15-401 through R313-15-406. The licensee shall, as appropriate:

(i) report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters--removable and fixed-- for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per

gram for solids such as soils or concrete; and

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

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

(a) radioactive material has been properly disposed;

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

(c) documentation is provided to the Director that:

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

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

R313-22-37. Renewal of Licenses.

Application for renewal of a specific license shall be filed on a form prescribed by the Director and in accordance with Section R313-22-32.

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

Applications for amendment of a license shall be filed in accordance with Section R313-22-32 and shall specify the respects in which the licensee desires the license to be amended and the grounds for the amendment.

R313-22-39. Director Action on Applications to Renew or Amend.

In considering an application by a licensee to renew or amend the license, the Director will use the criteria set forth in Sections R313-22-33, R313-22-50, and R313-22-75 and in Rules R313-24, R313-25, R313-32, R313-34, R313-36, or R313-38, as applicable.

R313-22-50. Special Requirements for Specific Licenses of Broad Scope.

Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity or other product containing byproduct material whose subsequent possession, use, transfer and disposal by all other persons who are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(1) The different types of broad licenses are set forth below:

(a) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

(b) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Section R313-22-100 for any authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Section R313-22-100, Column I. If two or more radionuclides are possessed thereunder, the possession limits are determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Section R313-22-100, Column I, for that radionuclide. The sum of the ratios for the radionuclides possessed under the license shall not exceed unity.

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

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

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

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

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

(i) the establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;

(ii) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(iii) the establishment of appropriate administrative procedures to assure:

(A) control of procurement and use of radioactive material,

(B) completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures, and

(C) review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with Subsection R313-22-50(2)(c)(iii)(B) prior to use of the radioactive material.

(3) An application for a Type B specific license of broad scope shall be approved if all of the following are complied with:

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

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

(i) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(ii) the establishment of appropriate administrative procedures to assure:

(A) control of procurement and use of radioactive material,

(B) completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures, and

(C) review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with Subsection R313-22-50(3)(b)(iii)(B) prior to use of the radioactive material.

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

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

(b) the applicant submits a statement that radioactive material will be used only by, or under the direct supervision of individuals, who have received:

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

(ii) at least forty hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

(c) the applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, recordkeeping, material control and accounting, and management review necessary to assure safe operations.

(5) Specific licenses of broad scope are subject to the following conditions:

(a) unless specifically authorized by the Director, persons licensed pursuant to this section shall not:

(i) conduct tracer studies in the environment involving direct release of radioactive material;

(ii) receive, acquire, own, possess, use, or transfer devices containing 100,000 curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;

(iii) conduct activities for which a specific license issued by the Director under Section R313-22-75, and Rules R313-25, R313-32 or R313-36 is required; or

(iv) add or cause the addition of radioactive material to a food, beverage, cosmetic, drug or other product designed for ingestion or inhalation by, or application to, a human being.

(b) Type A specific licenses of broad scope issued under Rule R313-22 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(c) Type B specific license of broad scope issued under Rule R313-22 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

(d) Type C specific license of broad scope issued under Rule R313-22 shall be subject to the condition that radioactive material possessed under the license may only be used, by or under the direct supervision of, individuals who satisfy the requirements of Subsection R313-22-50(4).

R313-22-54. Requirements for a Specific License to Initially Transfer Source Material for Use Under Section R313-21-21.

(1) An application for a specific license to initially transfer source material for use under Section R313-21-21, or 10 CFR 40.22 for a non-Agreement State, or equivalent regulations of an Agreement State, will be approved if:

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

(b) The applicant submits adequate information on, and the Director approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.

R313-22-55. Conditions of Specific Licenses to Initially Transfer Source Material for Use Under Section R313-21-21.

(1)(a) Each person licensed under Section R313-22-54 shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words, "radioactive material."

(b) Each person licensed under Section R313-22-54 shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

(c) Each person licensed under Section R313-22-54 shall provide the information specified in Subsections R313-22-55(1)(c)(i) and (c)(ii) to each person to whom source material is transferred for use under Section R313-21-21 or 10 CFR 40.22 for non-Agreement States or equivalent provisions in Agreement State regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

(i) A copy of Sections R313-21-21 and R313-19-41, or relevant equivalent regulations of the Agreement State.

(ii) Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

(d) Each person licensed under Section R313-22-54 shall report transfers as follows:

(i) File a report with the Director. The report shall include the following information:

(A) The name, address, and license number of the person who transferred the source material;

(B) For each general licensee under Section R313-21-21 or 10 CFR 40.22 for non-Agreement States or equivalent Agreement State provisions to whom greater than 50 grams (0.11 pounds) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name or position or both and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

(C) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

(ii) File a report with:

(A) Each responsible Agreement State agency that identifies all persons, operating under provisions equivalent to 10 CFR 40.22 (2016), to whom greater than 50 grams (0.11 pounds) of source material has been transferred within a single calendar quarter; or

(B) The U.S. Nuclear Regulatory Commission for non-Agreement States, that identifies all persons, operating under 10 CFR 40.22 (2016), to whom greater than 50 grams (0.11 pounds) of source material has been transferred within a single calendar quarter.

(C) The report shall include the following information specific to those transfers made to the Agreement State being reported to:

(I) The name, address, and license number of the person who transferred the source material; and

(II) The name and address of the general licensee to whom source material was distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred.

(III) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the Agreement State or non-Agreement State.

(iii) Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under Section R313-21-21 or 10 CFR 40.22, or equivalent Agreement State provisions during the current period, a report shall be submitted to the Director indicating so. If no transfers have been made to general licensees in a particular Agreement State or non-Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency or the U.S. Nuclear Regulatory Commission upon request of the agency or Commission.

(e) Each person licensed under Section R313-22-54 shall maintain all information that supports the reports required by Section R313-22-55 concerning each transfer to a general licensee for a period of one year after the event is included in a report to the Director.

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

(1) Licensing the introduction of radioactive material in exempt concentrations into products or materials, and transfer of ownership or possession of the products and materials.

(a) The authority to introduce radioactive material in exempt concentrations into equipment, devices, commodities or other products may be obtained only from the Nuclear Regulatory Commission, Washington, D.C. 20555; and

(b) The manufacturer, processor or producer of equipment, devices, commodities or other products containing exempt concentrations of radioactive materials may obtain the authority to transfer possession or control of the equipment, devices, commodities, or other products containing exempt concentrations to persons who are exempt from regulatory requirements only from the Nuclear Regulatory Commission, Washington, D.C. 20555.

(2) Licensing the distribution of radioactive material in exempt quantities. Authority to transfer possession or control by the manufacturer, processor or producer of equipment, devices, commodities or other products containing byproduct material whose subsequent possession, use, transfer, and disposal by other persons who are exempted from regulatory requirements may be obtained only from the Nuclear Regulatory Commission, Washington, D.C. 20555.

(3) Reserved

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

(a) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under Subsection R313-21-22(4) or equivalent regulations of the Nuclear Regulatory Commission, an Agreement State or a Licensing State will be approved if:

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

(ii) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(A) the device can be safely operated by persons not having training in radiological protection,

(B) under ordinary conditions of handling, storage and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that a person will receive in one year, a dose in excess of ten percent of the annual limits specified in Subsection R313-15-201(1), and

(C) under accident conditions, such as fire and explosion, associated with handling, storage and use of the device, it is unlikely that a person would receive an external radiation dose or dose commitment in excess of the following organ doses:

TABLE

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

(iii) each device bears a durable, legible, clearly visible label or labels approved by the 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.

(iv) 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.

(v) 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.

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

(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 Director'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 (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, and 10 CFR 70.39 (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, 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 commits to 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); 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) A licensee shall satisfy the labeling requirements in R313-22-75(9)(a)(iv).

(e) 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) 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(7) 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(7) and a copy of form DWMRC-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(7) 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(7) and a copy of form DWMRC-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(7);

(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(7). 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(7) 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(7),

(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(7) or equivalent regulations of the Nuclear Regulatory Commission or an Agreement State. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in the product or device transferred, and compliance with the report requirements of Subsection R313-22-75(11).

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

TABLE

Radioactive Material(1)	Release Fraction	Quantity (curies)
Actinium-228	0.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252 (20 mg)	.001	9
Carbon-14	.01	50,000
	Non CO	
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000

Germanium-68	.01	2,000
Gadolinium-153	.01	5,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holmium-166m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10
Indium-114m	.01	1,000
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Ruthenium-106	.01	200
Radium-226	.001	100
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment, beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000

Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma(2)	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha(2)	.0001	20
Combinations of radioactive materials listed above(1)	-----	-----

(1) For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Section R313-22-90 exceeds one.

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

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

TABLE

RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	1	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1
Cesium-134m	100	1
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1
Chromium-51	100	1
Cobalt-57	10	0.1
Cobalt-58m	100	1
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1

Dysprosium-165	100	1
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 (9.2h)	10	0.1
Europium-152 (13y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1
Indium-113m	100	1
Indium-114m	1	0.01
Indium-115m	100	1
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.01
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1
Krypton-87	10	0.1
Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1
Osmium-185	1	0.01
Osmium-191m	100	1
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	0.01

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

Thulium-171	1	0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-187	10	0.1
Vanadium-48	1	0.01
Xenon-131m	1,000	10
Xenon-133	100	1
Xenon-135	100	1
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01
Zinc-69m	10	0.1
Zinc-69	100	1
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01
Any radioactive material other than source material, special nuclear material, or alpha-emitting radioactive material not listed above	0.1	0.001

R313-22-201. Serialization of Nationally Tracked Sources.

Each licensee who manufacturers a nationally tracked source after October 19, 2007, shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

R313-22-210. Registration of Product Information.

Licensees who manufacture or initially distribute a sealed source or device containing a sealed source whose product is intended for use under a specific license or general license are deemed to have provided reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and the environment if the sealed source or device has been evaluated in accordance with 10 CFR 32.210 (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: August 9, 2019
Notice of Continuation: July 1, 2016
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-104

State of Utah
Administrative Rule Analysis
Revised December 2019

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION		
	Title No. - Rule No.	
Utah Admin. Code Ref (R no.):	**R313-25**	**Filing No. (Office Use Only)**

Agency Information

1. Department:	Department of Environmental Quality	
Agency:	Waste Management and Radiation Control	
Room no.:	Second Floor	
Building:	MASOB	
Street address:	195 North 1950 West	
City, state, zip:	Salt Lake City, Utah 84116	
Mailing address:	PO Box 144880	
City, state, zip:	Salt Lake City, Utah 84114-4880	
Contact person(s):		
Name:	**Phone:**	**Email:**
Tom Ball	801-536-0251	tball@utah.gov
Please address questions regarding information on this notice to the agency.		

General Information

2. Rule catchline:

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

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Utah Code Subsection 19-3-104(4) allows the Waste Management and Radiation Control Board to make rules to meet the requirements of federal law relating to radiation control to ensure the radiation control program under this part is qualified to maintain primacy from the federal government. R313-25 contains the rules adopted by the board and as part of the state primacy of the radiation control program, the rules in R313-25 have been reviewed by the U.S. Nuclear Regulatory Commission (NRC) and have been determined to be compatible with the corresponding federal radiation protection regulations.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

Since the last five-year review, the division has received comments related to R313-25. In October of 2016, an entity submitted a petition to initiate rulemaking requesting that R313-25 by repealed and reenacted by adopting 10 CFR Part 61 by reference in its place. In December of 2016, the entity rescinded its petition.
Following the publication of the notice of continuation associated with the last five-year review of R313-25 an entity submitted comments requesting wording changes to R313-25-31(10)(a) so that the rule would only apply to above-ground structures and the deletion of R313-25-31.5(3) because they did not believe that legislation did not support the existence of the rule. These same comments were re-submitted in November of 2017 during the public comment period for a proposed amendment to R313-25.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

This rule is necessary because it establishes the procedures, criteria, and terms and conditions upon which a license may be issued for the land disposal of radioactive wastes. It is necessary to continue this rule because of the presence of an active low-level radioactive waste disposal facility in the State of Utah. As an Agreement State the rule is necessary for maintaining the appropriate regulatory compatibility with the NRC.
In response to the comment suggesting wording changes to R313-25-31(10)(a) the division stated that the language in the rule was taken verbatim from legislation and thus making the suggested changes would require legislative action.
In response to the comment to delete R313-25-31.5(3) the division responded by making the deletion.

Agency Authorization Information

To the agency: Information requested on this form is required by Section 63G-3-305. Incomplete forms will be returned to the agency for completion, possibly delaying the effective date.

Agency head or designee, and title:		**Date** (mm/dd/yyyy)**:**	
Reminder: Text changes cannot be made with this type of rule filing. To change any text, please file an amendment or nonsubstantive change.			

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.
R313-25. License Requirements for Land Disposal of Radioactive Waste - General Provisions.
R313-25-1. Purpose and Authority.

(1) The purpose of this rule is to prescribe the requirements for the issuance of licenses for the land disposal of wastes received from other persons.

(2) The rules set forth herein are adopted pursuant to the provisions of Subsections 19-3-104(4), 19-3-104(7), 19-3-104(10), and 19-3-104(11).

(3) The requirements of Rule R313-25 are in addition to, and not in substitution for, other applicable requirements of these rules.

R313-25-2. Definitions.

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

"Active maintenance" means significant activity needed during the period of institutional control to maintain a reasonable assurance that the performance objectives in Sections R313-25-20 and R313-25-21 are met. Active maintenance may include the pumping and treatment of water from a disposal unit, the replacement of a disposal unit cover, or other episodic or continuous measures. Active maintenance does not include custodial activities like repair of fencing, repair or replacement of monitoring equipment, revegetation, minor additions to soil cover, minor repair of disposal unit covers, and general disposal site upkeep.

"Approval application" means an application by a radioactive waste facility regulated under Title 19, Chapter 3 or Title 19, Chapter 5, for a permit, permit modification, license, license amendment, or other authorization.

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

"Competitive site-specific estimate" means a market-based cost estimate identifying and calculating the reasonable closure costs of a land disposal facility, including the cost of each activity in the closure, post-closure and institutional care of such facility, and market-based overhead(s) provided in sufficient detail to allow the Director to review and approve the same.

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

"Day" for purposes of this Rule means calendar days.

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

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

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

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

"Groundwater permit" means a groundwater quality discharge permit issued under the authority of Title 19, Chapter 5 and Rule R317-6.

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

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

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

"Land disposal facility" means the land, buildings and structures, and equipment which are intended to be used for the disposal of radioactive waste. Land disposal facility also includes any land, buildings and structures, and equipment adjacent to such land disposal facility used for the receipt, storage, treatment, or processing of radioactive waste.

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

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

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

"Stability" means structural stability.

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

"Tolling period," for purposes of this Rule, means a period during which days are not counted toward the deadlines specified in Subsections R313-25-6(3)(c), (4)(c)(i), (5)(b)(i), and (6)(b)(i).

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

"Unlicensed facility" means a structure, road, or property adjacent to, but outside of, a licensed or permitted area and that is not used for waste disposal or management.

"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 (b), (c), and (d) of the definition for byproduct material found in Section R313-12-3.

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

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

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

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

(a) within or underlain by:

(i) national, state, and county parks, monuments, and recreation areas; designated wilderness and wilderness study areas; wild and scenic river areas;

(ii) ecologically and scientifically significant natural areas, including wildlife management areas and habitats for listed or proposed endangered species as designated by federal law;

(iii) 100 year floodplains;

(iv) areas 200 feet distant from Holocene faults;

(v) underground mines, salt domes and salt beds;

(vi) dam failure flood areas;

(vii) areas subject to landslide, mud flow, or other earth movement, unless adverse impacts can be mitigated;

(viii) farmlands classified or evaluated as "prime", "unique", or of "statewide importance" by the U.S. Department of Agricultural Soil Conservation Service under the Prime Farmland Protection Act;

(ix) areas five miles distant from existing permanent dwellings, residential areas, and other habitable structures, including schools, churches, and historic structures;

(x) areas five miles distant from surface waters including intermittent streams, perennial streams, rivers, lakes, reservoirs, and wetlands;

(xi) areas 1000 feet distant from archeological sites to which adverse impacts cannot reasonably be mitigated;

(xii) recharge zones of aquifers containing ground water which has a total dissolved solids content of less than 10,000 mg/l; or

(xiii) drinking water source protection areas designated by the Utah Drinking Water Board;

(b) in areas:

(i) above or underlain by aquifers containing ground water which has a total dissolved solids content of less than 500 mg/l and which aquifers do not exceed state ground water standards for pollutants;

(ii) above or underlain by aquifers containing ground water which has a total dissolved solids content between 3000 and 10,000 mg/l when the distance from the surface to the ground water is less than 100 ft.;

(iii) areas of extensive withdrawal of water, mineral or energy resources.

(iv) above or underlain by weak and unstable soils, including soils that lose their ability to support foundations as a result of hydrocompaction, expansion, or shrinkage;

(v) above or underlain by karst terrains.

(4) Commercial radioactive waste disposal facilities may not be located within a distance to existing drinking water wells and watersheds for public water supplies of five years ground water travel time plus 1000 feet.

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

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

(7) Emergency response and safety.

(a) The plan approval siting application shall demonstrate the availability and adequacy of services for on-site emergencies, including medical and fire response. The application shall provide written evidence that the applicant has coordinated on-site emergency response plans with the local emergency planning committee (LEPC).

(b) The plan approval siting application shall include a comprehensive plan for responding to emergencies at the site.

(c) The plan approval siting application shall show proposed routes for transportation of radioactive wastes within the state. The plan approval siting application shall address the transportation means and routes available to evacuate the population at risk in the event of on-site accidents, including spills and fires.

(8) The plan approval siting application shall provide evidence that if the proposed disposal site is on land not owned by state or federal government, that arrangements have been made for assumption of ownership in fee by a state or federal agency.

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

R313-25-4. License Required.

(1) Persons shall not receive, possess, store, treat, or dispose of waste at a land disposal facility unless authorized by a license

issued by the Director pursuant to the Utah Radiation Control Act and Rules R313-25 and R313-22.

