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

Douglas J. Hansen
Director

A meeting of the Waste Management and Radiation Control Board has been scheduled for October 14, 2021 at 1:30 pm at the Utah Department of Environmental Quality, (Multi-Agency State Office Building) Conference Room #1015, 195 North 1950 West, SLC.

(Board members and interested persons may participate electronically/telephonically.)
Join via the Internet: meet.google.com/gad-sxsd-uvs
Join via the Phone: (US) +1 978-593-3748 PIN: 902 672 356#

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 September 9, 2021 Board Meeting ..... Tab 1 (**Board Action Item**).

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

VI. Administrative Rules ..... Tab 3

A. Five-Year Review of Utah Administrative Code Rules R313-15, 21, 24, 30, 34, 35, 37, and 38 (Information Item).

B. Approval to proceed with formal rulemaking and 30-day public comment period on proposed rule changes to Utah Administrative Code Rule R315-101 of the Hazardous Waste Rules amending the rule to include the most up-to-date methods and procedures being used by industry to conduct cleanups of contaminated sites and risk assessments based on EPA guidance (**Board Action Item**).

VII. Other Business.

A. Miscellaneous Informational Items.
B. Scheduling of next Board meeting (November 18, 2021).

VIII. 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".

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Waste Management and Radiation Control Board Meeting
Utah Department of Environmental Quality
Multi-Agency State Office Building, (Conf. Room #1015)
195 North 1950 West, SLC
September 9, 2021
1:30 p.m.

Board Members participating at Anchor Location:
Brett Mickelson (Chair), Dennis Riding (Vice-Chair), Richard Codell, Danielle Endres, Mark Franc, Vern Rogers, Kim Shelley, Shane Whitney

Board Members Participating Virtually: Steve McIff, Nathan Rich

UDEQ staff members participating at Anchor Location:
Doug Hansen, Brent Everett, Morgan Atkinson, Tom Ball, Tyler Hegburg, Avery Holyoak, Arlene Lovato, Mike Pecorelli, Elisa Smith, Otis Willoughby , David Wilson

Others attending at Anchor Location: Tim Orton

Other UDEQ employees, and interested members of the general public also participated either electronically or telephonically.

I. Call to Order.

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

II. Public Comments on Agenda Items – None.

III. Declarations of Conflict of Interest.

Vern Rogers declared a conflict of interest and abstained from voting on Agenda Item VIII. A. & B. - Low-Level Radioactive Waste Section.

IV. Approval of the Meeting Minutes for the July 8, 2021 Board Meeting (Board Action Item).

It was moved by Shane Whitney and seconded by Dennis Riding and UNANIMOUSLY CARRIED to approve the July 8, 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 July 2021, was $21,751,253.00. The preliminary estimate of the cash balance of the PST Trust Fund for the end of August 2021, was $22,894,296.00. The DERR continues to watch the balance of the PST Trust Fund closely to ensure sufficient cash is available to provide coverage of qualified claims for releases.

VI. Final adoption on proposed rule changes to UAC R311-200, 201, 203, 204, 205, 206, 207, 208, 209, and 212 of the Underground Storage Tank Rules (Board Action Item).

David Wilson, the UST Rules Coordinator, requested final adoption of the rule changes for:

- R311-200, Underground Storage Tanks: Definitions
- R311-201, Underground Storage Tanks: Certification Programs and UST Operator Training
- R311-203, Underground Storage Tanks: Technical Standards
- R311-204, Underground Storage Tanks: Closure and Remediation

- R311-205, Underground Storage Tanks: Site Assessment Protocol
- R311-206, Underground Storage Tanks: Certificate of Compliance and Financial Assurance Mechanisms
- R311-207, Accessing the Petroleum Storage Tank Trust Fund for Leaking Petroleum Storage Tanks
- R311-208, Underground Storage Tank Penalty Guidance
- R311-209, Petroleum Storage Tank Cleanup Fund and State Cleanup Appropriation
- R311-212, Administration of the Petroleum Storage Tank Loan Program

Notice of the public comment period was sent to interested parties and published in major newspapers. The proposed changes were published in the Utah State Bulletin on July 1, 2021. The public comment period was held from July 1, 2021 to August 2, 2021. The public hearing to receive comments was held on July 15, 2021. No comments were received during the public comment period.

Mr. Riding asked what stakeholder input had been obtained. Mike Pecorelli, the PST Trust Fund Section Manager, stated that meetings were held with UST consultants in addition to open discussions that followed the meetings. Mr. Riding asked about feedback received. Mr. Pecorelli stated that they have worked with consultants, contractors, owners and operators who have provided feedback on the proposed rules. No other questions or comments were made.

Board Chair, Brett Mickelson, asked for Board action regarding the final adoption of the proposed rule changes as presented with an effective date of September 13, 2021.

It was moved by Danielle Endres and seconded by Steve McIff and UNANIMOUSLY CARRIED to approve the adoption of the proposed rule changes to the Underground Storage Tank Rules.

VII. Administrative Rules.

A. Approval to proceed with formal rulemaking and public comment period on proposed rule changes to UAC R315-260, 261, 264, 265, 268, 270, and 273 of the Hazardous Waste Rules to incorporate federal regulatory changes promulgated by the Environmental Protection Agency (EPA) and published in the Federal Register on December 9, 2019 (84 FR 67202) (Board Action Item).

Tom Ball, Planning and Technical Support Manager of the Division of Waste Management and Radiation Control, reviewed the request for the Board's approval to initiate formal rulemaking and public comment on the proposed rule changes to UAC R315-260, R315-261, R315-264, R315-265, R315-268, R315-270, and R315-273 of the hazardous waste rules to incorporate federal regulatory changes promulgated by the Environmental Protection Agency (EPA) and published in the Federal Register on December 9, 2019 (84 FR 67202).