(2) Persons shall file an application with the Director pursuant to Section R313-22-32 and obtain a license as provided in Rule R313-25 before commencement of construction of a land disposal facility. Failure to comply with this requirement may be grounds for denial of a license and other penalties established by law and rules.

R313-25-5. Content of Application.

In addition to the requirements set forth in Section R313-22-33, an application to receive from others, possess, and dispose of wastes shall consist of general information, specific technical information, institutional information, and financial information as set forth in Sections R313-25-7 through R313-25-11.

R313-25-6. Director Review of Application.

(1) The Director shall review each approval application to determine whether it complies with applicable statutory and regulatory requirements. Approval applications will be categorized as Category 1, 2, 3 and 4 applications, as provided in Subsections R313-25-6(2) through (5).

(2) Category 1 applications.

(a) A Category 1 application is an application that:

(i) is administrative in nature;

(ii) requires limited scrutiny by the Director; and

(iii) does not require public comment.

(b) Examples of a Category 1 application include an application to:

(i) correct typographical errors;

(ii) Change the name, address, or phone number of persons or agencies identified in the license or permit;

(iii) change the procedures or location for maintaining records; or

(iv) extend the date for compliance with a permit or license requirement by no more than 120 days.

(c) The Director shall review and approve or deny a Category 1 application within 30 days after the day on which the Director Receives the application.

(3) Category 2 applications:

(a) A Category 2 application is one that is not a Category 1, 3 or 4 application.

(b) Examples of a Category 2 application include:

(i) Increase in process, storage, or disposal capacity

(ii) Change engineering design, construction, or process controls;

(iii) Approve a proposed corrective action plan; or

(iv) Transfer direct control of a license or groundwater permit.

(c)(i) The Director shall review and approve or deny a Category 2 application within 180 days after the day on which the Director receives the application.

(ii) The period described in Subsection R313-25-6(3)(c)(i) shall be tolled as provided in Subsection R313-25-6(7).

(4) Category 3 applications.

(a) Category 3 application is an application for:

(i) a radioactive waste license renewal;

(ii) a groundwater permit renewal;

(iii) an amendment to an existing radioactive waste license or groundwater permit to allow a new disposal cell;

(iv) an amendment to an existing radioactive waste license or groundwater permit that would allow the facility to eliminate groundwater monitoring; or

(v) approval of a radioactive waste disposal facility closure plan.

(b)(i) The Director shall review and approve or deny a Category 3 application within 365 days after the day on which the Director receives the application.

(ii) The period described in Subsection R313-25-6(4)(b)(i) shall be tolled as provided in Subsection R313-25-6(7).

(5) Category 4 applications.

(a) A Category 4 application is an application for:

(i) a new radioactive waste license; or

(ii) a new groundwater permit.

(b)(i) The Director shall review and approve or deny a Category 4 application within 540 days after the day on which the Director receives the application.

(ii) The period described in Subsection R313-25-6(5)(b)(i) shall be tolled as provided in Subsection R313-25-6(7).

(6)(a) Within 60 days after the day on which the Director receives a Category 2, 3 or 4 approval application, the Director shall determine whether the application is complete and contains all the information necessary to process it for approval and make a finding by issuance of a written:

(i) notice of completeness to the applicant; or

(ii) notice of deficiency to the applicant, including a list of the additional information necessary to complete the application.

(b) The Director shall review written information submitted in response to a notice of deficiency within 30 days after the day on

which the Director receives the supplemental information and shall again follow the procedures specified in Subsection R313-25-6(1)(a).

(c) If a document that is submitted as an application is substantially deficient, the Director may determine that it does not qualify as an application. Any such determination shall be made within 45 days of the document's submission and will include the Director's written findings.

(7) Tolling Periods. The periods specified for the Director's review and approval or denial under Subsections R313-25-6(3)(c)(i), (4)(b)(i), and (5)(b)(i) shall be tolled:

(a) while an owner or operator of a facility responds to the Director's request for information;

(b) during a public comment period; and

(c) while the federal government reviews the application.

(8) The Director shall prepare a detailed written explanation of the technical and regulatory basis for the Director's approval or denial of an approval application.

R313-25-7. General Information.

The general information shall include the following:

(1) identity of the applicant including:

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

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

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

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

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

(d) if the applicant is acting as an agent or representative of another person in filing the application, the applicant shall provide, with respect to the other person, information required under Subsection R313-25-7(1).

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

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

(b) the technical qualifications, including training and experience of the applicant and members of the applicant's staff, to engage in the proposed activities. Minimum training and experience requirements for personnel filling key positions described in Subsection R313-25-7(2)(a) shall be provided;

(c) a description of the applicant's personnel training program; and

(d) the plan to maintain an adequate complement of trained personnel to carry out waste receipt, handling, and disposal operations in a safe manner.

(3) A description of:

(a) the location of the proposed disposal site;

(b) the general character of the proposed activities;

(c) the types and quantities of waste to be received, possessed, and disposed of;

(d) plans for use of the land disposal facility for purposes other than disposal of wastes; and

(e) the proposed facilities and equipment; and

(4) proposed schedules for construction, receipt of waste, and first emplacement of waste at the proposed land disposal facility.

R313-25-8. Specific Technical Information.

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

(1) A description of the natural and demographic disposal site characteristics shall be based on and determined by disposal site selection and characterization activities. The description shall include geologic, geochemical, geotechnical, hydrologic, ecologic, archaeologic, meteorologic, climatologic, and biotic features of the disposal site and vicinity.

(2) Descriptions of the design features of the land disposal facility and of the disposal units for near-surface disposal shall include those design features related to infiltration of water; integrity of covers for disposal units; structural stability of backfill, wastes, and covers; contact of wastes with standing water; disposal site drainage; disposal site closure and stabilization; elimination to the extent practicable of long-term disposal site maintenance; inadvertent intrusion; occupational exposures; disposal site monitoring; and adequacy of the size of the buffer zone for monitoring and potential mitigative measures.

(3) Descriptions of the principal design criteria and their relationship to the performance objectives.

(4) Descriptions of the natural events or phenomena on which the design is based and their relationship to the principal design criteria.

(5) Descriptions of codes and standards which the applicant has applied to the design, and will apply to construction of the land disposal facilities.

(6) Descriptions of the construction and operation of the land disposal facility. The description shall include as a minimum the methods of construction of disposal units; waste emplacement; the procedures for and areas of waste segregation; types of intruder barriers; onsite traffic and drainage systems; survey control program; methods and areas of waste storage; and methods to control surface water and ground water access to the wastes. The description shall also include a description of the methods to be employed in the handling and

disposal of wastes containing chelating agents or other non-radiological substances which might affect meeting the performance objectives of Rule R313-25

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

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

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

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

(11) A description of the radiation safety program for control and monitoring of radioactive effluents to ensure compliance with the performance objective in Section R313-25-20 and monitoring of occupational radiation exposure to ensure compliance with the requirements of Rule R313-15 and to control contamination of personnel, vehicles, equipment, buildings, and the disposal site. The applicant shall describe procedures, instrumentation, facilities, and equipment appropriate to both routine and emergency operations.

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

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

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

R313-25-9. Technical Analyses.

(1) The licensee or applicant shall conduct a site-specific performance assessment and receive Director approval prior to accepting any radioactive waste if:

(a) the waste was not considered in the development of the limits on Class A waste and not included in the analyses of the Draft Environmental Impact Statement on 10 CFR Part 61 "Licensing Requirements for Land Disposal of Radioactive Waste," NUREG-0782. U.S. Nuclear Regulatory Commission. September 1981, or

(b) the waste is likely to result in greater than 10 percent of the dose limits in Section R313-25-19 during the time period at which peak dose would occur, or

(c) the waste will result in greater than 10 percent of the total site source term over the operational life of the facility, or

(d) the disposal of the waste would result in an unanalyzed condition not considered in Rule R313-25.

(2) A licensee that has a previously-approved site-specific performance assessment that addressed a radioactive waste for which a site-specific performance assessment would otherwise be required under Subsection R313-25-9(1) shall notify the Director of the applicability of the previously-approved site-specific performance assessment at least 60 days prior to the anticipated acceptance of the radioactive waste.

(3) The licensee shall not accept radioactive waste until the Director has approved the information submitted pursuant to Subsections R313-25-9(1) or (2).

(4) The licensee or applicant shall also include in the specific technical information the following analyses needed to demonstrate that the performance objectives of Rule R313-25 will be met:

(a) Analyses demonstrating that the general population will be protected from releases of radioactivity shall consider the pathways of air, soil, ground water, surface water, plant uptake, and exhumation by burrowing animals. The analyses shall clearly identify and differentiate between the roles performed by the natural disposal site characteristics and design features in isolating and segregating the wastes. The analyses shall clearly demonstrate a reasonable assurance that the exposures to humans from the release of radioactivity will not exceed the limits set forth in Section R313-25-20.

(b) Analyses of the protection of inadvertent intruders shall demonstrate a reasonable assurance that the waste classification and segregation requirements will be met and that adequate barriers to inadvertent intrusion will be provided.

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

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

(5)(a) Notwithstanding Subsection R313-25-9(1), any facility that proposes to land dispose of significant quantities of concentrated depleted uranium (more than one metric ton in total accumulation) after June 1, 2010, shall submit for the Director's review and approval a performance assessment that demonstrates that the performance standards specified in 10 CFR Part 61 and corresponding provisions of Utah rules will be met for the total quantities of concentrated depleted uranium and other wastes, including wastes already disposed of and the quantities of concentrated depleted uranium the facility now proposes to dispose. Any such performance assessment shall be revised as needed to reflect ongoing guidance and rulemaking from NRC. For purposes of this performance assessment, the compliance period shall be a minimum of 10,000 years. Additional simulations shall be performed for the period where peak dose occurs and the results shall be analyzed qualitatively.

(b) No facility may dispose of significant quantities of concentrated depleted uranium prior to the approval by the Director of the performance assessment required in Subsection R313-25-9(5)(a).

(c) For purposes of this Subsection R313-25-9(5) only, "concentrated depleted uranium" means waste with depleted uranium concentrations greater than 5 percent by weight.

R313-25-10. Institutional Information.

The institutional information submitted by the applicant shall include:

(1) A certification by the federal or state agency which owns the disposal site that the agency is prepared to accept transfer of the license when the provisions of Section R313-25-17 are met and will assume responsibility for institutional control after site closure and for post-closure observation and maintenance.

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

R313-25-11. Financial Information.

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

R313-25-12. Requirements for Issuance of a License.

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

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

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

(3) the applicant's proposed disposal site, land disposal facility design, land disposal facility operations, including equipment, facilities, and procedures, disposal site closure, and post-closure institutional control, are adequate to protect the public health and safety as specified in the performance objectives of Section R313-25-20;

(4) the applicant's proposed disposal site, land disposal facility design, land disposal facility operations, including equipment, facilities, and procedures, disposal site closure, and post-closure institutional control are adequate to protect the public health and safety in accordance with the performance objectives of Section R313-25-21;

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

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

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

(8) the applicant's proposal for institutional control provides reasonable assurance that control will be provided for the length of time found necessary to ensure the findings in Subsections R313-25-12(3) through (6) and that the institutional control meets the requirements of Section R313-25-29.

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

R313-25-13. Conditions of Licenses.

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

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

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

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

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

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

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

(a) protect health or to minimize danger to life or property;

(b) require reports and the keeping of records, and to provide for inspections of licensed activities as the Director deems necessary or appropriate to effectuate the purposes of the Radiation Control Act and Rules.

(8) The authority to dispose of wastes expires on the expiration date stated in the license. An expiration date on a license applies only to the above ground activities and to the authority to dispose of waste. Failure to renew the license shall not relieve the licensee of responsibility for implementing site closure, post-closure observation, and transfer of the license to the site owner.

R313-25-14. Application for Renewal or Closure.

(1) An application for renewal or an application for closure under Section R313-25-15 shall be filed at least 90 days prior to license expiration.

(2) Applications for renewal of a license shall be filed in accordance with Sections R313-25-5 and R313-25-7 through 25-11. Applications for closure shall be filed in accordance with Section R313-25-15. Information contained in previous applications, statements, or reports filed with the Director under the license may be incorporated by reference if the references are clear and specific.

(3) If a licensee has filed an application in proper form for renewal of a license, the license shall not expire unless and until the Director has taken final action to deny application for renewal.

(4) In evaluating an application for license renewal, the Director will apply the criteria set forth in Section R313-25-12.

R313-25-15. Contents of Application for Site Closure and Stabilization.

(1) Prior to final closure of the disposal site, or as otherwise directed by the Director, the licensee shall submit an application to amend the license for closure. This closure application shall include a final revision and specific details of the land disposal facility closure plan included in the original license application submitted and approved under Section R313-25-8(7). The plan shall include the following:

(a) additional geologic, hydrologic, or other data pertinent to the long-term containment of emplaced wastes obtained during the operational period;

(b) the results of tests, experiments, or other analyses relating to backfill of excavated areas, closure and sealing, waste migration and interaction with emplacement media, or other tests, experiments, or analyses pertinent to the long-term containment of emplaced waste within the disposal site;

(c) proposed revision of plans for:

(i) decontamination or dismantlement of surface facilities;

(ii) backfilling of excavated areas; or

(iii) stabilization of the disposal site for post-closure care.

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

(2) Upon review and consideration of an application to amend the license for closure submitted in accordance with Subsection R313-25-15(1), the Director shall issue an amendment authorizing closure if there is reasonable assurance that the long-term performance objectives of Rule R313-25 will be met.

R313-25-16. Post-Closure Observation and Maintenance.

The licensee shall observe, monitor, and carry out necessary maintenance and repairs at the disposal site until the site closure is complete and the license is transferred by the Director in accordance with Section R313-25-17. The licensee shall remain responsible for the disposal site for an additional five years. The Director may approve closure plans that provide for shorter or longer time periods of post-closure observation and maintenance, if sufficient rationale is developed for the variance.

R313-25-17. Transfer of License.

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

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

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

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

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

(5) that the Federal or State agency which will assume responsibility for institutional control of the disposal site is prepared to assume responsibility and ensure that the institutional requirements found necessary under Subsection R313-25-12(8) will be met.

R313-25-18. Termination of License.

(1) Following the period of institutional control needed to meet the requirements of Section R313-25-12, the licensee may apply for an amendment to terminate the license.

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

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

(a) that the institutional control requirements of Subsection R313-25-12(8) have been met;

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

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

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

R313-25-19. General Requirement.

Land disposal facilities shall be sited, designed, operated, closed, and controlled after closure so that reasonable assurance exists that exposures to individuals do not exceed the limits stated in Sections R313-25-20 and 25-23.

R313-25-20. Protection of the General Population from Releases of Radioactivity.

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

R313-25-21. Protection of Individuals from Inadvertent Intrusion.

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

R313-25-22. Protection of Individuals During Operations.

Operations at the land disposal facility shall be conducted in compliance with the standards for radiation protection set out in Rule R313-15 of these rules, except for release of radioactivity in effluents from the land disposal facility, which shall be governed by Section R313-25-20. Every reasonable effort should be made to maintain radiation exposures as low as is reasonably achievable, ALARA.

R313-25-23. Stability of the Disposal Site After Closure.

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

R313-25-24. Disposal Site Suitability Requirements for Land Disposal - Near-Surface Disposal.

(1) The primary emphasis in disposal site suitability is given to isolation of wastes and to disposal site features that ensure that the long-term performance objectives are met.

(2) The disposal site shall be capable of being characterized, modeled, analyzed and monitored.

(3) Within the region where the facility is to be located, a disposal site should be selected so that projected population growth and future developments are not likely to affect the ability of the disposal facility to meet the performance objectives of Rule R313-25.

(4) Areas shall be avoided having known natural resources which, if exploited, would result in failure to meet the performance objectives of Rule R313-25.

(5) The disposal site shall be generally well drained and free of areas of flooding or frequent ponding. Waste disposal shall not take place in a 100-year flood plain, coastal high-hazard area or wetland, as defined in Executive Order 11988, "Floodplain Management Guidelines."

(6) Upstream drainage areas shall be minimized to decrease the amount of runoff which could erode or inundate waste disposal units.

(7) The disposal site shall provide sufficient depth to the water table that ground water intrusion, perennial or otherwise, into the waste will not occur. The Director will consider an exception to this requirement to allow disposal below the water table if it can be conclusively shown that disposal site characteristics will result in molecular diffusion being the predominant means of radionuclide movement and the rate of movement will result in the performance objectives being met. In no case will waste disposal be permitted in the zone of fluctuation of the water table.

(8) The hydrogeologic unit used for disposal shall not discharge ground water to the surface within the disposal site.

(9) Areas shall be avoided where tectonic processes such as faulting, folding, seismic activity, vulcanism, or similar phenomena may occur with such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives of Rule R313-25 or may preclude defensible modeling and prediction of long-term impacts.

(10) Areas shall be avoided where surface geologic processes such as mass wasting, erosion, slumping, landsliding, or weathering occur with sufficient such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives of Rule R313-25, or may preclude defensible modeling and prediction of long-term impacts.

(11) The disposal site shall not be located where nearby facilities or activities could adversely impact the ability of the site to meet the performance objectives of Rule R313-25 or significantly mask the environmental monitoring program.

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

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

(2) The disposal site design and operation shall be compatible with the disposal site closure and stabilization plan and lead to disposal site closure that provides reasonable assurance that the performance objectives will be met.

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

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

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

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

R313-25-26. Near Surface Land Disposal Facility Operation and Disposal Site Closure.

(1) Wastes designated as Class A pursuant to Section R313-15-1009 of these rules shall be segregated from other wastes by placing them in disposal units which are sufficiently separated from disposal units for the other waste classes so that any interaction between Class A wastes and other wastes will not result in the failure to meet the performance objectives of Rule R313-25. This segregation is not necessary for Class A wastes if they meet the stability requirements of Subsection R313-15-1009(2)(b).

(2) Wastes designated as Class C pursuant to Section R313-15-1009 shall be disposed of so that the top of the waste is a minimum of five meters below the top surface of the cover or shall be disposed of with intruder barriers that are designed to protect against an inadvertent intrusion for at least 500 years.