The final rule published in the December 9, 2019 Federal Register adds hazardous waste aerosol cans to the universal waste program under the Federal Resource Conservation and Recovery Act (RCRA) regulations. Utah is one of several states where aerosol cans were already included as a universal waste and therefore the proposed action is to amend the Utah rules to keep them equivalent to the federal regulations.

The major changes being made by this amendment include:

Amending the definition of "aerosol can" so that it is consistent with the DOT definition; Universal waste aerosol cans that show evidence of leakage must be packaged in a separate closed container or overpacked with absorbents or be immediately punctured and drained; Generators of universal waste aerosol cans may sort can by type, consolidate intact cans in larger containers, and remove actuators to reduce the risk of accidental release; Empty, punctured aerosol cans are required to be recycled; Separation of specific types of intact aerosol cans whose contents may pose an incompatibility risk is

no longer required because the fact that the cans are intact will ensure the contents of these cans will not mix and therefore will not pose incompatibility risks; Containers where universal waste aerosol cans are being accumulated are required to be protected from sources of heat; Generators that puncture aerosol cans are required to maintain a copy of the puncturing device manufacturers instructions on site and ensure employees are trained on the use of the device. Puncturing of cans must be done in a manner designed to prevent fires and the release of the aerosol can contents to the environment. Equipment must be located on a solid, flat surface in a well-ventilated area. There must be a written spill cleanup procedure and a spill cleanup kit; Pesticides in aerosol cans can be managed as universal waste aerosol cans instead of universal waste pesticides; Aerosol cans that meet the standard for empty containers are exempt from being managed as universal waste; and some re-numbering of R315-273 was required so that the numbering corresponded to the numbering in the federal regulations.

These rule changes became effective at the Federal level on February 7, 2020. In addition to the changes listed above the Division has amended the definition of antifreeze contained in Rule R315-273. The definition is being expanded to include not only antifreeze used as an engine coolant, but antifreeze used in electronics cooling applications, winterizing equipment, and used in heating, ventilating and air conditioning units.

In addition to the proposed changes detailed above, the Division at the request of the Governor's Office, is correcting typographical and formatting errors found in the rules. Additionally, the Division has incorporated 40 CFR 265.1100 through 40 CFR 265.1102 as R315-265-1100 through R315-265-1102 as part of an ongoing effort to update Rule R315-265.

A copy of the December 9, 2019 (84 FR 67202) Federal Register, Executive Summary and the proposed changes to R315-260, R315-261, R315-264, R315-265, R315-268, R315-270, and R315-273 (highlighted in the document in yellow) were included in the September 14 Board packet.

The Board is authorized under Subsection 19-6-105(1)(c) to make rules governing generators and transporters of hazardous waste and owners and operators of hazardous waste treatment, storage and disposal facilities. The rule changes also meet existing DEQ and state rulemaking procedures.

Board approval is necessary to begin the formal rulemaking process by filing the appropriate documents with the Office of Administrative Rules for publishing the proposed rule changes in the Utah State Bulletin and conducting a public comment period. The Director recommends the Board approve proceeding with formal rulemaking and public comment by publishing in the October 1, 2021, Utah State Bulletin the proposed changes to UAC R315-260, R315-261, R315-264, R315-265, R315-268, R315-270, and R315-273 and conducting a public comment period from October 1 to November 1, 2021.

Mr. Ball provided additional information regarding the differences including the way the State of Utah has been regulating aerosol cans (stringency issues) and the rule changes promulgated by EPA.

It was moved by Danielle Endres and seconded by Richard Codell and UNANIMOUSLY CARRIED to approve to proceed with formal rulemaking and a 30-day public comment period on proposed rule changes to UAC R315-260, 261, 264, 265, 268, 270, and 273 of the Hazardous Waste Rules to incorporate federal regulatory changes promulgated by the Environmental Protection Agency (EPA) and published in the Federal Register on December 9, 2019 (84 FR 67202).

B. Approval to proceed with formal rulemaking and public comment period on proposed rule changes to R313-16-290 of the Radiation Control Rules to amend the inspection frequency found in Table I of Subsection R313-16-290(2) for facilities using fluoroscopic or computed tomography units to include veterinary facilities (Board Action Item).

Tom Ball, Planning and Technical Support Manager of the Division of Waste Management and Radiation Control, reviewed the request for the Board's approval to initiate formal rulemaking and public comment on the proposed rule changes to R313-16-290 to amend the inspection frequency found in Table I of Subsection R313-16-290(2) for facilities using fluoroscopic or computed tomography units to include veterinary facilities.

Mr. Ball explained that when the rules were written it was not envisioned that veterinary offices would be using fluoroscopic or computed tomography x-ray units. Because the x-ray units being used by veterinarians at the time were lower power with less scatter than a fluoroscopic or computed tomography x-ray unit, they posed a lower risk to employees and animals if they were operating improperly, therefore the inspection frequency for veterinary offices was set at five years like other facilities using similar equipment. Currently nine veterinary offices in Utah have installed and are using fluoroscopic or computed tomography units. These Units produce more scatter and therefore pose a higher risk. Current rules specify that medical facilities using fluoroscopic or computed tomography units have an inspection frequency of one year due to the higher risk.

The proposed change will amend the inspection frequency found in Table I of Subsection R313-16-290(2) for facilities using fluoroscopic or computed tomography units to include veterinary facilities. In addition to the proposed changes detailed above, the Division, at the request of the Governor's Office, is correcting typographical and formatting errors found in the rules.

An Executive Summary and the proposed changes to R313-16-290 (highlighted in the document in yellow) were included in the September 9, 2021 Board packet.