(3) Except as provided in Subsection R313-25-1(1), only waste classified as Class A, B, or C shall be acceptable for near-surface disposal. Wastes shall be disposed of in accordance with the requirements of Subsections R313-25-26(4) through 11.

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

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

(6) Waste shall be placed and covered in a manner that limits the radiation dose rate at the surface of the cover to levels that at a minimum will permit the licensee to comply with all provisions of Sections R313-15-301 and 302 at the time the license is transferred pursuant to Section R313-25-17.

(7) The boundaries and locations of disposal units shall be accurately located and mapped by means of a land survey. Near-surface disposal units shall be marked in such a way that the boundaries of the units can be easily defined. Three permanent survey marker control points, referenced to United States Geological Survey or National Geodetic Survey control stations, shall be established on the site to facilitate surveys. The United States Geological Survey or National Geodetic Survey control stations shall provide horizontal and vertical controls as checked against United States Geological Survey or National Geodetic Survey record files.

(8) A buffer zone of land shall be maintained between any buried waste and the disposal site boundary and beneath the disposed waste. The buffer zone shall be of adequate dimensions to carry out environmental monitoring activities specified in Subsection R313-25-27(4) and take mitigative measures if needed.

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

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

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

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

R313-25-27. Environmental Monitoring.

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

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

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

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

R313-25-28. Alternative Requirements for Design and Operations.

The Director may, upon request or on the Director's own initiative, authorize provisions other than those set forth in Sections R313-25-25 and 25-27 for the segregation and disposal of waste and for the design and operation of a land disposal facility on a specific basis, if it finds reasonable assurance of compliance with the performance objectives of Rule R313-25.

R313-25-29. Institutional Requirements.

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

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

R313-25-30. Applicant Qualifications and Assurances.

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

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

(1) The applicant shall provide assurances prior to the commencement of operations, and a licensee shall provide assurances annually, that sufficient funds are or will be available to carry out land disposal facility closure and stabilization, including:

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

(b) closure and stabilization of the disposal site so that following transfer of the disposal site to the site owner, the need for ongoing active maintenance is eliminated to the extent practicable and only minor custodial care, surveillance, and monitoring are required. These assurances shall be based on Director approved cost estimates reflecting the Director approved plan for disposal site closure and stabilization. The applicant's or the licensee's cost estimates shall take into account total costs that would be incurred if an independent contractor were hired to perform the closure and stabilization work, in accordance with R313-25-31.5.

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

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

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

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

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

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

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

(9) The financial assurance shall be based on an annual estimate and shall include closure and post-closure costs in all areas subject to the licensed or permitted portions of the facility;

(10) Financial assurance for an unlicensed facility that supports the operation of a licensed or permitted facility shall include the estimated cost of:

(a) the removal of structures;

(b) the testing of structures, roads, and property to ensure no radiological contamination has occurred outside of the licensed area;

and

(c) stabilization and water infiltration control;

(11) Financial assurance cost estimates for a single approved waste disposal unit for which the volume of waste already placed and proposed to be placed in the unit within the surety period is less than the full waste capacity of the unit shall reflect the closure and post-closure costs for a waste disposal unit smaller than the approved waste disposal unit, if the unit could be reduced in size, meet closure requirements, and reduce closure costs;

(12) Financial assurance cost estimates for two approved adjacent waste disposal units that have been approved to be combined into a single unit and for which the combined volume of waste already placed and proposed to be placed in the units within the surety period is less than the combined waste capacity for the two separate units shall reflect either two separate waste disposal units or a single combined unit, whichever has the lowest closure and post-closure costs;

(13) The licensee or permittee shall annually propose closure and post-closure costs upon which financial assurance amounts are based, including costs of potential remediation at the licensed or permitted facility and, notwithstanding the obligations described in Subsection R313-25-31(10), any unlicensed facility;

(14) To provide the information in Subsection R313-25-31(13), the licensee or permittee shall provide:

(a) a proposed annual cost estimate using the current edition of RS Means Facilities Construction Cost Data or using a process, including an indirect cost multiplier, previously agreed to between the licensee or permittee and the Director; or

(b)(i) for an initial financial assurance determination and for each financial assurance determination every five years thereafter, a proposed competitive site-specific estimate for closure and post-closure care of the facility at least once every five years; and

(ii) for each year between a financial assurance determination described in Subsection R313-25-31(14)(b)(i), a proposed financial assurance estimate that accounts for current site conditions and that includes an annual inflation adjustment to the financial assurance determination using the Gross Domestic Product Implicit Price Deflator of the Bureau of Economic Analysis, United States Department of Commerce, calculated by dividing the latest annual deflator by the deflator for the previous year; and

(15) The Director shall:

(a) annually review the licensee's or permittee's proposed closure and postclosure estimate; and

(b) approve the estimate if the Director determines that the estimate would be sufficient to provide for closure and post-closure costs.

R313-25-31.5. Calculation of Closure Costs.

(1) In order to demonstrate the adequacy of closure, stabilization, post-closure, and institutional control funding in compliance with Section 19-3-104 and Subsection R313-25-31(1)(b), the applicant or licensee shall establish the level of costs that an independent contractor would incur by reliance on one of two methods, as follows:

(a) using the current edition of RS Means Facility Construction Cost Data; or

(b) using a competitive site-specific estimate.

(2) Any proposed competitive site-specific estimate submitted pursuant to Subsection R313-25-31(14)(b)(i) shall:

(a) be certified by a professional engineer or geologist licensed in Utah; and

(b) include sufficient detail so that the Director can determine that the cost estimate would be sufficient to provide for closure, post closure costs, and institutional control costs in compliance with Chapter 19-3 and Section R313-25-31.

(3) In the intervening four years following Director approval of a competitive site-specific estimate, a proposed cost estimate that accounts for current site conditions or changes to site conditions under Subsection R313-25-31(14)(b)(ii) shall be submitted by using either:

(a) the current edition of RS Means Facility Construction Cost Data; or

(b) the cost estimating rationale developed in the approved competitive site-specific estimate.

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

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

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

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

(1) Licensees shall maintain records and make reports in connection with the licensed activities as may be required by the conditions of the license or by the rules and orders of the Director.

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

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

(4) Notwithstanding Subsections R313-25-33(1) through (3), copies of records of the location and the quantity of wastes

contained in the disposal site shall be transferred upon license termination to the chief executive of the nearest municipality, the chief executive of the county in which the facility is located, the county zoning board or land development and planning agency, the State Governor, and other state, local, and federal governmental agencies as designated by the Director at the time of license termination.

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

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

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

(b) The reports shall include:

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

(ii) the results of the environmental monitoring program;

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

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

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

(vi) other information the Director may require.

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

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

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

(i) that required in Appendix G of 10 CFR 20.1001 to 20.2402, (2006), which is incorporated into these rules by reference, with the exception of shipper and carrier telephone numbers and shipper and consignee certifications; and

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

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

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

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

(1) wastes;

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

(3) radiation detection and monitoring instruments; or

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

R313-25-35. Director Inspections of Land Disposal Facilities.

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

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

KEY: radiation, radioactive waste disposal, depleted uranium
Date of Enactment or Last Substantive Amendment: April 16, 2018
Notice of Continuation: July 1, 2016
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-104(1); 19-6-107

State of Utah
Administrative Rule Analysis
Revised December 2019

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION		
	Title No. - Rule No.	
Utah Admin. Code Ref (R no.):	**R313-28**	**Filing No. (Office Use Only)**

Agency Information

1. Department:	Department of Environmental Quality	
Agency:	Waste Management and Radiation Control	
Room no.:	Second Floor	
Building:	MASOB	
Street address:	195 North 1950 West	
City, state, zip:	Salt Lake City, Utah 84116	
Mailing address:	PO Box 144880	
City, state, zip:	Salt Lake City, Utah 84114-4880	
Contact person(s):		
Name:	**Phone:**	**Email:**
Tom Ball	801-536-0251	tball@utah.gov
Please address questions regarding information on this notice to the agency.		

General Information

2. Rule catchline:

Use of X-Rays in the Healing Arts.

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Utah Code Subsection 19-3-104(4) allows the Waste Management and Radiation Control Board to make rules to meet the requirements of federal law relating to radiation control to ensure the radiation control program under this part is qualified to maintain primacy from the federal government. R313-28 contains the rules adopted by the board and as part of the state primacy of the radiation control program, the rules in R313-28 have been reviewed by the U.S. Nuclear Regulatory Commission (NRC) and have been determined to be compatible with the corresponding federal radiation protection regulations.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

Since the last five-year review there have been no comments from interested persons specifically supporting or opposing this rule.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

It is necessary to continue this rule because it prescribes the requirement for the use of X-rays in the healing arts to protect human health. The rule establishes X-ray machine parameters for limiting the size of the X-ray beam, controlling radiation exposure, maintaining accuracy and linearity, and defining performance of mammography X-ray systems. There have been no opposing comments to the rule since the last five-year review in 2016.

Agency Authorization Information

To the agency: Information requested on this form is required by Section 63G-3-305. Incomplete forms will be returned to the agency for completion, possibly delaying the effective date.

Agency head or designee, and title:		**Date** (mm/dd/yyyy)**:**	

Reminder: Text changes cannot be made with this type of rule filing. To change any text, please file an amendment or nonsubstantive change.

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.
R313-28. Use of X-Rays in the Healing Arts.
R313-28-10. Purpose and Scope.

(1) The purpose of the rules in R313-28 is to prescribe the requirements for the use of x-rays in the healing arts.

(2) The rules set forth herein are adopted pursuant to the provisions of Sections 19-3-104(4) and 19-3-104(7).

R313-28-20. Definitions.

As used in R313-28, the following definitions apply:

"Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

"Actual focal spot" refer to "Focal spot."

"Aluminum equivalent" means the thickness of aluminum, type 1100 alloy, affording the same attenuation, under specified conditions, as the material in question. The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

"Assembler" means individuals engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent if they assemble components into an x-ray system that is subsequently used to provide professional or commercial services.

"Attenuation block" means a block or stack, having appropriate dimensions 20 cm by 20 cm by 3.8 cm, of type 1100 aluminum alloy or other materials having equivalent attenuation.

"Automatic EXPOSURE control" means a device which automatically controls one or more technique factors in order to obtain, at a preselected location, a required quantity of radiation. Phototimer and ion chamber devices are included in this category.

"Barrier" refer to "Protective barrier".

"Beam axis" means a line from the source through the centers of the x-ray fields.

"Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.

"Certified components" means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.

"Certified system" means an x-ray system which has one or more certified components.

"Changeable filters" means filters designed to be removed by the operator.

"Coefficient of variation (C)" means the ratio of the standard deviation to the mean value of a population of observations.

"Computed tomography" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

"Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, push buttons, and other hardware necessary for setting the technique factors.

"Cooling curve" means the graphical relationship between heat units stored and cooling time.

"CT" means computed tomography.

"CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which house these components.

"Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

"Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

"Diagnostic x-ray system" means an x-ray system designed for irradiation of part of the human body for the purpose of recording or visualization for diagnostic purposes.

"Entrance EXPOSURE rate" means the EXPOSURE free in air per unit time at the point where the useful beam enters the patient.

"Equipment" refer to "X-ray equipment".

"Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

"Filter" means material placed in the useful beam to absorb preferentially selected radiations.

"Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes equipment housing, electrical interlocks, the primary protective barrier, and structural material providing linkage between the image receptor and the diagnostic source assembly.

"Focal spot" means the area on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates. Also referred to as "Actual focal spot."

"Gonad shield" means a protective barrier for the testes or ovaries.

"Half-value layer or HVL" means the thickness of specified material which attenuates the beam of radiation to an extent that the EXPOSURE rate is reduced to one-half of its original value. In this definition, the contribution of scatter radiation, other than that which might be present initially in the beam concerned, is deemed to be excluded.

"Healing arts screening" means the use of x-ray equipment to examine individuals who are asymptomatic for the disease for which the screening is being performed and the use of x-rays are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to order x-ray tests for the purpose of diagnosis.

"Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds: for example, kVp times mA times seconds.

"HVL" refer to "half value layer."

"Image intensifier" means a device installed in its housing which instantaneously converts an x-ray pattern into a light image of higher energy density.

"Image receptor" means a device, for example, a fluorescent screen radiographic film, solid state detector, or gaseous detector, which transforms incident x-ray photons to produce a visible image or stores the information in a form which can be made into a visible image. In those cases where means are provided to preselect a portion of the image receptor, the term "image receptor" shall mean the preselected portion of the device.

"Irradiation" means the exposure of matter to ionizing radiation.

"Kilovolts peak" refer to "Peak tube potential".

"kV" means kilovolts.

"kVp" refer to "Peak tube potential."

"Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

"Leakage radiation" means radiation emanating from the diagnostic source assembly except for:

(a) the useful beam, and

(b) radiation produced when the exposure switch or timer is not activated.

"Leakage technique factors" means the technique factors associated with the diagnostic source assembly which are used in measuring leakage radiation. They are defined as follows:

(a) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being ten millicoulombs, ten milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

(b) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.

(c) For other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

"Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

"mA" means tube current in milliamperes.

"mAs" means milliampere second or the product of the tube current in milliamperes and the time of exposure in seconds.

"Mammography imaging medical physicist" means an individual who conducts mammography surveys of mammography facilities.

"Mammography survey" means an evaluation of x-ray imaging equipment and oversight of a mammography facility's quality control program.

"Mobile x-ray equipment" refer to "X-ray equipment".

"Multiple scan average dose" means the average dose at the center of a series of scans, specified at the center of the axis of rotation of a CT x-ray system.

"New installation" means change, modification or relocation of new or existing shielding or equipment.

"Operator of diagnostic x-ray equipment" means either:

(a) The individual responsible for insuring that the appropriate technique factors are set on the x-ray equipment, or

(b) The individual who makes the radiation exposure.

"Patient" means an individual subjected to healing arts examination, diagnosis, or treatment.

"PBL" refer to "Positive beam limitation."

"Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

"Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

"PID" refer to "Position indicating device."

"Portable x-ray equipment" refer to "X-ray equipment".

"Position indicating device (PID)" means a device, on dental x-ray equipment which indicates the beam position and establishes a definite source-surface (skin) distance. The device may or may not incorporate or serve as a beam-limiting device.

"Positive beam limitation" means the automatic or semi-automatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

"Primary beam scatter" means scattered radiation which has been deviated in direction or energy by materials irradiated by the primary beam.

"Primary protective barrier" refer to "Protective barrier".

"Protective apron" means an apron made of radiation absorbing materials, used to reduce radiation exposure.

"Protective barrier" means a barrier of radiation absorbing material used to reduce radiation exposure.

(a) "Primary protective barrier" means the material, excluding filters, placed in the useful beam to reduce the radiation exposure for protection purposes.

(b) "Secondary protective barrier" means the material which attenuates stray radiation.

"Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

"Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and for confirming the position and size of the therapeutic irradiation field.

"Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

"Rating" means the operating limits of an x-ray system or subsystem as specified by the component manufacturer.

"Recording" means producing a permanent form of an image resulting from x-ray photons.

"Reference plane" means a plane which is displaced from and parallel to the tomographic plane.

"Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

"Scan increment" means the amount of relative displacement of the patient with respect to the computer tomographic x-ray system between successive scans measured along the direction of such displacement.

"Scattered radiation" means radiation that, during passage through matter, has been deviated in direction, energy or both direction and energy. Also refer to "Primary Beam Scatter".

"Shutter" means a device attached to the tube housing assembly which can intercept the entire cross sectional area of the useful beam and which has a lead equivalency at least that of the tube housing assembly.

"SID" refer to "Source-image receptor distance".

"Source" means the focal spot of the x-ray tube.

"Source to image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

"Special purpose x-ray system" means that which is designed for irradiation of specific body parts.

"Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

"Spot film device" means a device intended to transport or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor, including a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

"SSD" means the distance between the source and the skin entrance plane of the patient.

"Stationary x-ray equipment" refer to "X-ray equipment".

"Stray radiation" means the sum of leakage and scattered radiation.

"Technique factors" means the following conditions of operation.

(a) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs.

(b) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses.

(c) For other equipment, peak tube potential in kV and either;

(i) the tube current in mA and exposure time in seconds, or

(ii) the product of tube current and exposure time in mAs.

"Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

"Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

"Tomographic plane" means that geometric plane which is identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

"Tube" means an x-ray tube, unless otherwise specified.

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage or filament transformers and other appropriate elements when they are contained within the tube housing.

"Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

"Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the switch or timer is activated.

"Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

"X-ray exposure control" means a device, switch, button, or other similar means by which an operator initiates or terminates the radiation exposure. The x-ray exposure control may include associated equipment, for example, timers and back-up timers.

"X-ray equipment" means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

(a) "Mobile" means x-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

(b) "Portable" means x-ray equipment designed to be hand-carried.

(c) "Stationary" means x-ray equipment which is installed in a fixed location.

"X-ray field" means that area of the intersection of the useful beam and one of the sets of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the EXPOSURE rate is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament

transformers for the x-ray tube high-voltage switches, electrical protective devices, and other appropriate elements.

"X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

"X-ray tube" means an electron tube which is designed to be used primarily for the production of x-rays.

R313-28-31. General and Administrative Requirements.

(1) Persons shall not make, sell, lease, transfer, lend, or install x-ray equipment or the accessories used in connection with x-ray equipment unless the accessories and equipment, when properly placed in operation and properly used, will meet the applicable requirements of these rules.

(a) X-ray equipment shall be FDA approved for use in the United States and shall be certified in accordance with 21 CFR 1010.2 and identified in accordance with 21 CFR 1010.3.

(2) The registrant shall be responsible for directing the operation of the x-ray machines which are under the registrant's administrative control. The registrant or registrant's agent shall assure that the requirements of R313-28-31(2)(a) through R313-28-31(2)(i) are met in the operation of the x-ray machines.

(a) An x-ray machine which does not meet the provisions of these rules shall not be operated for diagnostic purposes, when directed by the Director.

(b) Individuals who will be operating the x-ray equipment shall be instructed in the registrant's written radiation safety program and be qualified in the safe use of the equipment. Required operator qualifications are listed in R313-28-350.