The Board is authorized under Subsection 19-6-104 to make rules that are necessary to implement the provision of the Radiation Control Act. The rule changes also meet existing DEQ and state rulemaking procedures. Board approval is necessary to begin the formal rulemaking process by filing the appropriate documents with the Office of Administrative Rules for publishing the proposed rule changes in the Utah State Bulletin and conducting a public comment period.

The Director recommends the Board approve proceeding with formal rulemaking and public comment by publishing in the October 1, 2021, Utah State Bulletin the proposed changes to UAC R313-16-290 and conducting a public comment period from October 1 to November 1, 2021.

Mr. Ball clarified that fluoroscopic or computed tomography units inspection cost can be expensive, but these veterinary offices are already paying this cost because Division inspectors are not certified and qualified to inspect fluoroscopic or computed tomography units. The veterinary offices with a fluoroscopic or computed tomography units are already having to utilize a qualified expert to conduct their inspections. Mr. Ball stated that the UDEQ does not regulate what a qualified inspector charges to conduct their inspections, costs basically are whatever the market will bear.

Mr. Ball briefly discussed the various costs qualified inspectors charge and clarified that the information that was provided in the Rule Analysis associated with this Rule included in the September 9, 2021 Board packet was based on a worst-case-scenario analysis.

Richard Codell asked how often does a computed tomography unit (CTE) unit fail inspection in a hospital setting? Mr. Ball stated it is fairly rare for a CTE unit to fail an inspection. The Division inspectors don't see a lot of issues with x-ray equipment operating outside their acceptable tolerance limits. Mr. Ball further stated that most of the issues Division inspectors encounter are administrative issues. These include failure to display warning signs or activation switch concerns, i.e.. the switch as moved into an area where the operators are no longer shielded, etc.

Danielle Endres questioned if this is a trend and is it anticipated that more veterinary offices are going to be using CTE units? Mr. Ball stated that it is anticipated that this trend will continue as

these units can be more accurate. Ms. Endres asked if there is a capacity to conduct all the inspections required of the CTU units. Mr. Ball stated yes.

Dennis Riding asked if the state of Utah will be supplanting the contractors to conduct the CTE unit inspections. Mr. Ball clarified that State inspectors are not certified or qualified to do CTE unit inspections. Therefore, CTU inspections are required to be conducted by only qualified experts and at this point in time the State does not have any plans to have their inspectors become certified/qualified to conduct these type of inspections.

It was moved by Mark Franc and seconded by Shane Whitney and UNANIMOUSLY CARRIED to approve to proceed with formal rulemaking and 30-day public comment period on proposed rule changes to R313-16-290 of the Radiation Control Rules to amend the inspection frequency found in Table I of Subsection R313-16-290(2) for facilities using fluoroscopic or computed tomography units to include veterinary facilities.

C. Final adoption of proposed rule changes to R313-19-100 of the Radiation Control Rules to incorporate changes requested by the Nuclear Regulatory Commission (NRC) to maintain the compatibility of Utah Radiation Control Rules with the federal regulations (Board Action Item).

Tom Ball, Planning and Technical Support Manager of the Division of Waste Management and Radiation Control reviewed the request for the Board's approval for final adoption of the proposed changes to R313-19-100 of the Radiation Control Rules to incorporate changes requested by the Nuclear Regulatory Commission (NRC) to maintain the compatibility of Utah Radiation Control Rules with the federal regulations.

The Division of Waste Management and Radiation Control received a comment from the Nuclear Regulatory Commission (NRC) in March of 2021 indicating that they had discovered an incompatibility in our rules. The purpose of this amendment is to correct that incompatibility. Section R313-19-100 incorporates by reference 10 CFR 71.97. This federal regulation requires certain transportation notifications to be submitted to state and federal agencies. Subsections R313-19-100(4)(a)(ii) and (iii) substitute the Director of the Division of Waste Management and Radiation Control for the Directors of two different NRC offices. The NRC commented that the notifications need to be sent to the NRC as well as the state agency and indicated that to remain compatible with the federal program Utah needs to delete Subsections R313-19-100(4)(a)(ii) and (iii). Deleting these two subsections will not impact the Utah radiation control program because the federal regulations already require the notifications to be submitted to the states as well as the federal agencies.

In the May 13, 2021 meeting, the Board approved the proposed changes to be filed and published in the Utah State Bulletin, initiating formal rulemaking and a public comment period. The proposed rule changes were published in the June 15, 2021 issue of the Bulletin. The public comment period concluded on July 15, 2021. No comments were received.

An Executive Summary and copies of the pertinent pages of the Utah State Bulletin were included in the September 9, 2021 Board packet.

The Board is authorized under Subsection 19-3-104(4) to make rules to meet the requirements of federal law and maintain primacy of the radioactive materials program from the federal government and under Subsection 19-3-103.1(1)(a) to make rules necessary to implement the Radiation Control Act. The proposed rule changes also meet existing DEQ and state rulemaking procedures.

Board action is required for final adoption of the rule changes published in the Utah State Bulletin and to set an effective date. The Director recommends that the Board adopt the rule changes published in the June 15, 2021 issue of the Utah State Bulletin and set an effective date of September 13, 2021.

Mr. Ball briefly explained the process involving requests made by the NRC to the state of Utah to incorporate rule changes to maintain the compatibility of Utah Radiation Control Rules with the federal regulations.

It was moved by Dennis Riding and seconded by Vern Rogers and UNANIMOUSLY CARRIED to approve for final adoption the proposed rule changes to R313-19-100 of the Radiation Control Rules to incorporate changes requested by the Nuclear Regulatory Commission (NRC) to maintain the compatibility of Utah Radiation Control Rules with the federal regulations and set an effective date of September 13, 2021.

VIII. Low-Level Radioactive Waste Section.

A. Energy*Solutions* request for a one-time site-specific treatment variance from the Utah Hazardous Waste Management Rules. Energy*Solutions* seeks authorization to receive ash contaminated with dioxins and furans as UHCs for treatment and disposal (Board Action Item).

Tyler Hegburg, Environmental Scientist in the Low-Level Radioactive Waste Section, Division of Waste Management and Radiation Control, reviewed Energy*Solutions* June 16, 2021, 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. This variance request was presented to the Board in their July 8, 2021 as an informational item. Energy*Solutions* seeks authorization to receive ash contaminated with dioxins and furans as UHCs for treatment and disposal.

Energy*Solutions* requests approval to receive ash from incinerator and metal recycling processes that contains dibenzo-p-dioxin and dibenzofuran UHCs above their respective treatment standards denoted with the Universal Treatment Standards (UTS) in R315-268-48. All other required treatment standards associated with the waste will be met prior to disposal.

Requiring the waste to meet the dioxin and furan treatment standards is inappropriate based on the processes that generated the waste. Because of the waste generation processes, all the ash waste contains dioxins and furans; however, in accordance with regulations, only a portion of the waste needs to be treated for those contaminants. The generator has previously analyzed each container of ash for metals contamination.

If metals were below the toxicity characteristic concentrations described in 40 CFR 261.24 (R315-261-24), the waste would be shipped to the Clive facility as Low-Level Radioactive Waste (LLRW) and disposed in the Class A Embankment. If metals were above the Toxicity Characteristic concentrations, then the waste would need treated for those metals as well as all UHCs, including dioxins and furans. It is inappropriate to require treatment of dioxin and furan contaminants in instances where characteristic metals are found in the waste when treatment is not required if metals are below characteristic concentrations in the waste.

Furthermore, the stabilized ash was re-incinerated in an attempt to reduce the concentration of dioxins and furans in the ash. Re-incineration resulted in very little reduction in the concentrations. It is inappropriate to require this additional incineration in order to attempt to meet the standards.

Final disposal of the waste will occur in the Mixed Waste Landfill Cell at the Energy*Solutions* Mixed Waste Facility.

A notice for public comment was published in the Salt Lake Tribune, the Deseret News and the Tooele County Transcript Bulletin. The 30-day public comment period began July 12, 2021 and ended August 10, 2021. No comments were received.

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.

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.

A copy of the variance request and its supporting documentation were included in the July 8, 2021 Board packet.

Dennis Riding asked if the Board has previously approved this same type of variance request. Tim Orton, Energy*Solutions* representative, informed the Board that this is the third time Energy*Solutions* has sought approval from the Board for this type of variance request.

Danielle Endres asked for clarification regarding what is producing the ash bi-product. Mr. Oton clarified Energy*Solutions* request to receive ash is from incinerator and metal processes.

It was moved by Richard Codell and seconded by Shane Whitney and UNANIMOUSLY CARRIED to approve Energy*Solutions*' request for a one-time site-specific treatment variance from the Utah Hazardous Waste Management Rules to receive ash contaminated with dioxins and furans as UHCs for treatment and disposal. (Vern Rogers abstained from voting.)

B. Approval of Proposed Stipulation and Consent Order between the Division Director and Energy*Solutions* (Board Action Item).

Otis Willoughby, Low-Level Radioactive Waste (LLRW) Section Manager, Division of Waste Management and Radiation Control (DWMRC), provided an overview of the proposed Stipulation and Consent Order (SCO), No. 2105037, to resolve Notice of Violation (NOV) No. 2007067, issued to Energy*Solutions*, LLC on April 3, 2020. A draft SCO was presented to the Board in their July 8, 2021.

The NOV was based on self-reported violations that dealt with MACRO treatment issues. The SCO includes a penalty of $51,181.00

A 30-day public comment period was held from July 5, 2021 to August 3, 2021. No comments were received.

§19-6-104 of the Utah Solid and Hazardous Waste Act authorizes the Board to issue orders and approve or disapprove settlements negotiated by the Director with a civil penalty over $25,000.

The Director recommends approval of the proposed SCO, including the penalty in the amount of $51,181.00.

Copies of the NOV, the SCO, and the penalty narrative worksheet were included in the July 8, 2021 Board packet.

Nathan Rich expressed appreciation to Energy*Solutions* for self-reporting the violations and questioned if there was a lessons learned and/or an evaluation conducted on how the violations occurred. Specifically, if the violations were caused by a lack of training, a lack of oversight or something else and if appropriate corrective actions have been taken to ensure that these same types of violations are not repeated.

Mr. Willoughby stated that Energy*Solutions* does have a very aggressive corrective action program and as issues/violations are identified they are addressed at both the facility and at the corporate level. Specifically, Energy*Solutions* will look at the issues/violations and figure out the best corrective action whether it involves re-training all staff or whether it involves looking at action issues/actions caused by an individual employee or whether it involves procedures not being specific enough, etc. In this specific incident, Energy*Solutions* did immediately make changes to their program/procedures/training to correct these violations once they were aware of the violations.

Mr. Willoughby further clarified that the violation regarding the bonding agent was because an employee was being lackadaisical, this violation is to be attributed to operator error. The violation regarding the batch tickets violation required Energy*Solutions* to conduct more specific training with their employees to ensure this violation does not occur again.

Scott Williams, Heal Utah, stated that it appeared from the NOV that the violations occurred over a period of two to three years and questioned why it took so long to identify this problem?

Otis Willoughby deferred to Tim Orton. Mr. Orton stated that Energy*Solutions* conducts quality assurance inspections on their items usually on an annual/semiannual up to a two year basis. So, that is the reason it took so long. The last quality assurance audit conducted showed processes being conducted correctly. So somewhere in-between the two quality assurance audit is where the violations occurred. Mr. Orton stated that regarding the violation regarding the macroencapsulation process was discovered by the quality assurance and at that point then began corrective action measurements that same day.