(c) The registrant of a facility shall create and make available to x-ray operators written safety procedures, including patient holding and restrictions of the operating technique required for the safe operation of the x-ray systems. Individuals who operate x-ray systems shall be responsible for complying with these rules.

(d) Except for individuals who cannot be moved out of the room and the patient being examined, only the staff and ancillary personnel or other individuals needed for the medical procedure or training shall be present in the room during the radiographic exposure and shall be positioned as follows:

(i) individuals other than the patient shall be positioned so that no part of the body will be struck by the useful beam unless protected by not less than 0.5 mm lead equivalent material;

(ii) the x-ray operator, other staff, ancillary personnel and other individuals needed for the medical procedure shall be protected from primary beam scatter by protective aprons or barriers unless it can be shown that by virtue of distances employed, EXPOSURE levels are reduced to the limits specified in R313-15-201; and

(iii) patients who are not being examined and cannot be removed from the room shall be protected from the primary beam scatter by whole body protective barriers of not less than 0.25 mm lead equivalent material or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and nearest edge of the image receptor.

(e) For patients who have not passed reproductive age, gonad shielding of not less than 0.5 mm lead equivalent material shall be used during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

(f) Individuals shall be exposed to the useful beam for healing arts purposes only when the exposure has been specifically ordered and authorized by a licensed practitioner of the healing arts after a medical consultation. Deliberate exposures for the following purposes are prohibited:

(i) exposure of an individual for training, demonstration or other non-healing arts purposes except for low dose, whole body scanners used for security purposes in correctional facilities; and

(ii) exposure of an individual for the purpose of healing arts screening except as authorized by R313-28-31(2)(i).

(g) When a patient or film must be provided with auxiliary support during a radiation exposure:

(i) mechanical holding devices shall be used when the technique permits. The written procedures, required by R313-28-31(2)(c), shall list individual projections where mechanical holding devices can be utilized;

(ii) written safety procedures, as required by R313-28-31(2)(c), shall indicate the requirements for selecting an individual to hold patients or films and the procedure that individual shall follow;

(iii) the individual holding patients or films during radiographic examinations shall be instructed in personal radiation safety and protected as required by R313-28-31(2)(d)(i);

(iv) Individuals shall not be used routinely to hold film or patients;

(v) In those cases where the patient must hold the film, except during intraoral examinations, portions of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 mm lead equivalent material; and

(vi) Facilities shall have protective aprons and gloves available in sufficient numbers to provide protection to personnel who are involved with x-ray operations and who are otherwise not shielded.

(h) Personnel monitoring. Individuals who are associated with the operation of an x-ray system are subject to the applicable requirements of R313-15.

(i) Healing arts screening. Persons proposing to conduct a healing arts screening program shall not initiate the program without prior approval of the Director. When requesting approval, that person shall submit the information outlined in R313-28-400. If information submitted becomes invalid or outdated, the Director shall be notified immediately.

(3) Maintenance of records and information. The registrant shall maintain at least the following information for each x-ray

machine:

(a) model numbers of major components;

(b) record of surveys or calculations to demonstrate compliance with R313-15-302, calibration, maintenance and modifications performed on the x-ray machine; and

(c) a shielding design report for the x-ray suite which states assumed values for workload and use factors and includes a drawing of surrounding areas showing assumed values for occupancy factors.

(4) X-ray records. Facilities shall maintain an x-ray record containing the patient's name, the types of examinations, and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded. The registrant shall retain these records for three years after the record is made.

(5) Portable or mobile equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary radiographic installation.

(6) Hand-held medical x-ray systems. X-ray equipment designed to be hand-held shall comply with Section R313-28-31, excluding Subsection R313-28-31(5), and R313-28-52, excluding Subsections R313-28-52(8)(b)(i) and (ii).

(a) When operating hand-held equipment for which it is not possible for the operator to remain at least six feet from the x-ray machine during x-ray exposure, protective aprons of at least 0.5 millimeter lead equivalence shall be provided for the operator to protect the operator's torso and gonads from backscatter radiation;

(b) In addition to the dose limits in R313-15-301, operators of hand-held x-ray equipment shall ensure that members of the public that may be exposed to scatter radiation or primary beam transmission from the hand-held device are not exposed above 2 milliroentgen per hour;

(i) Operators will ensure that members of the public likely to be exposed to greater than 2 milliroentgen per hour will be provided protective aprons of at least 0.5 millimeter lead equivalence or are moved to a distance such that the exposure rate to the individual is below 2 milliroentgen per hour; and

(c) In addition to the requirements of Subsection R313-28-350(1), each operator of hand-held x-ray equipment shall complete the training program supplied by the manufacturer prior to using the x-ray unit. Records of training shall be maintained on file for examination by an authorized representative of the Director.

(7) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

(a) The speed of the screen and film combinations used shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for routine diagnostic radiological imaging, with the exception of standard film packets for intra-oral use in dental radiography. If the requirements of R313-28-31(6)(a) cannot be met, an exemption may be requested pursuant to R313-12-55.

(b) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

(c) X-ray systems, other than fluoroscopic, computed tomography, dental or veterinary units, shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.

R313-28-32. Plan Review.

(1) Prior to construction, the floor plans, shielding specifications and equipment arrangement of all new installations, or modifications of existing installations, utilizing ionizing radiation shall be submitted to a Qualified Expert for review. The required information is denoted in R313-28-200 and R313-28-450.

(2) A copy of the Qualified Expert's conclusions regarding shielding specifications must be submitted to the Director within 14 working days.

(3) The Director may require additional modifications should a subsequent analysis of operating conditions, for example, a change in workload or use and occupancy factors, indicate the possibility of an individual receiving a dose in excess of the limits prescribed in R313-15.

R313-28-35. General Requirements for Diagnostic X-Ray Systems.

In addition to other requirements of R313-28, all diagnostic x-ray systems shall meet the following requirements:

(1) Warning label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(2) Battery charge indicator. On battery powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(3) Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 25.8 uC/kg (100 milliroentgens) in one hour when the x-ray tube is operated at its leakage technique factors.

(4) Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 0.516 uC/kg (two milliroentgens) in one hour at five centimeters from accessible surfaces of the component when it is operated in an assembled x-ray system under the conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(5) Beam quality.

(a) The half value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in R313-28-35, Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

TABLE I

DESIGN OPERATING RANGE (KILO VOLTS PEAK	MEASURED POTENTIAL (KILOVOLTS PEAK)	DENTAL INTRA-ORAL MANUFACTURED BEFORE AUGUST 1, 1974 AND ON OR AFTER DECEMBER 1, 1980	ALL OTHER DIAGNOSTIC X-RAY SYSTEMS
Below 51	30	(use prohibited)	0.3
	40	(use prohibited)	0.4
	50	1.5	0.5
	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

(b) For capacitor discharge equipment, compliance with the requirements of R313-28-35(5)(a) shall be determined with the system fully charged and a setting of 10 mAs for exposures.

(c) The required minimal half-value layer of the useful beam shall include the filtration contributed by materials which are permanently present between the focal spot of the tube and the patient.

(d) Filtration control. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filters and shall prevent an exposure unless the minimum amount of filtration necessary to produce the HVL required by R313-28-35(5)(a) is in the useful beam for the given kVp which has been selected.

(6) Multiple tubes. When two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. For equipment manufactured after August 1, 1974, indications shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

(7) Mechanical support of tube head. The tube housing assembly supports shall be adjusted so that the tube housing assembly will remain stable during an exposure unless the tube housing movement during exposure is a designed function of the x-ray system.

(8) Technique indicators.

(a) The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic EXPOSURE controls are used, in which case the technique factors which are set prior to the exposure shall be indicated.

(b) On equipment having fixed technique factors, the requirements, in R313-28-35(8)(a) may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(9) Maintaining compliance. Diagnostic x-ray systems and their associated components certified pursuant to the provisions of 21 CFR Part 1020 (2006) shall be maintained in compliance with applicable requirements of that standard.

(10) Locks. All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.

(11) X-ray systems which have been granted a variance by the Director, Center for Devices and Radiological Health, Food and Drug Administration (Director), from the performance standards for ionizing radiation emitting products, in accordance with 21 CFR 1010.4 (2006) shall be deemed to satisfy the requirements in R313-28 that correspond to the variance granted by the Director. The registrant shall insure that labeling pursuant to 21 CFR 1010.5(f) (2006) remains legible and visible on the x-ray system.

R313-28-40. Fluoroscopic X-Ray Systems.

All fluoroscopic x-ray systems used shall be image intensified and meet the following requirements:

(1) Primary barrier.

(a) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at SIDs for which the unit was designed.

(b) The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

(2) Fluoroscopic beam limitation.

(a) For certified fluoroscopic systems with or without a spot film device neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent of the SID. The sum of the excess length and the excess width shall be no greater than four percent of the SID.

(b) For uncertified fluoroscopic systems with a spot film device, the x-ray beam with the shutters fully open, during fluoroscopy or spot filming, shall be no larger than the largest image receptor size for which the device is designed. Measurements shall be made at the minimum SID available but at no less than 20 centimeters table top to the film plane distance.

(c) For uncertified fluoroscopic systems without a spot film device, the requirements of R313-28-40(1) apply.

(d) Other requirements for fluoroscopic beam limitation:

(i) means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field;

(ii) equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less;

(iii) if provided, stepless adjustment shall at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of five centimeters by five centimeters or less;

(iv) for equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor; and

(v) for non-circular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

(3) Spot-film beam limitation. Spot-film devices shall meet the following requirements:

(a) means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Adjustments shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

(b) neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than three percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed four percent of the SID;

(c) it shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, five by five centimeters;

(d) the center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent of the SID; and

(e) on spot film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(4) Override. If a means exists to override the automatic x-ray field size adjustments required in R313-28-40(2) and (3), that means:

(a) shall be designed for use only in the event of system failure;

(b) shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and

(c) shall be clearly and durably labeled as follows: FOR X-RAY FIELD LIMITATION SYSTEM FAILURE.

(5) Activation of the fluoroscopic tube. X-ray production in the fluoroscopic mode shall be controlled by a dead-man switch. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure immediately, but means may be provided to permit completion of a single exposure of the series in process.

(6) Entrance EXPOSURE rate allowable limits.

(a) For fluoroscopic equipment manufactured before May 19, 1995, the following requirements apply:

(i) fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at combinations of tube potential and current which will result in an EXPOSURE rate in excess of 2.58 mC/kg (ten roentgens) per minute at the point where the center of the useful beam enters the patient, except:

(A) during recording of fluoroscopic images, or

(B) when an optional high level control is provided. When so provided, the equipment shall not be operable at combinations of tube potential and current which will result in an EXPOSURE rate in excess of 1.29 mC/kg (five roentgens) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(ii) fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at combinations of tube potential and current which will result in a EXPOSURE rate in excess of 1.29 mC/kg (five roentgens) per minute at the point where

the center of the useful beam enters the patient, except:

(A) during recording of fluoroscopic images, or

(B) when an optional high level control is activated. Special means of activation of high level controls shall be required. The high level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(iii) fluoroscopic equipment which is provided with both automatic exposure rate control and a manual mode shall not be operable at combinations of tube potential and current that will result in an exposure rate of 2.58 mC/kg (ten roentgens) per minute in either mode at the point where the center of the useful beam enters the patient except:

(A) during recording of fluoroscopic images, or

(B) when an optional high level control is provided. When so provided, the equipment shall not be operable at combinations of tube potential and current which will result in an EXPOSURE rate in excess of 1.29 mC/kg (five roentgens) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(b) For fluoroscopic equipment manufactured on and after May 19, 1995, the following requirements apply:

(i) fluoroscopic equipment operable at combinations of tube potential and current which will result in an EXPOSURE rate greater than 1.29 mC/kg (five roentgens) per minute at the point where the center of the useful beam enters the patient shall be equipped with automatic exposure rate control. Provision for manual selection of technique factors may be provided.

(ii) fluoroscopic equipment shall not be operable at combinations of tube potential and current which will result in an EXPOSURE rate in excess of 2.58 mC/kg (ten roentgens) per minute at the point where the center of the useful beam enters the patient except:

(A) during recording of images from an x-ray image-intensifier tube using photographic film or a video camera when the x-ray source is operated in pulsed mode, or

(B) when an optional high level control is activated. When the high level control is activated, the equipment shall not be operable at combinations of tube potential and current which will result in an EXPOSURE rate in excess of 5.16 mC/kg (20 roentgens) per minute at the point where the center of the useful beam enters the patient. Special means of activation of high level controls shall be required. The high level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(c) Compliance with the requirements of R313-28-40(6) shall be determined as follows:

(i) if the source is below the x-ray table, the EXPOSURE rate shall be measured one centimeter above the tabletop or cradle;

(ii) if the source is above the x-ray table, the EXPOSURE rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;

(iii) for a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at available SID's, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly; or

(iv) for a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as close as possible to the point of measurement. If the tabletop is movable, it shall be positioned as close as possible to the lateral x-ray source with the end of the beam-limiting device or spacer no closer than 15 centimeters to the x-ray table.

(d) Fluoroscopic radiation therapy simulation systems are exempt from the requirements of R313-28-40(6).

(7) Measurement of entrance EXPOSURE rates shall be performed for both maximum and typical values as follows:

(a) measurements shall be made annually or after maintenance of the system which might affect the EXPOSURE rate;

(b) results of these measurements shall be posted where the fluoroscopist may have ready access to the results while using the fluoroscope and in the record required in R313-28-31(3)(b). The measurement results shall be stated in roentgens per minute and include the machine settings used in determining results. The name of the person performing the measurements and the date the measurements were performed shall be included in the results;

(c) conditions of the annual measurement of maximum entrance EXPOSURE rate shall be performed as follows:

(i) the measurement shall be made under the conditions that satisfy the requirements of R313-28-40(6)(c);

(ii) the kVp, mA, and other selectable parameters shall be adjusted to those settings which give the maximum entrance EXPOSURE rate; and

(iii) x-ray systems that incorporate automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum output of that system; and

(d) conditions of the annual measurement of typical entrance EXPOSURE rate are as follows:

(i) the measurement shall be made under the conditions that satisfy the requirements of R313-28-40(6)(c);

(ii) the kVp, mA, and other selectable parameters shall be those settings typical of clinical use of the x-ray system; and

(iii) the x-ray system that incorporates automatic EXPOSURE rate control shall have an appropriate phantom placed in the useful beam to produce a milliamperage and kilovoltage typical of the use of the x-ray system.

(8) Barrier transmitted radiation rate limits.

(a) The EXPOSURE rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 0.516 uC/kg (two milliroentgens) per hour at ten

centimeters from accessible surfaces of the fluoroscopic imaging assembly beyond the plane of the image receptor for each mC/kg (roentgen) per minute of entrance EXPOSURE rate.

(b) Measuring compliance of barrier transmission.

(i) The EXPOSURE rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(ii) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

(iii) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

(iv) Movable grids and compression devices shall be removed from the useful beam during the measurement.

(9) Indication of potential and current. During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously indicated.

(10) Source-skin distance. The source to skin distance shall not be less than:

(a) 38 centimeters on stationary fluoroscopic systems manufactured on or after August 1, 1974;

(b) 35.5 centimeters on stationary fluoroscopic systems manufactured prior to August 1, 1974;

(c) 30 centimeters on all mobile fluoroscopes; or

(d) 20 centimeters for all mobile fluoroscopes when used for specific surgical applications.

(11) Fluoroscopic timer.

(a) Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.

(b) A signal audible to the fluoroscopist shall indicate the completion of a preset cumulative on-time. The signal shall continue to sound while x-rays are produced until the timing device is reset.

(12) Control of scatter radiation.

(a) The tables of fluoroscopic assemblies when combined with normal operating procedures shall provide protection from scatter radiation so that unprotected parts of a staff or ancillary individual's body shall not be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 mm lead equivalent.

(b) Equipment configuration when combined with procedures shall not allow portions of a staff member's or ancillary person's body, except the extremities, to be exposed to unattenuated scattered radiation emanating from above the tabletop unless:

(i) the radiation has passed through not less than 0.25 mm lead equivalent material including, but not limited to, drapes, bucky-slot cover panel, or self supporting curtains, in addition to the lead equivalency provided by the protective apron referred to in R313-28-31(2)(d),

(ii) that individual is at least 120 centimeters from the center of the useful beam, or

(iii) it is not feasible to attach shielding to special procedures equipment and personnel are wearing protective aprons.

(13) Spot film exposure reproducibility. Fluoroscopic systems equipped with radiographic spot film mode shall meet the exposure reproducibility requirements of R313-28-54.

(14) Radiation therapy simulation systems. Radiation therapy simulation systems shall be exempt from all the requirements R313-28-40(1), (8), and (11) provided that:

(a) the systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and

(b) the systems which do not meet the requirements of R313-28-40(11) are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require, in these cases, that the timer be reset between examinations.

R313-28-51. Radiographic Systems Other than Fluoroscopic, Dental Intraoral, or Computed Tomography -- Beam Limitation.

The useful beam shall be limited to the area of clinical interest and show evidence of collimation. This shall be deemed to have been met if a positive beam limiting device meeting the manufacturer's specifications or the requirements of R313-28-300 has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film, for example, projections of the shutters of the collimator, cone cutting at the corners or a border at the film's edge.

(1) General purpose stationary and mobile x-ray systems.

(a) Only x-ray systems provided with a means for independent stepless adjustment of at least two dimensions of the x-ray field shall be used.

(b) A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(c) The Board may grant an exemption on non-certified x-ray systems to R313-28-51(1)(a) and (b) provided the registrant makes a written application for the exemption and in that application:

(i) demonstrates it is impractical to comply with R313-28-51(1)(a) and (b); and

(ii) demonstrates the purpose of R313-28-51(1)(a) and (b) will be met by other methods.

(2) In addition to the requirements of R313-28-51(1) above, stationary general purpose x-ray systems, both certified and non-certified shall meet the following requirements:

(a) a method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within two percent of the SID, and to indicate the SID to within two percent;

(b) the beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted; and

(c) indication of field size dimensions and SID's shall be specified in inches or centimeters and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those of the image receptor to within two percent of the SID when the beam axis is perpendicular to the plane of the image receptor.

(3) Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two percent of the SID, or shall be provided with means to both size and align the x-ray field so that the x-ray field at the plane of the image receptor does not extend beyond the edges of the image receptor.

(4) Special purpose x-ray systems.

(a) Means shall be provided to limit the x-ray field in the plane of the image receptor so that the x-ray field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(b) Means shall be provided to align the center of the x-ray field with the center of the image receptor to within two percent of the SID, or means shall be provided to both size and align the x-ray field so that the x-ray field at the plane of the image receptor does not extend beyond the edges of the image receptor. Compliance shall be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor.

(c) R313-28-51(4)(a) and R313-28-51(4)(b) may be met with a system that meets the requirements for a general purpose x-ray system as specified in R313-28-51(1) or, when alignment means are also provided, may be met with either;

(i) an assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirements for the combination of image receptor sizes and SID's for which the unit is designed with the beam limiting device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(ii) a beam-limiting device having multiple fixed apertures sufficient to meet the requirement for the combinations of image receptor sizes and SID's for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which the aperture is designed and shall indicate which aperture is in position for use.

R313-28-52. Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, or Computed Tomography -- Radiation Exposure Control Devices.

(1) Exposure Initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, for example, the depression of a switch. Radiation exposure shall not be initiated without a deliberate action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(2) Exposure termination. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(3) Manual Exposure Control: An x-ray control shall be incorporated into x-ray systems so that an exposure can be terminated at times except for:

(a) exposure of one-half second or less; or

(b) during serial radiography when means shall be provided to permit completion of a single exposure of the series in process.

(4) Automatic EXPOSURE controls, phototimers. When automatic EXPOSURE control is provided:

(a) indication shall be made on the control panel when this mode of operation is selected;

(b) when the x-ray tube potential is equal to or greater than 51 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than the interval equivalent to two pulses; and

(c) the minimum exposure time for all equipment other than that specified in R313-28-52(4)(b) shall be equal to or less than 1/60 second or a time interval required to deliver five mAs, whichever is greater.

(5) Exposure Indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(6) Exposure Duration, Timer, Linearity. For systems having independent selection of exposure time settings, the average ratio of exposure to the indicated milliampere-seconds product obtained at two consecutive timer settings or at two settings not differing by more than a factor of two shall not differ by more than 0.10 times their sum.

(7) Exposure Control Location. The x-ray exposure control shall be placed so that the operator can view the patient while making the exposure.

(8) Operator Protection.

(a) Stationary x-ray systems shall be required to have the x-ray exposure switch permanently mounted in a protected area.

(b) Mobile and portable x-ray systems which are:

(i) used continuously for greater than one week at the same location, one room or suite, shall meet the requirements of R313-28-52(8)(a); or

(ii) used for less than one week at one location, one room, or suite shall be provided with either a protective barrier at least two meters (6.5 feet) high for operator protection during exposures, or means shall be provided to allow the operator to be at least 2.7 meters (nine feet) from the tube housing assembly during the exposure.

R313-28-53. Radiographic Systems Other Than Fluoroscopic, or Dental Intraoral Systems -- Source-to-Skin or Receptor Distance.

Mobile or portable radiographic systems shall be provided with a means to limit the source-to-skin distance to 30 or more centimeters.

R313-28-54. Radiographic Systems Other Than Fluoroscopic, or Dental Intraoral Systems -- Exposure Reproducibility.

When technique factors, including control panel selections associated with automatic exposure control systems, are held constant the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. This requirement applies to clinically used techniques.

R313-28-55. Radiographic Systems - Standby Radiation From Capacitor Discharge Equipment.

Radiation emitted from the x-ray tube when the system is fully charged and the exposure switch or timer is not activated shall not exceed a rate of 0.516 uC/kg (two milliroentgens) per hour at five centimeters from accessible surfaces of the diagnostic source assembly, with the beam-limiting device fully open.

R313-28-56. Radiographic Systems Other Than Fluoroscopic, or Dental Intraoral Systems -- Accuracy.

Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed ten percent of the indicated value for kVp and ten percent of the indicated value for times greater than 50 milliseconds.

R313-28-57. Radiographic Systems Other Than Fluoroscopic, or Dental Intraoral Systems -- mA/mAs Linearity.

The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for fixed x-ray tube potentials within the range of 40 percent to 100 percent of the maximum rated potentials.

(1) Equipment having independent selection of x-ray tube current, mA. Where the tube current is continuous, the average ratios of exposure to the indicated milliampere-seconds product, C/kg/mAs or mR/mAs, obtained at two consecutive tube current settings or at two settings differing by no more than a factor of two shall not differ by more than 0.10 times their sum.

(2) Equipment having a combined x-ray tube current-exposure time product, mAs, selector, but not a separate tube current, mA, selector. Where the tube current is continuous, the average ratios of exposure to the indicated milliampere-seconds product, C/kg/mAs or mR/mAs, obtained at two consecutive milliampere-seconds settings or at two settings differing by no more than a factor of two shall not differ by more than 0.10 times their sum.

R313-28-80. Intraoral Dental Radiographic Systems.

In addition to the provisions of R313-28-31, R313-28-32 and R313-28-35, the requirements of this section apply to x-ray equipment and associated facilities used for dental radiography. Criteria for extraoral dental radiographic systems are covered in R313-28-51, R313-28-52 and R313-28-53. Intraoral dental radiographic systems used must meet the requirements of R313-28-80.

(1) Source-to-Skin distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:

(a) 18 centimeters if operable above 50 kilovolts peak, or

(b) 10 centimeters if not operable above 50 kilovolts peak.

(2) Field limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray field so that:

(a) if the minimum source-to-skin distance (SSD) is 18 centimeters or more, the x-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than seven centimeters; and

(b) if the minimum SSD is less than 18 centimeters, the x-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than six centimeters.

(3) Exposure Initiation.

(a) Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, for example, the depression of a switch. Radiation exposure shall not be initiated without a deliberate action; and

(b) It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(4) Exposure Termination.

(a) Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

(b) An x-ray exposure control shall be incorporated into x-ray systems so that an exposure of more than 0.5 seconds can be terminated immediately by the operator.

(c) Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(5) Exposure Indication. Means shall be provided for visual indication, observable from the operator's protected position, whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(6) Timer Linearity. For systems having independent selection of exposure time settings, the average ratio of exposure to the indicated milliampere-seconds product obtained at two consecutive timer settings or at two settings not differing by more than a factor of two shall not differ by more than 0.10 times their sum.

(7) Exposure Control Location and Operator Protection.

(a) Stationary x-ray systems shall be required to have the x-ray exposure control mounted in a protected area or a means to allow the operator to be at least 2.7 meters (9.0 feet) from the tube housing assembly while making exposures; and

(b) Mobile and portable x-ray systems which are:

(i) used for greater than one week in the same location, for example, a room or suite, shall meet the requirements of R313-28-80(7)(a); or

(ii) used for less than one week in the same location shall be provided with either a protective barrier at least two meters high for operator protection, or means to allow the operator to be at least 2.7 meters (nine feet) from the tube housing assembly while making exposures.

(8) Exposure Reproducibility. When all technique factors are held constant, the coefficient of variation of exposure shall not exceed 0.05 for certified x-ray systems or 0.10 for non-certified x-ray systems. This requirement applies to clinically used techniques.

(9) mA/mAs Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for fixed x-ray tube potentials within the range of 40 to 100 percent of the maximum rated potentials.

(a) For equipment having independent selection of x-ray tube current, the average ratios of exposure to the indicated milliampere-seconds product obtained at two consecutive tube current settings or, when the tube current selection is continuous, two settings differing by no more than a factor of two shall not differ by more than 0.10 times their sum.

(b) For equipment having a combined x-ray tube current-exposure time product selector but not a separate tube current selector, the average ratios of exposure to the indicated milliampere-seconds product obtained at two consecutive mAs selector settings, or when the mAs selector provides continuous selection, at two settings differing by no more than a factor of two shall not differ by more than 0.10 times their sum.

(10) Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications the deviation shall not exceed ten percent of the indicated value.

(11) Administrative Controls.

(a) Patient and film holding devices shall be used when the technique permits and holding is required.

(b) The x-ray tube housing and the position indicating device shall not be hand-held during an exposure.

(c) The x-ray system shall be operated so that the useful beam at the patient's skin does not exceed the requirements of R313-28-80(2).

(d) Dental fluoroscopy without image intensification shall not be used.

(12) Hand-held Portable Dental X-ray Systems.

(a) X-ray equipment designed to be hand-held shall comply with Section R313-28-31, excluding Subsection R313-28-31(5), and with Section R313-28-80, excluding Subsections R313-28-80(7)(b) and R313-28-80(11)(b).

(b) Protective shielding of at least 0.5 millimeter lead equivalence shall be provided for the operator to protect the operator's torso, hands, face, and gonads from backscatter radiation. If the protective shielding is a backscatter shield attached to the x-ray unit, the shield shall be positioned as close to the patient as possible and the operator shall take care to remain in a protective position.

(c) Portable radiation machines designed to be hand-held are exempt from Subsection R313-28-35(7). The portable radiation machines shall be held by the tube housing support or handle and shall be used in accordance with the manufacturer's operating procedures.

(d) In addition to the requirements of Subsection R313-28-350(1), each operator shall complete the training program supplied by the manufacturer prior to using the x-ray unit. Records of training shall be maintained on file for examination by an authorized representative of the Director.

R313-28-120. Mammography X-Ray Systems - Equipment Design and Performance Standards.

Only x-ray equipment meeting the following standards shall be used for mammography examinations.

(1) Equipment Design.

(a) FDA Standards. The requirements of 21 CFR 1020.30 and 21 CFR 1020.31 (2006) are adopted and incorporated by reference.

(b) Dedicated Equipment. The x-ray equipment shall be specifically designed for mammography.

(c) Compression. Devices parallel to the imaging plane shall be available to immobilize and compress the breast during mammography procedures.

(d) Image Receptor. The x-ray equipment shall have both an 18 cm by 24 cm and a 24 cm by 30 cm image receptor and moving grids matched to each image receptor size.

(e) Automatic Exposure Control. X-ray equipment used in healing arts screening shall have automatic exposure control capabilities with a post exposure meter which indicates either milliampere-seconds or time values.

(f) Focal Spot. The focal spot size and source to image receptor distance configurations shall be limited to those appropriate for mammography.

(g) Beam Limitation. The x-ray equipment must allow for the x-ray field to extend to or beyond the chest wall edge of the image receptor.

(h) Magnification. X-ray equipment used in a noninvasive manner, requiring techniques beyond those utilized in standard

mammography of asymptomatic patients, shall have x-ray magnification capability for noninvasive procedures. The equipment shall be able to provide at least one magnification within the range of 1.4 to 2.0.

(2) Performance Standards.

(a) State Standards. The x-ray equipment shall meet the applicable performance standards in R313-28.

(b) Filtration. The useful beam shall have a half-value layer between the values of the measured kilovolts peak divided by 100 and the measured kilovolts peak divided by 100 plus 0.1 mm of aluminum equivalent. These values are to include the contribution to filtration by the compression device.

(c) Minimum Radiation Output. X-ray equipment installed after the effective date of this rule shall meet the following standard: at 28 kilovolts peak on the focal spot used in routine healing arts screening the x-ray equipment shall be capable of sustaining a minimum output of 500 mR per second for at least three seconds. This output shall be measured at a point 4.5 centimeters from the surface of the patient support device when the source to image receptor distance is at its maximum and the compression paddle is in the beam. Existing x-ray equipment shall meet this minimum radiation output standard within one year of the effective date of this rule.

(d) Exposure Linearity. For kilovolts peak settings used clinically, the exposure per mAs shall be within plus or minus ten percent of the average exposure per mAs for those mAs stations or time stations, if applicable, that are tested.

(e) Automatic Exposure Control. The automatic exposure control mode shall produce consistent film density under changing patient and examination conditions. These conditions include breast thickness, adiposity, kilovolts peak and density settings. This requirement will be deemed satisfied when:

(i) an automatic exposure control technique guide is posted, and

(ii) for a series of films obtained for attenuator thicknesses of two to seven centimeters the resulting radiographic optical densities are within plus or minus 0.2 of the average value when the kVp and density control setting are adjusted as indicated on the technique guide. The attenuator used for determining compliance shall be either acrylic or other tissue equivalent material.

(f) Patient Dose. The x-ray equipment must be capable of giving an average glandular dose to an average size breast of average tissue density that does not exceed 3.0 mGy (0.3 rad) with a grid or 1.0 mGy (0.1 rad) without a grid. This will be deemed satisfied when using an acrylic phantom of 4.5 cm thickness. In addition, under all clinical use conditions, the average glandular dose to the breast must be less than 5.0 mGy (0.5 rad) per film for healing arts screening procedures.

(3) Mammography X-ray Equipment Quality Control.

(a) Initial Installation. Upon completion of the initial installation of the x-ray equipment, and before it is commissioned for clinical use, the equipment shall be evaluated by a mammography imaging medical physicist who has been approved by the Board. The evaluation results shall be submitted to the Director for review and approval.

(b) Annual Evaluation. At intervals not to exceed 12 months or at the request of the Director, the x-ray equipment shall be evaluated by a mammography imaging medical physicist who has been approved by the Board.

(c) The registrant shall develop and implement a quality control testing procedure for monitoring the radiation performance of the x-ray equipment.

R313-28-140. Qualifications of Mammography Imaging Medical Physicist.

An individual seeking certification by the Board for approval as a mammography imaging medical physicist shall file an application for certification on forms furnished by the Division. The Board may certify individuals who meet the requirements for initial qualifications. To remain certified by the Board as a mammography imaging medical physicist, an individual shall satisfy the requirements for continuing qualifications.

(1) Initial qualifications.

(a) Be certified by the American Board of Radiology in Radiological Physics or Diagnostic Radiological Physics, or the American Board of Medical Physicists in Diagnostic Imaging Physics; or

(b) Satisfy the following educational and experience requirements:

(i) Have a master's or higher degree from an accredited university or college in physical sciences; and

(ii) Have two years full-time experience conducting mammography surveys. Five mammography surveys shall be equal to one year full-time experience.

(2) Continuing qualifications.

(a) During the three-year period after initial certification and for each subsequent three-year period, the individual shall earn 15 hours of continuing educational credits in mammography imaging; and

(b) Perform at least two mammography surveys during the 12-month period from June 1 and May 31 to remain certified by the Board.

(3) Mammography imaging medical physicists who fail to maintain the required continuing qualifications stated in R313-28-140(2) shall re-establish their qualifications before independently surveying another mammography facility. To re-establish their qualifications, mammography imaging physicists who fail to meet:

(a) The continuing education requirements of R313-28-140(2)(a) must obtain a sufficient number of continuing educational credits to bring their total credits up to the required 15 in the previous three years.

(b) The continuing experience requirement of R313-28-140(2)(b) must obtain experience by surveying two mammography facilities for each year of not meeting the continuing experience requirements under the supervision of a mammography imaging medical physicist approved by the Board.

R313-28-160. Computed Tomography X-ray Equipment.

(1) Equipment Requirements.

(a) In the event of equipment failure affecting data collection, means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or intercepting the x-ray beam with a shutter mechanism through the use of either a back-up timer or devices which monitor equipment function.

(b) A visible signal shall indicate when the x-ray exposure has been terminated through the means required by R313-28-160 (1)(a).

(c) The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans, of greater than 0.5 second duration.

(2) Tomographic Plane Indication and Alignment.

(a) Means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic plane.

(b) If a device using a light source is used to satisfy R313-28-160 (2)(a), the light source shall provide illumination at levels sufficient to permit visual determination of the location of the tomographic plane or reference plane.

(c) The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.

(3) Beam-On and Shutter Status Indicators.

(a) The computed tomography (CT) x-ray control panel and CT gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

(b) Each emergency button or switch shall be clearly labeled as to its function.

(4) Indication of CT Conditions of Operation.

(a) The CT x-ray system shall be designed such that technique factors, tomographic section thickness, and scan increment shall be indicated prior to the initiation of a scan or series of scans.

(5) Quality Assurance Procedures. Quality assurance procedures shall be conducted on the CT x-ray equipment.

(a) The quality assurance procedures shall be in writing. Such procedures shall include, but not be limited to, the following:

(i) Specifications of the tests that are to be performed, including instructions to be employed in the performance of those tests; and

(ii) Specifications of the frequency at which tests are to be performed, the acceptable tolerance for each parameter measured and actions to be taken if tolerances are exceeded.

(b) The parameters measured to satisfy R313-28-160(5)(a)(ii) shall include, but not be limited to, kVp, mA and reproducibility of dose appropriate to the type of CT procedures performed.

(c) Records of tests performed to satisfy the requirements of R313-28-160(5)(a) and (b) shall be maintained for three years for inspection by the Division.

(6) Dose Calibration.

(a) Radiation measurements shall be performed at least annually and after change or replacement of components which could cause a change in the radiation output.

(b) The calibration of the radiation measuring instrument shall be traceable to a national standard and shall be calibrated at intervals not to exceed two years.

(c) Measurements shall be specified in terms of the multiple scan average dose, using phantoms and technique factors appropriate to the type of CT procedures performed.

R313-28-200. Information on Radiation Shielding Required for Plan Reviews.

In order to evaluate a need for radiation shielding associated with a plan review, the following information shall be submitted to a Qualified Expert so that an adequate review may be performed.

(1) The plans showing, as a minimum, the following:

(a) the normal location of the radiation producing equipment's radiation port, the port's travel and traverse limits, general directions of the radiation beam, locations of windows, the location of the operator's booth, and the location of the x-ray control panel;

(b) structural composition and thickness of walls, doors, partitions, floor, and ceiling of the rooms concerned;

(c) the dimensions, including height, floor to floor, of the rooms concerned;

(d) the type of occupancy of adjacent areas inclusive of space above and below the rooms concerned. If there is an exterior wall, show distance to the closest existing occupied areas;

(e) the make and model of the x-ray equipment, the maximum energy output, and the energy waveform; and

(f) the type of examination or treatment which will be performed with the equipment.