Mr. Orton provided a brief explanation regarding their old bonding process and their new improved bonding process and how they have incorporated their quality control group in this process. Mr. Orton stated by implementing these new measures, these violations should not occur again.

Dennis Riding questioned what happened to the individuals involved that short circuited the process in order to make their lives easier? Mr. Orton stated that Human Resources handles these types of matters, but in this instance the employee was dismissed.

It was moved by Dennis Riding and seconded by Danielle Endres and UNANIMOUSLY CARRIED to approve the proposed Stipulation and Consent Order between the Division Director and Energy*Solutions*. (Vern Rogers abstained from voting.)

IX. Other Business.

A. Director's Report.

Doug Hansen, Director of the Division of Waste Management and Radiation Control, stated that during the July 8, 2021 Board meeting, Tom Ball presented as an informational item a Five Year Review of UAC Rule R315-319 that addressed Coal Combustion Residuals (CCR) Requirements. During the meeting, Richard Codell questioned if Utah has any power plant coal waste problematic sites. Specifically, are there any facilities in Utah that are bankrupt or in poor repair that would be affected by this rule? At that time, Mr. Ball did not have an answer but stated he would obtain the answer and report back at the next meeting. Mr. Hansen stated Division staff have looked into this question and the Division currently regulates four CCR landfills in the State and at this point all of them are in significant operational compliance. However, there is one other facility in the State that is located on Indian lands and is regulated by the US EPA. Hence, the status of this facility is unknown since the Division does not regulate it or are we involved in their operations.

B. Miscellaneous Informational Items – None to Report.

C. Discussion of rescheduling the November 11, 2021 Board meeting (Veterans Day Observed).

After confirming Board room availability, Board members will be polled to determine their preference of either November 4th or November 18th to conduct the November Board meeting.

D. Scheduling of the next Board meeting.

The next meeting is scheduled at the UDEQ on October 14, 2021 at 1:30 p.m.

X. Adjourn.

The meeting adjourned at 2:10 p.m.

UST STATISTICAL SUMMARY

September 1, 2020 -- August 31, 2021

PROGRAM

	September	October	November	December	January	February	March	April	May	June	July	August	(+/-) OR Total
Regulated Tanks	4,135	4,130	4,127	4,130	4,144	4,144	4,145	4,136	4,146	4,139	4,142	4,140	**5**
Tanks with Certificate of Compliance	4,027	4,027	4,039	4,044	4,051	4,051	4,053	4,058	4,063	4,067	4,065	4,056	**29**
Tanks without COC	108	103	88	86	93	93	92	78	83	72	77	84	**(24)**
Cumulative Facilitlies with Registered A Operators	1,084	1,104	1,108	1,111	1,252	1,252	1,256	1,251	1,250	1,291	1,294	1,290	**98.40%**
Cumulative Facilitlies with Registered B Operators	1,142	1,147	1,150	1,147	1,285	1,285	1,292	1,253	1,251	1,295	1,295	1,292	**98.55%**
New LUST Sites	5	8	8	8	5	5	10	5	2	10	8	3	**77**
Closed LUST Sites	3	7	2	6	4	4	16	3	4	17	6	0	**72**
Cumulative Closed LUST Sites	5302	5310	5315	5323	5329	5329	5350	5352	5356	5374	5378	5378	**76**

FINANCIAL

	September	October	November	December	January	February	March	April	May	June	July	August	(+/-)
Tanks on PST Fund	2,657	2,654	2,666	2,667	2,666	2,666	2,666	2,663	2,664	2,664	2,662	2,653	**(4)**
PST Claims (Cumulative)	687	688	688	688	688	688	689	690	693	696	701	701	**14**
Equity Balance	-$7,311,417	-$10,201,999	-$9,462,843	-$9,547,189	-$8,950,746	$8,633,383	-$8,709,493	-$8,272,438	-$7,719,626	-$6,964,420	-$6,684,027	-$5,540,984	**$1,770,433**
Cash Balance	$18,806,863	$18,233,281	$18,972,437	$18,888,091	$19,484,534	$19,801,897	$19,725,787	$20,162,842	$20,715,654	$21,470,860	$21,751,253	$22,894,296	**$4,087,433**
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	2	2	2	2	2	2	2	2	2	2	2	2	**0**

	September	October	November	December	January	February	March	April	May	June	July	August	TOTAL
Speed Memos	95	72	73	42	48	48	75	42	81	76	82	51	**785**
Compliance Letters	32	30	9	14	15	15	18	13	8	7	15	16	**192**
Notice of Intent to Revoke	0	0	0	0	0	0	0	1	0	0	0	0	**1**
Orders	1	2	1	0	0	0	1	0	1	0	0	0	**6**

WASTE MANAGEMENT AND RADIATION CONTROL BOARD
Executive Summary
Five-Year Review for UAC Rules R313-15, 21, 24, 30, 34, 35, 37, and 38
October 14, 2021

What is the issue before the Board?	The following Utah Administrative Code rules are due for a five-year review. R313-15 Standards for Protection Against Radiation R313-21 General Licenses R313-24 Uranium Mills and Source Material Mill Tailings Disposal Facility Requirements R313-30 Therapeutic Radiation Machines R313-34 Requirements for Irradiators R313-35 Requirements for X-Ray Equipment Used for Non-Medical Applications R313-37 Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material R313-38 Licenses and Radiation Safety Requirements for Well Logging 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 January 17, 2022.
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.