(2) Information on the anticipated workload of the x-ray systems in mA-minutes per week.

(3) A report showing all basic assumptions used in the development of the shielding specifications.

R313-28-300. Additional Requirements Applicable to Certified Systems Only.

Diagnostic x-ray systems incorporating one or more certified components shall be required to comply with the following additional requirements which relate to the certified component.

(1) Beam limitation for stationary and mobile general purpose x-ray systems.

(a) There shall be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters.

(b) When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 LUX (15 foot-candles) at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of the quadrants of the light field. Radiation therapy simulation systems are exempt from this requirement.

(2) Beam Limitation for Portable X-ray Systems. Beam limitation for portable x-ray systems shall meet the additional field limitation requirements of R313-28-51(1) or R313-28-300(1).

(3) Beam limitation and alignment on stationary general purpose x-ray systems equipped with PBL.

(a) PBL shall prevent the production of x-rays when:

(i) either the length or the width of the x-ray field in the plane of the image receptor differs, except as permitted by R313-28-300(3)(c), from the corresponding image receptor dimensions by more than three percent of the SID; or

(ii) the sum of the length and width differences as stated in R313-28-300(3)(a)(i) without regard to sign exceeds four percent of the SID.

(b) Compliance with R313-28-300(3)(a) shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than five seconds after insertion of the image receptor.

(c) The PBL system shall be capable of operation, at the discretion of the operator, so that the field size at the image receptor can be adjusted to a size smaller than the image receptor through stepless adjustment of the field size. The minimum field size at a distance of 100 centimeters shall be equal to or less than five centimeters by five centimeters.

(d) The PBL system shall be designed so that if a change in image receptor does not cause an automatic return to PBL function as described in R313-28-300(3)(a), then change of the image receptor size or SID must cause the automatic return.

(4) Tube Stands for Portable X-Ray Systems. A tube stand or other mechanical support shall be used for portable x-ray systems, so that the x-ray tube housing assembly need not be hand-held during exposures.

R313-28-350. Qualifications of Operators.

Operators of diagnostic x-ray systems must be licensed to practice in Utah in accordance with Title 58 Chapter 54.

(1) The registrant shall document that the operator of diagnostic x-ray equipment is trained in the proper choice of technique factors to be used and in the safe and effective operation of the x-ray equipment.

R313-28-400. Information to be Submitted by Persons Proposing to Conduct Healing Art Screening.

(1) Individuals requesting that the Director approve a healing arts screening program shall submit the following information:

(a) name and address of the applicant and, where applicable, the names and addresses of agents within this State;

(b) diseases or conditions for which the x-ray examinations are to be used;

(c) description, in detail, of the x-ray examinations proposed in the screening program including the frequency of screening and the duration of the entire screening program;

(d) description of the population to be examined in the screening program including age, sex, physical condition, and other appropriate information;

(e) an evaluation of known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used in preference to the x-ray examinations; and

(f) written evidence that:

(i) an Investigational Review Board, which has been approved by the United States Food and Drug Administration, has reviewed and approved the healing arts screening program; or

(ii) the United States Food and Drug Administration has approved the use of the x-ray examination for the diseases or conditions of interest.

(2) The Director shall not approve a request for a healing arts screening program unless the submissions required by R313-28-400(1) are determined by the Director to be complete and adequate.

R313-28-450. Minimum Design Requirements for an X-ray Machine Operator's Booth - New Installations Only.

(1) Space requirements:

(a) The operator shall be allotted not less than 0.70 square meter (7.5 square feet) of unobstructed floor space in the booth.

(b) The minimum space as indicated above may be geometric configurations with no dimension of less than 0.61 meters (two feet).

(c) The space shall be allotted excluding encumbrances by the console, for example, overhang or cables, or other similar encroachments.

(d) The booth shall be located or constructed to ensure that unattenuated primary beam scatter originating on the examination table or at the wall mounted image receptor will not reach the operator's position in the booth.

(2) Structural Requirements.

(a) The booth walls shall be permanently fixed barriers of at least 2.13 meters (seven feet) high.

(b) When a door or movable panel is used as an integral part of the booth shielding, it must have a permissive device which will prevent an exposure when the door or panel is not closed.

(c) Shielding shall be provided to meet the requirements of R313-15.

(3) X-Ray Exposure Control Placement: The x-ray exposure control for the system shall be fixed within the booth and:

(a) shall be at least one meter (40 inches) from points subject to primary beam scatter, leakage or primary beam radiation; and

(b) shall allow the operator to use the majority of the available viewing windows.

(4) Viewing system requirements:

(a) When the viewing system is a window:

(i) the viewing window shall have a visible area of at least 0.09 square meters (one square foot);

(ii) regardless of size or shape, at least 0.09 square meters (one square foot) of the window area must be centered no less than 0.6 meters (two feet) from the open edge of the booth and no less than 1.5 meters (five feet) from the floor; and

(iii) the window shall have at least the same lead equivalence of that required in the booth's wall in which it is mounted.

(b) When the viewing system is by mirrors, the mirrors shall be so located as to accomplish the general requirements of R313-28-450(4)(a).

(c) When the viewing system is by electronic means:

(i) the camera shall be so located as to accomplish the general requirements of R313-28-450(4)(a); and

(ii) there shall be an alternate viewing system as a backup for the primary system.

KEY: dental, X-rays, mammography, beam limitation
Date of Enactment or Last Substantive Amendment: March 1, 2019
Notice of Continuation: July 1, 2016
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-107

State of Utah
Administrative Rule Analysis
Revised December 2019

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION		
	Title No. - Rule No.	
Utah Admin. Code Ref (R no.):	**R313-32**	**Filing No. (Office Use Only)**

Agency Information

1. Department:	Department of Environmental Quality	
Agency:	Waste Management and Radiation Control	
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City, state, zip:	Salt Lake City, Utah 84116	
Mailing address:	PO Box 144880	
City, state, zip:	Salt Lake City, Utah 84114-4880	
Contact person(s):		
Name:	**Phone:**	**Email:**
Tom Ball	801-536-0251	tball@utah.gov
Please address questions regarding information on this notice to the agency.		

General Information

2. Rule catchline:

Medical Use of Radioactive Material.

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Utah Code Subsection 19-3-104(4) allows the Waste Management and Radiation Control Board to make rules to meet the requirements of federal law relating to radiation control to ensure the radiation control program under this part is qualified to maintain primacy from the federal government. R313-32 contains the rules adopted by the board and as part of the state primacy of the radiation control program, the rules in R313-32 have been reviewed by the U.S. Nuclear Regulatory Commission (NRC) and have been determined to be compatible with the corresponding federal radiation protection regulations.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

Since the last five-year review there have been no comments from interested persons specifically supporting or opposing this rule.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

This rule is necessary because it establishes the requirements for medical use of radiation and radioactive material. This rule needs to be continued to ensure that the state's rules are adequate to protect public health and safety, and to meet compatibility requirements of the U.S. Nuclear Regulatory Commission's program. This rule provides protection of public health by regulating the internal and external administration of radioactive material to humans. This rule also establishes training requirements for individuals who are authorized to use radioactive material in the practice of medicine. There have been no opposing comments to this rule since the last five-year review in 2016.

Agency Authorization Information

To the agency: Information requested on this form is required by Section 63G-3-305. Incomplete forms will be returned to the agency for completion, possibly delaying the effective date.

Agency head or designee, and title:		**Date** (mm/dd/yyyy)**:**	

Reminder: Text changes cannot be made with this type of rule filing. To change any text, please file an amendment or nonsubstantive change.

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

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

(2) The rules set forth herein are adopted pursuant to the provisions of Subsections 19-3-104(4) and 19-3-104(7).

R313-32-2. Clarifications or Exceptions.

For the purposes of Rule R313-32, 10 CFR 35.2 through 35.7; 35.10(d) through 35.10(f); 35.11(a) through 35.11(b); 35.12; and 35.13(b) through 35.3204 (2019) are incorporated by reference with the following clarifications or exceptions:

(1) The exclusion of the following:

(a) In 10 CFR 35.2, exclude definitions for "Address of Use," "Agreement State," "Area of Use," "Dentist," "Pharmacist," "Physician," "Podiatrist," and "Sealed Source";

(b) In 10 CFR 35.19, exclude "or the common defense and security ";

(c) In 10 CFR 35.3067, exclude ", with a copy to the Director, Office of Nuclear Material Safety and Safeguards";

(d) In 10 CFR 35.3045(d), 10 CFR 3047(d), 10 CFR 35.3067, and 10 CFR 35.3204(b), exclude "By an appropriate method listed in Sec. 30.6(a) of this chapter,".

(2) The substitution of the following date references:

(a) "May 13, 2005" for "October 24, 2002"; and

(b) "December 31, 2019" for "January 14, 2019";

(3) The substitution of the following rule references:

(a) "Rules R313-32 and R313-15" for reference to "this part and 10 CFR Part 20" in 10 CFR 35.61(a);

(b) "Rule R313-15 for reference to "Part 20 of this chapter" in 10 CFR 35.70(a) and 10 CFR 35.80(a)(4);

(c) "Rules R313-19 and R313-22" for reference to "Part 30 of this chapter" in 10 CFR 35.18(a)(4);

(d) "Rules R313-19 and R313-22 or equivalent Nuclear Regulatory Commission or Agreement State requirements for reference to "10 CFR Part 30 or the equivalent requirements of an Agreement State" in 10 CFR 35.49(c);

(e) "10 CFR Part 30" for reference to "Part 30 of this chapter" as found in 10 CFR 35.65(a)(4);

(f) "Rules R313-15, R313-19, and R313-22" for reference to "parts 20 and 30 of this chapter" as found in 10 CFR 35.63(e)(1);

(g) "Section R313-12-110" for reference to "Sec. 30.6 of this chapter" as found in 10 CFR 35.14(c).;

(h) "Section R313-15-101" for reference to "Sec. 20.1101 of this chapter" as found in 10 CFR 35.24(a);

(i) "Subsection R313-15-301(1)(a)" for reference to "Sec. 20.1301(a)(1) of this chapter" as found in 10 CFR 35.310(a)(2)(i) and 10 CFR 35.410(a)(4)(i);

(j) "Subsection R313-15-301(1)(c)" for reference to "Sec. 20.1301(c) of this chapter" as found in 10 CFR 35.310(a)(2)(ii) and 10 CFR 35.410(a)(4)(ii);

(k) "Section R313-15-501" for reference to "Sec. 20.1501 of this chapter" as found in 10 CFR 35.652(a);

(l) "Section R313-18-12" for reference to "Sec. 19.12 of this chapter" as found in 10 CFR 35.27(a)(1), 10 CFR 35.27(b)(1), 10 CFR 35.310, and 10 CFR 35.410;

(m) "Rules R313-19, R313-22 and Subsection R313-22-75(10) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements" for reference to "10 CFR Part 30 and Sec. 32.74 of this chapter or equivalent requirements of an Agreement State" as found in 10 CFR 35.49(a);

(n) "Subsection R313-22-75(10) or equivalent Nuclear Regulatory Commission or Agreement State requirements" for references to "Sec. 32.74 of this chapter or equivalent Agreement State regulations" found in 10 CFR 35.65(a)(1) and 10 CFR 35.65(a)(2);

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

(p) "Subsection R313-19-34(2)" for reference to "Sec. 30.34(b) of this chapter" as found in 10 CFR 35.14(b)(4);

(q) "Section R313-22-50" for reference to "Part 33 of this chapter" in 10 CFR 35.15;

(r) "Subsection R313-22-50(2)" for reference to "Sec. 33.13 of this chapter" in 10 CFR 35.12(e);

(s) "Subsection R313-22-75(9)(b)(iv)" for reference to "Sec. 32.72(b)(4)" in 10 CFR 35.2 for the definition of Authorized Nuclear Pharmacist;

(t) "Subsection R313-22-75(9) or equivalent Nuclear Regulatory Commission or Agreement State requirements" for reference to "Sec. 32.72 of this chapter or equivalent Agreement State requirements" as found in 10 CFR 35.63(b)(2)(i), 10 CFR 35.63(c)(3)(i), 10 CFR 35.100(a)(1), 10 CFR 35.200(a)(1), and 10 CFR 35.300(a)(1); and

(u) "Subsection R313-22-32(9) or equivalent Nuclear Regulatory Commission or Agreement State requirements" for reference to "Sec. 30.32(j) of this chapter or equivalent Agreement State requirements" as found in 10 CFR 35.63(b)(2)(iii), 10 CFR 35.63(c)(3)(ii), 10 CFR 35.100(a)(2), 10 CFR 35.200(a)(2), or 10 CFR 35.300(a)(2).

(4) The substitution of the following terms:

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

(b) "a Director, a Nuclear Regulatory Commission, or Agreement State" for reference to "an NRC or Agreement State" in 10 CFR 35.63(b)(2)(ii), 10 CFR 35.100(c), 10 CFR 35.200(c), or 10 CFR 35.300(c);

(c) "Director is (801) 536-0200 or after hours, (801) 536-4123" for "NRC Operations Center is (301) 816-5100" as found in the footnote included for 10 CFR 35.3045(c);

(d) "Form DWMRC-01, 'Application for Radioactive Material License'" for reference to "NRC Form 313, 'Application for Material License'" as found in 10 CFR 35.12(b)(1), 10 CFR 35.12(c)(1)(i) and 10 CFR 35.18(a)(1);

(e) "Form DWMRC-01" for reference to "NRC Form 313" as found in 10 CFR 35.12(c)(1)(ii);

(f) "medical use license issued by the Director" for reference to "NRC medical use license" in 10 CFR 35.6(c);

(g) "Director, the U.S. Nuclear Regulatory Commission, or an Agreement State" for reference to "Commission or Agreement State" in 10 CFR 35.2 for the definitions of Authorized Medical Physicist (2)(i), Authorized Nuclear Pharmacist (2)(iii) and Radiation Safety Officer (2)(i), in 10 CFR 35.57(b)(1) (first instance), 10 CFR 35.57(b)(2) (first instance), 10 CFR 35.433(a)(2)(i); or for references to "Commission or an Agreement State" in 10 CFR 35.2 for the definitions of Associate Radiation Safety Officer (2)(i) and Ophthalmic Physicist (2)(i), 10 CFR 35.11(a),in 10 CFR 35.50(a), 10 CFR 35.50(a)(2)(ii)(A), 10 CFR 35.50(c)(1), 10 CFR 35.51(a), 10 CFR 35.51(a)(2)(i), 10 CFR 35.55(a), 10 CFR 35.190(a), 10 CFR 35.290(a), 10 CFR 35.390(a), 10 CFR 35.392(a), 10 CFR 35.394(a), 10 CFR 35.396(a)(3), 10 CFR 35.433(a)(2)(i), 10 CFR 35.490(a), 10 CFR 35.590(a), 10 CFR 35.605(a), 110 CFR 35.605(b), 10 CFR 35.605(c), 10 CFR 35.655(b) and 10 CFR 35.690(a);

(h) "Director, a U.S. Nuclear Regulatory Commission, or an Agreement State" for references to "Commission or Agreement State" in 10 CFR 35.2 for the definitions of Authorized Medical Physicist (2)(iii), Authorized Nuclear Pharmacist (2)(i), Authorized User (2)(i), Authorized User (2)(iii) and Ophthalmic Physicist (2)(ii), in 10 CFR 13(b)(4)(ii), 10 CFR 35.14(a)(2)(second instance), 10 CFR 35.57(a)(1)(second instance), 10 CFR 35.57(b)(1)(second instance), 10 CFR 35.57(b)(2)(second instance), 10 CFR 35.433(a)(2)(ii)(second instance); or for references to "Commission or an Agreement State" in 10 CFR 35.50(c)(2)(second instance);

(i) "license issued by the Director, the Nuclear Regulatory Commission, or the Agreement State" for reference to "Commission or Agreement State license" in 10 CFR 35.14(a)(2)(first instance);

(j) "Director" for reference to "NRC Operations Center" in 10 CFR 35.3045(c), 10 CFR 35.3047(c), and 10 CFR 35.3204(a);

(k) "license issued by the Director, the Nuclear Regulatory Commission or an Agreement State" for reference to "Commission or Agreement State license" in 10 CFR 35.13(b)(4)(i), 10 CFR 35.14(a)(2)(first instance), 10 CFR 35.50(b)(1)(ii) or for reference to "Commission or an Agreement State license" in 10 CFR 35.50(b)(1)(ii), 10 CFR 35.50(c)(2), and 10 CFR 35.57(a)(2);

(l) "Director at the address specified in Section R313-12-110" for reference to "appropriate NRC Regional Office listed in Sec. 30.6 of this chapter" in 10 CFR 35.3045(d), 10 CFR 35.3047(d), 10 CFR 35.3067, and 10 CFR 35.3204(b);

(m) "Board" for reference to "Commission" in 10 CFR 35.18(a)(3)(second instance) and 10 CFR 35.19;

(n) "Director" for reference to "Commission" in 10 CFR 35.12(d)(4), 10 CFR 35.14(a), 10 CFR 35.14(b), 10 CFR 35.18(a), 10 CFR 35.18(a)(3)(first instance), 10 CFR 35.18(b), 10 CFR 35.24(a)(1), 10 CFR 35.24(c), 10 CFR 35.26(a), and 10 CFR 35.1000(b);

(o) "Director" for reference to "NRC" in 10 CFR 35.3045(g)(1), 10 CFR 35.3047(f)(1), and 10 CFR 35.3204(a)(second instance);

(p) "Nuclear Regulatory Commission" for reference to "Commission" in 10 CFR 35.67(b)(2);

(q) "Director" for reference to "NRC" in 10 CFR 35.3045(g)(1), 10 CFR 35.3047(f)(1), and 10 CFR 35.35.3204(a)(second instance); and

(r) "the Director" for reference to "NRC" in 10 CFR 35.13(b)(4)(i);

(s) "licenses issued by the Director" for reference to "NRC licenses" in 10 CFR 35.57(c);

(t) "Director, the Nuclear Regulatory Commission, or an Agreement State" for reference to "NRC" in 10 CFR 35.13(b)(5), 10 CFR 35.14(a)(2), 10 CFR 35.57(b)(3), and 10 CFR 35.57(a)(4);

(u) "(c)" for reference to "(b)" in 10 CFR 35.92.

(5) The addition of the following to 10 CFR 35.92:

(b) The Director may approve a radioactive material with a physical half-life of greater than 120 days but less than 175 days for decay-in-storage before disposal without regard to its radioactivity on a case by case basis if the licensee:

(1) Requests an amendment to the licensee's radioactive materials license for the approval;

(2) Can demonstrate that the radioactive waste will be safely stored, and accounted for during the decay-in-storage period and that the additional radioactive waste will not exceed the licensee's radioactive waste storage capacity; and

(3) Commits to monitor the waste before disposal as stated in paragraphs (a)(1) and (a)(2) of this section before the waste is disposed."

KEY: radioactive materials, radiopharmaceutical, brachytherapy, nuclear medicine
Date of Enactment or Last Substantive Amendment: August 9, 2019
Notice of Continuation: July 1, 2016
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-107

State of Utah
Administrative Rule Analysis
Revised December 2019

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION		
	Title No. - Rule No.	
Utah Admin. Code Ref (R no.):	**R313-36**	**Filing No. (Office Use Only)**

Agency Information

1. Department:	Department of Environmental Quality	
Agency:	Waste Management and Radiation Control	
Room no.:	Second Floor	
Building:	MASOB	
Street address:	195 North 1950 West	
City, state, zip:	Salt Lake City, Utah 84116	
Mailing address:	PO Box 144880	
City, state, zip:	Salt Lake City, Utah 84114-4880	
Contact person(s):		
Name:	**Phone:**	**Email:**
Tom Ball	801-536-0251	tball@utah.gov
Please address questions regarding information on this notice to the agency.		

General Information

2. Rule catchline:

Special Requirements for Industrial Radiographic Operations.

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Utah Code Subsection 19-3-104(4) allows the Waste Management and Radiation Control Board to make rules to meet the requirements of federal law relating to radiation control to ensure the radiation control program under this part is qualified to maintain primacy from the federal government. R313-36 contains the rules adopted by the board and as part of the state primacy of the radiation control program, the rules in R313-36 have been reviewed by the U.S. Nuclear Regulatory Commission (NRC) and have been determined to be compatible with the corresponding federal radiation protection regulations.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

Since the last five-year review there have been no comments from interested persons specifically supporting or opposing this rule.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

This rule is necessary to continue because it establishes the radiation safety requirements for person who use radioactive material to examine the macroscopic structure of materials. This rule needs to be continued to ensure that the states rules are adequate to protect public health and safety. The rule establishes the training criteria a person must meet to utilize a radiographic exposure device in an industrial setting. As an Agreement State the rule is necessary for maintaining the appropriate regulatory compatibility with the NRC. There have been no opposing comments to the rule since the last five-year review in 2016.

Agency Authorization Information

To the agency: Information requested on this form is required by Section 63G-3-305. Incomplete forms will be returned to the agency for completion, possibly delaying the effective date.

Agency head or designee, and title:		**Date** (mm/dd/yyyy)**:**	

Reminder: Text changes cannot be made with this type of rule filing. To change any text, please file an amendment or nonsubstantive change.

R313. Environmental Quality, Radiation Control.
R313-36. Special Requirements for Industrial Radiographic Operations.
R313-36-1. Purpose and Authority.

(1) The rules in R313-36 prescribe requirements for the issuance of licenses and establish radiation safety requirements for persons utilizing sources of radiation for industrial radiography.

(2) The rules set forth herein are adopted pursuant to the provisions of Subsections 19-3-104(4) and 19-3-104(7).

(3) The requirements of R313-36 are in addition to, and not in substitution for, the other requirements of these rules.

R313-36-2. Scope.

(1) The requirements of R313-36 shall apply to licensees using radioactive materials to perform industrial radiography.

(2) The requirements of R313-36 shall not apply to persons using electronic sources of radiation to conduct industrial radiography.

R313-36-3. Clarifications or Exceptions.

For purposes of R313-36, 10 CFR 34.3; 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 (2019), 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: February 14, 2020
Notice of Continuation: July 1, 2016
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-104

State of Utah
Administrative Rule Analysis
Revised December 2019

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION		
	Title No. - Rule No.	
Utah Admin. Code Ref (R no.):	**R313-70**	**Filing No. (Office Use Only)**

Agency Information

1. Department:	Department of Environmental Quality	
Agency:	Waste Management and Radiation Control	
Room no.:	Second Floor	
Building:	MASOB	
Street address:	195 North 1950 West	
City, state, zip:	Salt Lake City, Utah 84116	
Mailing address:	PO Box 144880	
City, state, zip:	Salt Lake City, Utah 84114-4880	
Contact person(s):		
Name:	**Phone:**	**Email:**
Tom Ball	801-536-0251	tball@utah.gov
Please address questions regarding information on this notice to the agency.		

General Information

2. Rule catchline:

Payments, Categories and Types of Fees.

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Utah Code Subsection 19-3-104(6) requires the division to assess fees for registration, licensing, and inspection of radiation sources. It also requires the division to comply with the requirements of Section 63J-1-504 in assessing fees for licensure and registration.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

Since the last five-year review there have been no comments from interested persons specifically supporting or opposing this rule.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

It is necessary to continue this rule because it establishes the requirements for payment of fees for the registration or licensing of sources of radiation. The rule identifies registration or license categories, the time period that a license is valid, and the type of fees the division has established pursuant to Section 63J-1-504. There have been no opposing comments to the rule since the last five-year review in 2016.

Agency Authorization Information

To the agency: Information requested on this form is required by Section 63G-3-305. Incomplete forms will be returned to the agency for completion, possibly delaying the effective date.

Agency head or designee, and title:		**Date** (mm/dd/yyyy)**:**	

Reminder: Text changes cannot be made with this type of rule filing. To change any text, please file an amendment or nonsubstantive change.

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.
R313-70. Payments, Categories and Types of Fees.
R313-70-1. Purpose and Authority.

(1) The purpose of this rule is to prescribe the requirements to assess fees of registrants and licensees possessing sources of radiation.

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

R313-70-2. Scope.

The requirements of Rule R313-70 apply to persons who receive, possess, or use sources of radiation provided: however, that nothing in these rules shall apply to the extent a person is subject to regulation by the U.S. Nuclear Regulatory Commission.

R313-70-3. Communications.

Communications concerning Rule R313-70 should be addressed to the Director, and may be sent to the Division of Waste Management and Radiation Control, Department of Environmental Quality. Communications may be delivered in person at the Division of Waste Management and Radiation Control offices.

R313-70-5. Payment of Fees.

(1) New Application Fee: Applications for radiation machine registration or radioactive material licensing for which a fee is prescribed, shall be accompanied by a remittance in the full amount of the fee. Applications will not be accepted for filing or processing prior to payment of the full amount specified. Applications for which no remittance is received will be returned to the applicant. Application fees will be charged irrespective of the Director's disposition of the application or a withdrawal of the application.

(2) Annual Fee: Persons and individuals who are subject to licensing or registration of radioactive material or radiation machine registration with the Director under provisions of the Utah Radiation Control Rules, are assessed an annual fee in accordance with categories of Sections R313-70-7 and R313-70-8. The appropriate fee shall be filed annually with the Director, by the due date the Director specifies for registrants or by the anniversary date for licensees. The account of a licensee or registrant that is delinquent on or after 61 days may be transferred to the Office of State Debt Collection in accordance with Section R21-1-5.

(3) Inspection Fee: Persons and entities who, under provisions of the Utah Radiation Control Rules, are subject to radiation machine registration with the Director are assessed an inspection fee in accordance with Section R313-70-8. Fees for inspection of a radiation machine are due within 30 days of receipt of an invoice from the Agency. The inspection account of a registrant that is delinquent on or after 61 days may be transferred to the Office of State Debt Collection in accordance with Section R21-1-5.

(4) Failure to pay the prescribed fee: the Director will not process applications and may suspend or revoke licenses or registrations or may issue an order with respect to the activities as the Director determines to be appropriate or necessary in order to carry out the provisions of this part of Rule R313-70, and of the Act.

(a) General license certificates of registration and new specific licenses issued pursuant to the provisions in Rules R313-21 or R313-22, will be valid for a period of five years unless failure to submit appropriate fee occurs. Specific license renewals issued pursuant to the provisions in Rule R313-22 may be valid for a period of ten years or less in accordance with Subsections R313-22-34(1)(b) and (1)(c). Machine registrations will be valid for one year during the schedule established by the Director in accordance with Section R313-16-230. Failure to submit appropriate fees will render the license, certificate or registration invalid, at which time a new application with appropriate fees shall be submitted.

(b) Renewal applications shall be filed in a timely manner in accordance with Sections R313-22-37 or R313-16-230. The radioactive material license will expire on the date specified on the license. A general license certificate of registration will expire on the date specified on the certificate of registration. A radiation machine registration will expire as outlined in Section R313-16-230. The Director may renew an expired license if the licensee provides information that explains why the renewal application was not submitted pursuant to the provisions in Subsection R313-22-36(1) and other information the Director may request to determine that issuance of the license will not be inimical to the health and safety of the public.

(5) Method of Payment: Fees shall be made payable to: Division of Waste Management and Radiation Control, Department of Environmental Quality.

R313-70-7. License Categories and Types of Fees for Radioactive Materials Licenses.

Fees shall be established in accordance with Section 63j-1-504. Copies of established fee schedules may be obtained from the Director.

TABLE

LICENSE CATEGORY	TYPE OF FEE
(1) Special Nuclear Material	
(a) Licenses for possession and use	New License or Renewal Annual Fee

of special nuclear material in sealed sources contained in devices used in industrial measuring systems, including x-ray fluorescence analyzers and neutron generators.	
(b) Licenses for possession and use of less than 15 g special nuclear material in unsealed form for research and development.	New License or Renewal Annual Fee
(c) All other special nuclear material licenses.	New License or Renewal Annual Fee
(d) Special nuclear material to be used as calibration and reference sources.	New License or Renewal Annual Fee
(2) Source Material.	
(a) Licenses for concentrations of uranium from other areas like copper or phosphates for the production of moist, solid, uranium yellow cake.	New License or Renewal Annual Fee Review Fees
(b) Licenses for possession and use of source material in extraction facilities such as conventional milling, in-situ leaching, heap leaching, and other processes including licenses authorizing the possession of byproduct material (tailings and other wastes) from source material extraction facilities, as well as licenses authorizing the possession and maintenance of a facility in a standby mode, and licenses that authorize the receipt of byproduct material,	Monthly fee for active or inactive mill Review Fees

as defined in Section 19-3-102, from other persons for possession and disposal incidental to the disposal of the uranium waste tailings generated by the licensee's milling operations.	
(c) Licenses that authorize the receipt of byproduct material, as defined in Section 19-3-102, from other persons for possession and disposal.	Application Fee New License or Renewal Monthly Fee
(d) Licenses for possession and use of source material for shielding.	New License or Renewal Annual Fee
(e) All other source material licenses.	New License or Renewal Annual Fee
(3) Radioactive Material Other than Source Material and Special Nuclear Material.	
(a)(i) Licenses of broad scope for possession and use of radioactive material for processing or manufacturing of items containing radioactive material for commercial distribution.	New License or Renewal Annual Fee
(a)(ii) Other licenses for possession and use of radioactive material for processing or manufacturing of items containing radioactive material for commercial distribution.	New License or Renewal Annual Fee
(b) Licenses authorizing the processing or manufacturing and distribution or redistribution of radio-pharmaceuticals, generators, reagent kits, or sources or devices containing radioactive material.	New License or Renewal Annual Fee

(c) Licenses authorizing distribution or redistribution of radiopharmaceuticals, generators, reagent kits, or sources or devices not involving processing of radioactive material.	New License or Renewal Annual Fee
(d) Licenses for possession and use of radioactive material for industrial radiography operations.	New License or Renewal Annual Fee
(e) Licenses for possession and use of sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units).	New License or Renewal Annual Fee
(f)(i) Licenses for possession and use of less than 10,000 curies of radioactive material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes.	New License or Renewal Annual Fee
(f)(ii) Licenses for possession and use of 10,000 curies or more of radioactive material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes.	New License or Renewal Annual Fee
(g) Licenses to distribute items containing radioactive material that require device	New License or Renewal Annual Fee

review to persons exempt from the licensing requirements of Rule R313-19, except specific licenses authorizing redistribution of items that have have been authorized for distribution to persons exempt from the licensing requirements of Rule R313-19.	
(h) Licenses to distribute items containing radioactive material or quantities of radioactive material that do not require device evaluation to persons exempt from the licensing requirements of Rule R313-19, except for specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of Rule R313-19.	New License or Renewal Annual Fee
(i) Licenses to distribute items containing radio-active material that require sealed source or device review to persons generally licensed under Rule R313-21, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under Rule R313-21.	New License or Renewal Annual Fee
(j) Licenses to distribute items containing radioactive material	New License or Renewal Annual Fee

or quantities of radioactive material that do not require sealed source or device review to persons generally licensed under Rule R313-21, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under Rule R313-21.	
(k) Licenses for possession and use of radioactive material for research and development, which do not authorize commercial distribution.	New License or Renewal Annual Fee
(l) All other specific radioactive material licenses.	New License or Renewal Annual Fee
(m) Licenses of broad scope for possession and use of radioactive material for research and development which do not authorize commercial distribution.	New License or Renewal Annual Fee
(n) Licenses that authorize services for other licensees, except licenses that authorize leak testing or waste disposal services which are subject to the fees specified for the listed services.	New License or Renewal Annual Fee
(o) Licenses that authorize services for leak testing only.	New License or Renewal Annual Fee
(4) Radioactive Waste Disposal:	
(a) Licenses specifically authorizing the receipt of	Application Fee New License or Renewal Siting Review Fee

waste radioactive material from other persons for the purpose of commercial disposal by land by the licensee.	
(b) Licenses specifically authorizing the receipt of waste radioactive material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material.	New License or Renewal Annual Fee
(c) Licenses specifically authorizing the receipt of prepackaged waste radioactive material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material.	New License or Renewal Annual Fee
(d) Licenses authorizing packaging of radioactive waste for shipment to waste disposal site where licensee does not take possession of waste material.	New License or Renewal Annual Fee
(5) Well logging, well surveys and tracer studies.	
(a) Licenses for possession and use of radioactive material for well logging,	New License or Renewal Annual Fee

well surveys and tracer studies other than field flooding tracer studies.	
(b) Licenses for possession and use of radioactive material for field flooding tracer studies.	New License or Renewal Annual Fee
(6) Nuclear laundries.	
(a) Licenses for commercial collection and laundry of items contaminated with radioactive material.	New License or Renewal Annual Fee
(7) Human use of radioactive material.	
(a) Licenses for human use of radioactive material in sealed sources contained in teletherapy devices.	New License or Renewal Annual Fee
(b) Other licenses issued for human use of radioactive material, except licenses for use of radioactive material contained in teletherapy devices.	New License or Renewal Annual Fee
(c) Licenses of broad scope issued to medical institutions or two or more physicians authorizing research and development, including human use of radioactive material, except licenses for radio-active material in sealed sources contained in teletherapy devices.	New License or Renewal Annual Fee
(8) Civil Defense.	
(a) Licenses for possession and use of radioactive material for civil defense activities.	New License or Renewal Annual Fee
(9) Power Source.	

(a) Licenses for the manufacture and distribution of encapsulated radioactive material wherein the decay energy of the material is used as a source for power.	New License or Renewal	Annual Fee
(10) General License.		
(a) Measuring, gauging and control devices as described in Subsection R313-21-22(4), other than hydrogen-3 (tritium) devices and polonium-210 devices containing no more than 10 millicuries used for producing light or an ionized atmosphere.	Fee per device	
(b) In Vitro testing	Fee per registration certificate	
(c) Depleted uranium	Fee per registration certificate	
(d) Reciprocal recognition, as provided for in Section R313-19-30, of a license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.	Annual fee for license category listed in R313-70-7(1) through (10), per 180 days in one calendar year	

R313-70-8. Registration and Inspection Categories and Types of Fees for Registration of Radiation Machines.

(1) For machines registered under Section R313-16-230, registrants will pay an annual registration fee and an inspection fee that shall be established in accordance with Section 63j-1-504. Copies of established fee schedules may be obtained from the Director.

TABLE

FACILITY TYPE	TYPE OF FEE	
Hospital/Therapy	Registration	Annual per control unit and first tube plus annual per each additional tube connected to a control unit.
	State Inspection	Per tube.
Medical	Registration	Annual per control unit and first tube plus annual per each additional tube

			connected to a control unit.
	State Inspection	Per tube.	
Podiatry	Registration	Annual per control	unit and first tube plus annual per each additional tube connected to a control unit.
	State Inspection	Per tube.	
Veterinary	Registration	Annual per control	unit and first tube plus annual per each additional tube connected to a control unit.
	State Inspection	Per tube.	
Chiropractic	Registration	Annual per control	unit and first tube plus annual per each additional tube connected to a control unit.
	State Inspection	Per tube.	
Dental	Registration	Annual per control	unit and first tube plus annual per each additional tube connected to a control unit.
	State Inspection	Per control unit	and first tube plus each additional tube connected to a control unit.
Industrial Facility with High or Very High Radiation Areas Accessible to Individuals	Registration	Annual per control	unit and first tube plus annual per each additional tube connected to a control unit.
	State Inspection	Per tube.	
Industrial Facility with Cabinet X-ray or Units Designed for Other Industrial Purposes	Registration	Annual per control	unit and first tube plus annual per each additional tube connected to a control unit.
	State Inspection	Per tube.	
Other	Registration	Annual per control	unit and first tube plus annual per each

	additional tube connected to a control unit.	
State Inspection	Per tube.	
Acceptance of work, performed by a person meeting the qualifications in Section R313-16-292, that demonstrates compliance with these rules.	Per tube reviewed.	

R313-70-9. Other Fees for Services.