(OVER)

	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 June 2021

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION		
	Title No. - Rule No.	
Utah Admin. Code Ref (R no.):	**R313-15**	**Filing ID: (Office Use Only)**

Agency Information

1. Department:	Environmental Quality	
Agency:	Waste Management and Radiation Control	
Room no.:	Second Floor	
Building:	MASOB	
Street address:	195 N. 1950 W.	
City, state and zip:	Salt Lake City, Utah 84116	
Mailing address:	PO Box 144880	
City, state and 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:

R313-15. Standards for Protection Against Radiation

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 for controlling exposure to sources of radiation that constitute a significant health hazard. As part of the state primacy of the radiation control program, the provisions in R313-15 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 standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses issued by the Director. These rules are designed so the total dose of radiation to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation. As an Agreement State, this rule maintains the appropriate regulatory compatibility with the NRC. There have been no opposing comments to the rules since the last five-year review in 2017.

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 publication in the *Utah State Bulletin*.

Agency head or designee, and title:	Douglas J. Hansen, Division Director	**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.
R313-15. Standards for Protection Against Radiation.
R313-15-1. Purpose, Authority and Scope.

(1) Rule R313-15 establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses issued by the Director. These rules are issued pursuant to Subsections 19-3-104(4) and 19-3-104(7).

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

(3) Except as specifically provided in other sections of these rules, Rule R313-15 applies to persons licensed or registered by the Director to receive, possess, use, transfer, or dispose of sources of radiation. The limits in Rule R313-15 do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with Rule R313-32 (incorporating 10 CFR 35.75 by reference), or to exposure from voluntary participation in medical research programs.

R313-15-2. Definitions.

"Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix B of 10 CFR 20.1001 to 20.2402, (2010), which is incorporated by reference.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Inhalation class", refer to "Class".

"Labeled package" means a package labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S.

Department of Transportation regulations 49 CFR 172.403 and 49 CFR 172.436 through 440, (2009). Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403 and 49 CFR 173.421 through 424, (2009).

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

"Lung class", refer to "Class".

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

TABLE

ORGAN DOSE WEIGHTING FACTORS

Organ or Tissue	w_T
Gonads	0.25

Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30(1)
Whole Body	1.00(2)

(1) 0.30 results from 0.06 for each of five "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.
(2) For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

R313-15-3. Implementation.

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

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

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

R313-15-101. Radiation Protection Programs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as

specified in Subsection R313-15-502(1)(d), the effective dose equivalent for external radiation shall be determined as follows:

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

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

(4) Derived air concentration (DAC) and annual limit on intake (ALI) values are specified in Table I of Appendix B of 10 CFR 20.1001 to 20.2402, (2010), which is incorporated by reference, and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See Section R313-15-1107.

(5) Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to ten milligrams in a week in consideration of chemical toxicity. See footnote 3, of Appendix B of 10 CFR 20.1001 to 20.2402, (2010), which is incorporated by reference.

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

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

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

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

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

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

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

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

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

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

(1) Licensees or registrants shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, lens dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See footnotes 1 and 2 of Appendix B of 10 CFR 20.1001 to 20.2402, (2010), which is incorporated by reference.

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

R313-15-204. Determination of Internal Exposure.

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

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

(b) Quantities of radionuclides in the body; or

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

(d) Combinations of these measurements.

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

(3) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior

of the material in an individual is known, the licensee or registrant may:

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

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

(c) Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See Appendix B of 10 CFR 20.1001 to 20.2402, (2010), which is incorporated by reference.

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

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

(a) The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix B of 10 CFR 20.1001 to 20.2402, (2010), which is incorporated by reference, for each radionuclide in the mixture; or

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

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

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

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

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

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

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

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

(b) For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.50 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix B of 10 CFR 20.1001 to 20.2402, (2010), which is incorporated by reference. The licensee or registrant may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALI, the licensee or registrant shall also demonstrate that the limit in Subsection R313-15-201(1)(a)(ii) is met.

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

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

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

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

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

(3) In complying with the requirements of Subsections R313-15-205(1) or (2), a licensee or registrant may:

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

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

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

(4) The licensee or registrant shall record the exposure history, as required by Subsection R313-15-205(1) or (2), on form DWMRC-05, or other clear and legible record, of all the information required on form DWMRC-05. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing form DWMRC-05 or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on form DWMRC-05 or equivalent indicating the periods of time for which data are not available.

(5) For the purpose of complying with this requirement, licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the rules in Rule R313-15 in

effect before January 1, 1994. Further, occupational exposure histories obtained and recorded on form DWMRC-05 or equivalent before January 1, 1994, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

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

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

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

(7) The licensee or registrant shall retain the records on form DWMRC-05 or equivalent until the Director terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing form DWMRC-05 or equivalent for three years after the record is made. This includes records required under the standards for protection against radiation in effect prior to January 1, 1994.

R313-15-206. Planned Special Exposures.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed one mSv (0.1 rem) in a year, exclusive of the dose contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released, under Rule R313-32 (incorporating 10

CFR 35.75 by reference), from voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with Section R313-15-1003; and

(b) The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with Rule R313-32 (incorporating 10 CFR 35.75 by reference), does not exceed 0.02 mSv (0.002 rem) in any one hour; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) Demonstrating that:

(i) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B of 10 CFR 20.1001 to 20.2402, (2010), which is incorporated by reference; and

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

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

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

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

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

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

(b) Have previously submitted and received Director approval on a license termination plan or decommissioning plan; or

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

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

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

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

A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a total effective dose equivalent to an average member of the critical group that does not exceed 0.25 mSv (0.025 rem) per year, including no greater than 0.04 mSv (0.004 rem) committed effective dose equivalent or total effective dose equivalent to an

average member of the critical group from groundwater sources, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

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

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

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

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

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

(a) Funds placed into an account segregated from the licensee's assets outside the licensee's administrative control, and in which the adequacy of the trust funds is to be assessed based on an assumed annual one percent real rate of return on investment;

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

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

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

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

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

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

(B) Will be enforceable; and

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

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

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

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

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

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

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

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

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

(i) Demonstrates that further reductions in residual radioactivity necessary to comply with the one mSv (0.1 rem) per year value of Subsection R313-15-403(5)(a) are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(ii) Makes provisions for durable institutional controls; and

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

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

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

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

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

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

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

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

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

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

(e) Has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

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

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

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

(1) Notify and solicit comments from:

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

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

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

R313-15-406. Minimization of Contamination.