TABLE

(1) Expedited application review. Applicable when, by mutual consent of the applicant and affected staff, an application request is taken out of date order and processed by staff during non-work hours.	Hourly	
(2) Review of plans for decommissioning, decontamination, reclamation, or site restoration activities.	Plan Review Plus Hourly	
(3) Management and oversight of impounded radioactive material.	Actual Cost	
(4) License amendment, for greater than three applications in a calendar year.	Amendment Fee	

KEY: radioactive materials, x-rays, registration, fees
Date of Enactment or Last Substantive Amendment: October 21, 2014
Notice of Continuation: July 1, 2016
Authorizing, and Implemented or Interpreted Law: 19-3-104(6)

WASTE MANAGEMENT AND RADIATION CONTROL BOARD
Executive Summary
REQUEST FOR A SITE-SPECIFIC TREATMENT VARIANCE
Energy*Solutions*, LLC
April 8, 2021

What is the issue before the Board?	On March 17, 2021, Energy*Solutions*, LLC submitted a request to the Director of the Division of Waste Management and Radiation Control for a one-time site-specific treatment variance from the Utah Hazardous Waste Management Rules. Energy*Solutions* seeks authorization to receive lithium and lithium-ion batteries for treatment and disposal.
What is the historical background or context for this issue?	The Mixed Waste Facility proposes to receive lithium and lithium-Ion batteries for treatment and disposal at the Mixed Waste Facility. Lithium and lithium-ion batteries typically exhibit the hazardous characteristics of ignitability (D001) and reactivity (D003). Regulations in UAC R315-268-40 require that these characteristic hazards be deactivated to remove the characteristic prior to land disposal. As an alternative, UAC R315-268-45 allows hazardous debris to be treated using an immobilization technology (e.g., macroencapsulation). However, the Environmental Protection Agency (EPA) has ruled that intact batteries are containers and not considered debris. Furthermore, the definition of macroencapsulation in R315-268-42 states that "[M]acroencapsulation specifically does not include any material that would be classified as a tank or container." In order to meet the regulatory standards described above, lithium and lithium-ion batteries would need to be shredded and mixed with reagents to deactivate them; or punctured (and then considered debris) to macroencapsulate them. Both of these activities (shredding and puncturing) severely agitate the waste and would expose the reactive portion of the waste to open air which could cause an adverse reaction or explosion. EnergySolutions proposes to manage this waste by directly macroencapsulating the intact batteries as if they were debris. Macroencapsulation is a permitted treatment technology that isolates hazardous waste from the environment, eliminating the potential for harmful reactions from exposure to the environment. Final disposal of the waste will occur in the Mixed Waste Disposal Cell at the EnergySolutions Mixed Waste Facility. A notice for public comment was published in the *Salt Lake Tribune* on April 4, 2021 the *Deseret News* on April 2, 2021 and the *Tooele County Transcript Bulletin* on April 1, 2021. The comment period began April 5, 2021 and will end May 4, 2021.

What is the governing statutory or regulatory citation?	Variances are provided for in 19-6-111 of the Utah Solid and Hazardous Waste Act. This is a one-time site-specific variance from an applicable treatment standard as allowed by R315-268.44 of the Utah Administrative Code.
Is Board action required?	No. This is an informational item before the Board.
What is the Division/Director's recommendation?	The Director will provide a recommendation following the public comment period at the next Board meeting.
Where can more information be obtained?	For technical questions, please contact Otis Willoughby (801) 536-0220. For legal questions, please contact Bret Randall at (801) 536-0284.

DSHW-2021-004648

Division of Waste Management and Radiation Control

MAR 25 2021

March 17, 2021 CD-2021-039

Mr. Ty Howard
Director
Division of Waste Management and Radiation Control
195 North 1950 West
Salt Lake City, UT 84114-4880

Subject: EPA ID Number UTD982598898 ✓
Request for a Site-Specific Treatment Variance for the Macroencapsulation of Lithium and Lithium-Ion Batteries

Dear Mr. Howard:

Energy*Solutions* herein requests an exemption from Utah Administrative Code (UAC) R315-268-40 and R315-268-45 for the direct macroencapsulation treatment of lithium and lithium-ion batteries. This request is being submitted in accordance with the requirements of UAC R315-260-19.

The regulatory requirement authorizing this request is found in UAC R315-268-44 which allows a site-specific variance from an applicable treatment standard provided that the following condition is met:

> *UAC R315-268-44(h)(2) It is inappropriate to require the waste to be treated to the level specified in the treatment standard or by the method specified as the treatment standard, even though such treatment is technically possible.*

Lithium and lithium-ion batteries typically exhibit the hazardous characteristics of ignitability (D001) and reactivity (D003). Regulations in UAC R315-268-40 (40 CFR 268.40, 2015 Edition, incorporated by reference) require that these characteristic hazards be deactivated to remove the characteristic prior to land disposal. As an alternative, UAC R315-268-45 allows hazardous debris to be treated using an immobilization technology (e.g., macroencapsulation). However, the Environmental Protection Agency (EPA) has ruled that intact batteries are containers and not considered debris (see attached letter dated November 10, 1993). Furthermore, the definition of macroencapsulation in R315-268-42 states that "[M]acroencapsulation specifically does not include any material that would be classified as a tank or container."

In order to meet the regulatory standards described above, lithium and lithium-ion batteries would need to be shredded and mixed with chemicals to deactivate them; or punctured (and then

299 South Main Street, Suite 1700 • Salt Lake City, Utah 84111
(801) 649-2000 • Fax (801) 880-2879 • www.energysolutions.com

considered debris) to macroencapsulate them. Both of these activities (shredding and puncturing) severely agitate the waste and would expose the reactive portion of the waste to open air which could cause an adverse reaction or explosion. Although this type of waste management is possible, from a safety and health standpoint, it is inappropriate.

Energy*Solutions* proposes to manage this waste by directly macroencapsulating the intact batteries. Macroencapsulation is a permitted treatment technology that isolates hazardous waste from the environment, eliminating the potential for harmful reactions from exposure to the environment. Macroencapsulation requires less handling of the waste and creates a waste form for disposal that is protective of human health and the environment.

The name, phone number, and address of the person who should be contacted to notify Energy*Solutions* of decisions by the Director is

Mr. Vern Rogers
Director of Regulatory Affairs
Energy*Solutions* LLC
299 South Main Street, Suite 1700
Salt Lake City, UT 84111
(801) 649-2000

Should there be any questions to this request, please contact me at (801) 649-2144.

Sincerely,

Tim Orton
Mar 17 2021 10:59 AM
cosign

Timothy L. Orton, P.E.
Environmental Engineer and Manager

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

9441.1993(23)

REGULATORY STATUS OF BATTERY CARCASSES

United States Environmental Protection Agency
Washington, D.C. 20460
Office of Solid Waste and Emergency Response

November 10, 1993

Mr. Christopher L. Freed
Chemical Waste Management, Inc.
Manager - Environmental Regulations
3001 Butterfield Road
Oak Brook, Illinois 60521

Dear Mr. Freed:

Thank you for your letter of April 30, 1993 summarizing your meeting of April 29, 1993 with Richard Kinch of my staff. Upon further investigation of this issue since the receipt of your letter, however, it is clear that battery carcasses do not qualify as debris. They are considered to be containers, as explained below.

As discussed in detail in the preamble to the final rule establishing alternate treatment standards for hazardous debris, intact containers are not debris, and hence are not subject to the treatment standards for debris. 57 FR 37225 (August 18, 1992). In addition, in previous rulemakings EPA has stated that battery casings designed to hold free liquids for use other than storage are containers. I refer you specifically to 40 CFR 264.314(d)(3); 265.314(c)(3); and 55 FR 22637/2 (June 1, 1990). Thus, such intact battery casings are not debris.

In your letter, you state that EPA suggested, elsewhere in the preamble to the final debris rule, that batteries could be debris unless they are subject to a specific treatment standard. I believe you have based this statement on the discussion at 57 FR 37222 and footnote 10, which gives "lead acid or cadmium batteries" as an example of a debris subject to a specific treatment standard. Unfortunately, you then draw the inference that because mercury batteries are not mentioned in this footnote, they are therefore debris.

RO 13638

This is an incorrect conclusion. First, please note that the actual regulatory language does not contain the example of the lead acid battery. 57 FR at 37270. More important, as explained above, intact containers are never classified as debris. Consequently, the example in footnote 10 refers only to lead acid or cadmium batteries that are not intact. Such batteries would still not be subject to the treatment standards for debris because there is a more specific treatment standard for lead acid or cadmium batteries. The footnote does not, however, in any way vitiate the general principle that intact containers are not debris and that batteries are types of containers.

I hope this response, based on a thorough examination of the issue of concern, is helpful. If you need further information, please contact Richard Kinch, Chief of the Waste Treatment Branch in our Waste Management Division at (703) 308-8434.

Sincerely,
Bruce R. Weddle
Acting Director
Office of Solid Waste

RO 13638

WASTE MANAGEMENT AND RADIATION CONTROL BOARD
Executive Summary
REQUEST FOR A SITE-SPECIFIC TREATMENT VARIANCE
Energy*Solutions*, LLC
April 8, 2021

What is the issue before the Board?	On January 11, 2021, Energy*Solutions*, LLC submitted a request to the Director of the Division of Waste Management and Radiation Control for a one-time site-specific treatment variance from the Utah Hazardous Waste Management Rules. Energy*Solutions* seeks authorization to receive Cemented Uranium Extraction Process Residues for disposal.
What is the historical background or context for this issue?	The Mixed Waste Facility proposes to receive up to 1,000 cubic feet of cemented monoliths containing enriched uranium residuals. This material retains hazardous waste codes for barium, cadmium, chromium, lead, and spent solvents. The generator has encapsulated the waste in concrete for safety and security reasons. Energy*Solutions* proposes to receive this waste for macroencapsulation in the Mixed Waste Landfill Cell rather than chemical stabilization, as required. This request is based on the fact that the waste has already been encapsulated in concrete at the generator's site. Treating this waste by the required method would mean grinding the waste and potentially exposing workers to unnecessary contamination. The proposed treatment will further encapsulate the waste and protect it from contact with precipitation, thereby decreasing the potential of leaching. Energy*Solutions* has requested and received treatment variances for this waste stream every year from 2007 through 2020. Since the last variance was approved, approximately 894 cubic feet of this waste has been received. A 30-day notice for public comment was published in the *Salt Lake Tribune*, the *Deseret News* and the *Tooele County Transcript Bulletin.* The comment period began February 8, 2021 and ended March 9, 2021.
What is the governing statutory or regulatory citation?	Variances are provided for in 19-6-111 of the Utah Solid and Hazardous Waste Act. This is a one-time site-specific variance from an applicable treatment standard as allowed by R315-268.44 of the Utah Administrative Code.
Is Board action required?	Yes, this is an action item before the Board.
What is the Division/Director's recommendation?	The Director recommends approval of this variance request. The Director's recommendation is based on the following findings: the proposed alternative treatment method meets the regulatory basis for a variance and will be as safe to human health and the environment as the required method.
Where can more information be obtained?	For technical questions, please contact Otis Willoughby (801) 536-0220. For legal questions, please contact Bret Randall at (801) 536-0284.

DSHW-2021-004462
Attachment: DSHW-2021-000465

DSHW-2021-000465

Div of Waste Management
and Radiation Control

JAN 11 2021

January 11, 2021 CD-2021-005

Mr. Ty Howard
Director
Division of Waste Management and Radiation Control
195 North 1950 West
Salt Lake City, UT 84114-4880

Subject: EPA ID Number UTD982598898 - Request for a Site-Specific Treatment Variance for Cemented Uranium Extraction Process Residues

Dear Mr. Howard,

Energy*Solutions* herein requests an exemption from the treatment standards described in Utah Administrative Code (UAC) R315-40(a)(2) for uranium extraction process residuals encased in cement that retain the hazardous waste codes D005 (barium); D006 (cadmium); D007 (chromium); D008 (lead); D030 (2,4-dinitrotoluene); D032 (hexachlorobenzene) and F001, F002, and F005 (spent solvents). This exemption is requested for the purposes of safety, security, and transportation of the radioactive waste. This request is submitted in accordance with the requirements of UAC R315-260-19.

The regulatory requirement authorizing this request is found in UAC R315-268-44 which allows a site-specific variance from an applicable treatment standard provided the following condition is met:

> *UAC R315-268-44(h)(2) It is inappropriate to require the waste to be treated to the level specified in the treatment standard, or by the method specified as the treatment standard, even though such treatment is technically possible.*

This variance is being requested for approximately 1,000 cubic feet of cemented uranium extraction process residuals from Energy*Solutions* generator 9061-06. The waste is generated as part of uranium recovery processes at the generator's facility. The generator has three different points of generation for this waste: (1) an enriched uranium contaminated ash that has been thermally processed and then recovered through an organic solvent extraction process; (2) oxide powders and dried sludges associated with highly enriched uranium-thorium fuels; and (3) residue (sludge) from the bottom of salt baths used in the processing of uranium. The residual waste from each of these processes is collected in small cans (~ 2 ½ gallons each) and stored at the generator's facility. The

process residuals within the cans have been characterized through a random sampling and analysis process. At the beginning of this campaign, approximately 2,000 cans of process residues were collected and stored by the generator. The process is ongoing and additional cans are being generated every year. Further, due to safety concerns, some of the cans are being split prior to the repackaging process described below; thereby generating more total material for disposal.

F-listed solvent codes within this waste are derived from rags that are burned in a furnace in order to recover the uranium present within them. None of the F-listed constituents were present above their respective treatment standard concentrations within the random characterization samples of the process residues. The random characterization samples were also analyzed for metals using the Toxicity Characteristic Leaching Procedure (TCLP). These samples detected elevated concentrations of barium (up to 6,740 mg/L TCLP), cadmium (up to 16.4 mg/L TCLP), chromium (up to 15.2 mg/L TCLP), and lead (up to 10.5 mg/L TCLP). Based on these elevated metal concentrations, the characteristic waste codes D005, D006, D007, and D008 were applied to the process residues. Slightly elevated concentrations of 2,4-dinitrotoluene (D030) and hexachlorobenzene (D032) were also detected in separate analyses. The residue may potentially contain these codes also.

The uranium content within the process residues is enriched. From a health and safety standpoint, the enrichment makes the waste more hazardous to employees managing the waste. Further, enriched material has increased security concerns and must be managed appropriately. To ensure the enriched uranium concentration limits required for worker safety, security, and transportation of this waste are met, appropriate packaging procedures were created and are currently being utilized at the generator's facility. These packaging procedures include repackaging the cans into 16-gallon drums and filling the void spaces with cement; formal treatment for the elevated metals concentrations is not performed during this process. The generator has assessed other options, including treatment for the hazardous constituents; however, additional processing introduced unacceptable hazards from a health and safety and security viewpoint. Additionally, the waste within the cans is inherently safe from a criticality aspect and the generator concluded that it is unwise to perform extra processing that could potentially change this aspect. Furthermore, encasing enriched uranium within concrete is the preferred method of stabilization as recommended by the Nuclear Regulatory Commission (NRC). The waste material packaged in these 16-gallon monolithic forms is inherently safe and is the form that will be shipped and received at the Energy*Solutions* Clive facility.

The characteristic hazardous waste codes associated with the process residues has numerical concentration-based treatment standards based upon the leachability of the contaminants. Treatment of the monolithic form for these concentration-based treatment standards would entail a process that includes shredding of the monolith followed by mixing with a stabilizing reagent in a permitted mixer. Both of these steps could mobilize the enriched uranium and possibly cause airborne contamination, increasing the potential for releases to the environment as well as the potential for personnel exposure; thereby violating radiation protection (ALARA – As Low As Reasonably Achievable) principles. Also, the shredding of the solidified uranium ash results in a more accessible form of enriched uranium with potential security ramifications.

Energy*Solutions* proposes to macroencapsulate the waste, thereby isolating the waste from potential leaching media. Macroencapsulation is a permitted process utilized at the Clive facility that significantly reduces the potential for migration (leaching) of waste. Macroencapsulation requires less handling of the waste and creates a waste form for disposal that is protective of human health and the environment. Macroencapsulation also adds a further level of security restricting access to the enriched uranium.

In summary, a variance should be granted based upon three considerations:

1. for both health and security reasons, the enriched uranium concentration within the waste precludes actual treatment of the waste;

2. processing this waste in preparation for stabilization treatment would increase worker exposures and the potential for releases to the environment; and

3. the leachability of the waste would be significantly reduced through macroencapsulation, thereby protecting human health and the environment.

Energy*Solutions* requested this same variance for this generator in letters dated July 20, 2007; July 28, 2008; July 15, 2009; July 15, 2010; July 28, 2011; August 13, 2012; July 15, 2013; July 25, 2015; November 4, 2015; October 27, 2016; November 20, 2018; and December 9, 2019. These previous requests were approved on September 13, 2007; September 13, 2008; September 10, 2009; September 9, 2010; September 8, 2011; September 13, 2012; September 12, 2013; August 14, 2014; December 10, 2015; January 12, 2017; September 27, 2017; January 10, 2019; and March 12, 2020, respectively.

Shipments began in April, 2008 and have been relatively continuous since that time. Since the last variance was approved, Energy*Solutions* has received approximately 894

cubic feet of this waste (the 16-gallon monoliths). Energy*Solutions* has received approximately 12,000 cubic feet of this waste since the first variance approval in 2008. This variance request is for the ongoing processing and disposal of additional uranium extraction process residues created by the generator.

Energy*Solutions* requests that a variance be granted to allow the receipt, macroencapsulation treatment and disposal of approximately 1,000 cubic feet of cemented uranium extraction process residuals that retain hazardous waste codes. Upon approval of this variance, the monolithic waste will be managed as debris.

The name, phone number, and address of the person who should be contacted to notify Energy*Solutions* of decisions by the Director is:

Mr. Vern C. Rogers
Director of Regulatory Affairs
Energy*Solutions* LLC
299 South Main Street, Suite 1700
Salt Lake City, UT 84111
(801) 649-2000

Should there be any questions to this request, please contact me at 801-649-2144.

Sincerely,

Tim Orton
Jan 11 2021 11:26 AM
cosign

Timothy L. Orton, P.E.
Environmental Engineer and Manager

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.