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

(2) Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in Section R313-15-101 and radiological criteria for license termination in Sections R313-15-1401 through R313-15-1406.

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

(1) Each licensee or registrant shall make, or cause to be made, surveys of areas, including the subsurface, that:

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

(b) Are reasonable under the circumstances to evaluate:

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

(ii) Concentrations or quantities of residual radioactive material; and

(iii) The potential radiological hazards of the radiation levels and residual radioactivity detected.

(2) Notwithstanding R313-15-1103(1), records from surveys describing the location and amount of subsurface residual radioactivity identified at the site shall be kept with records important for decommissioning, and such records shall be retained in accordance with R313-22-35(7), as applicable.

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

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

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

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

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

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

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

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

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

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

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

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

(e) Individuals working with medical fluoroscopic equipment.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an

individual might receive a deep dose equivalent of one mSv (0.1 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

R313-15-702. Use of Other Controls.

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

(a) Control of access; or

(b) Limitation of exposure times; or

(c) Use of respiratory protection equipment; or

(d) Other controls.

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

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

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

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

(2) The licensee or registrant may use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health or for which there is no schedule for testing or certification, provided the licensee or registrant has submitted to the Director and the Director has approved an application for authorized use of that equipment. The application must include a demonstration

by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

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

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

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

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

(d) Written procedures regarding

(i) Monitoring, including air sampling and bioassays;

(ii) Supervision and training of respirator users;

(iii) Fit testing;

(iv) Respirator selection;

(v) Breathing air quality;

(vi) Inventory and control;

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

(viii) Recordkeeping; and

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

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

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

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

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

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

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

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

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

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

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

(e) Lack of noticeable odor.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

R313-15-901. Caution Signs.

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

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

(b) The background is to be yellow.

(2) Exception to Color Requirements for Standard Radiation Symbol. Notwithstanding the requirements of 10 CFR 20.1901(a), (2010), which is incorporated by reference, licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

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

R313-15-902. Posting Requirements.

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

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

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

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

(5) Posting of Areas or Rooms in which Licensed or Registered Material is Used or Stored. The licensee or registrant shall post each area or room in which there is used or stored an amount of licensed or registered material exceeding ten times the quantity of such material specified in Appendix C of 10 CFR 20.1001 to 20.2402, (2010), which is incorporated by reference, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL."

R313-15-903. Exceptions to Posting Requirements.

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

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

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

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

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

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

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

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

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

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

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

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

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

R313-15-905. Exemptions to Labeling Requirements.

A licensee or registrant is not required to label:

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

(2) Containers holding licensed or registered material in concentrations less than those specified in Table III of Appendix B of 10 CFR 20.1001 to 20.2402, (2010), which is incorporated by reference; or

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

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

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

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

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

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

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

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

(2) Each licensee or registrant shall:

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

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

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

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

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

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

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

(5) Each licensee or registrant shall:

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

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

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

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

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

(a) By transfer to an authorized recipient as provided in Section R313-15-1006 or in Rules R313-21, R313-22, R313-24, or R313-25, or to the U.S. Department of Energy; or

(b) By decay in storage; or

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

(d) As authorized pursuant to Sections R313-15-1002, R313-15-1003, R313-15-1004, R313-15-1005, or R313-15-1008.

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

(a) Treatment prior to disposal; or

(b) Treatment or disposal by incineration; or

(c) Decay in storage; or

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

(e) Storage until transferred to a storage or disposal facility authorized to receive the waste.

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

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

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

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

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

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

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

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

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

(b) The quantity of licensed or registered radioactive material that the licensee or registrant releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee or registrant does not exceed the concentration listed in Table III of Appendix B of 10 CFR 20.1001 to 20.2402, (2010), which is incorporated by reference; and

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

(i) The licensee or registrant shall determine the fraction of the limit in Table III of Appendix B of 10 CFR 20.1001 to 20.2402, (2010), which is incorporated by reference, represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee or registrant into the sewer by the concentration of that radionuclide listed in Table III of Appendix B of 10 CFR 20.1001 to 20.2402, (2010), which is incorporated by reference; and

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

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

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

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

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

R313-15-1005. Disposal of Specific Wastes.

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

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

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

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

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

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

(1) The requirements of Section R313-15-1006 and Appendix G of 10 CFR 20.1001 to 20.2402, (2019), which are incorporated into these rules by reference, are designed to:

(a) control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in Appendix G in 10 CFR 20.1001 to 20.2402, (2019), who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility as defined in Section R313-25-2;

(b) establish a manifest tracking system; and

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

(2) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G to 10 CFR 20.1001 to 20.2402, (2019), which is incorporated into these rules by reference.

(3) Each shipment manifest shall include a certification by the waste generator as specified in Section II of Appendix G to 10 CFR 20.1001 to 20.2402, (2019), which is incorporated by reference.

(4) Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix G to 10 CFR 20.1001 to 20.2402, (2019), which is incorporated by reference.

(5) A licensee shipping byproduct material as defined in paragraphs (c) and (d) of the Section R313-12-3 definition of byproduct material intended for ultimate disposal at a land disposal facility licensed under Rule R313-25 must document the information required on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer the recorded manifest information to the intended consignee in accordance with Appendix G to 10 CFR Part 20 (2019).

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

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

R313-15-1008. Disposal of Section R313-12-3 Byproduct Material Definition Paragraphs (c) and (d).

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

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

R313-15-1009. Classification and Characteristics of Low-Level Radioactive Waste.

(1) Classification of Radioactive Waste for Land Disposal

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

(b) Classes of waste.

(i) Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste shall meet the minimum requirements set forth in Subsection R313-15-1009(2)(a). If Class A waste also meets the stability requirements set forth in Subsection R313-15-1009(2)(b), it is not necessary to segregate the waste for disposal.

(ii) Class B waste is waste that shall meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste shall meet both the minimum and stability requirements set forth in Subsection R313-15-1009(2).

(iii) Class C waste is waste that not only shall meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste shall meet both the minimum and stability requirements set forth in Subsection R313-15-1009(2).

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

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

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

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

(iv) For wastes containing mixtures of radionuclides listed in Table I, the total concentration shall be determined by the sum of fractions rule described in Subsection R313-15-1009(1)(g).

TABLE I

Concentration

Radionuclide	curie/cubic meter(1)	nanocurie/gram(2)
C-14	8	
C-14 in activated metal	80	

Ni-59 in activated metal	220
Nb-94 in activated metal	0.2
Tc-99	3
I-129	0.08
Alpha emitting transuranic radionuclides with half-life greater than five years	100
Pu-241	3,500
Cm-242	20,000
Ra-226	100

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

(d) Classification determined by short-lived radionuclides. If the waste does not contain any of the radionuclides listed in Table I, classification shall be determined based on the concentrations shown in Table II. However, as specified in Subsection R313-15-1009(1)(f), if radioactive waste does not contain any nuclides listed in either Table I or II, it is Class A.

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

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

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

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

(v) For wastes containing mixtures of the radionuclides listed in Table II, the total concentration shall be determined by the sum of fractions rule described in Subsection R313-15-1009(1)(g).

TABLE II

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

NOTE: (1) To convert the Ci/m^3 value to gigabecquerel (GBq)/cubic meter, multiply the Ci/m^3 value by 37.
(2) There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other radionuclides in Table II determine the waste to be Class C independent of these radionuclides.

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

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

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

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

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

(h) Determination of concentrations in wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of

a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as becquerel (nanocurie) per gram.

(2) Radioactive Waste Characteristics

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

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

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

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

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

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

(vi) Waste shall not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with Subsection R313-15-1009(2)(a)(viii).

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

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

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

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

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

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

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

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

R313-15-1101. Records - General Provisions.

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

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

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

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

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

(a) The provisions of the program; and

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

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

R313-15-1103. Records of Surveys.

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

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

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

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

(c) Records showing the results of air sampling, surveys, and bioassays required pursuant to Subsections R313-15-703(3)(a) and R313-15-703(3)(b); and

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

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

For each individual who is likely to receive in a year an occupational dose requiring monitoring pursuant to Section R313-15-502, the licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in Section R313-15-205 on form DWMRC-05 or equivalent until the Director terminates each pertinent license requiring this record. The licensee or registrant shall retain records used in preparing form DWMRC-05 or equivalent for three years after the record is made.

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

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

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

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

(c) What actions were necessary; and

(d) Why the actions were necessary; and

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

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

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

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

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

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

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

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

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

(d) The specific information used to calculate the committed effective dose equivalent pursuant to Subsections R313-15-204(1) and R313-15-204(3) and when required by Section R313-15-502; and

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

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

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

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

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

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

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

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

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

R313-15-1109. Records of Waste Disposal.

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

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

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

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

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

R313-15-1111. Form of Records.

Each record required by Rule R313-15 shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

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

(1) Telephone Reports. Each licensee or registrant shall report to the Director by telephone as follows:

(a) Immediately after its occurrence becomes known to the licensee or registrant, stolen, lost, or missing licensed or registered radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C of 10 CFR 20.1001 to 20.2402, (2010), which is incorporated by reference, under such circumstances that it appears to the licensee or registrant that an exposure could result to individuals in unrestricted areas;

(b) Within 30 days after its occurrence becomes known to the licensee or registrant, lost, stolen, or missing licensed or registered radioactive material in an aggregate quantity greater than ten times the quantity specified in Appendix C of 10 CFR 20.1001 to 20.2402, (2010), which is incorporated by reference, that is still missing.

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

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

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

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

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

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

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

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

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

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

R313-15-1202. Notification of Incidents.

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

(a) An individual to receive:

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

(ii) A lens dose equivalent of 0.75 Sv (75 rem) or more; or

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

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

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

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

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

(ii) A lens dose equivalent exceeding 0.15 Sv (15 rem); or

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

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

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

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

(5) The provisions of Section R313-15-1202 do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to Section R313-15-1204.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) Contents of Reports.

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

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

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

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

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

(b) Each report filed pursuant to Subsection R313-15-1203(1) shall include for each occupationally overexposed individual: the name, Social Security account number, and date of birth. With respect to the limit for the embryo/fetus in Section R313-15-208, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

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

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

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

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

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

R313-15-1206. Reports of Transactions Involving Nationally Tracked Sources.

Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in paragraphs (1) through (5) of this section for each type of transaction.

(1) Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The manufacturer, model, and serial number of the source;

(d) The radioactive material in the source;

(e) The initial source strength in becquerels (curies) at the time of manufacture; and

(f) The manufacture date of the source.

(2) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The name and license number of the recipient facility and the shipping address;

(d) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(e) The radioactive material in the source;

(f) The initial or current source strength in becquerels (curies);

(g) The date for which the source strength is reported;

(h) The shipping date;

(i) The estimated arrival date; and

(j) For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source.

(3) Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The name, address, and license number of the person that provided the source;

(d) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(e) The radioactive material in the source;

(f) The initial or current source strength in becquerels (curies);

(g) The date for which the source strength is reported;

(h) The date of receipt; and

(i) For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

(4) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(d) The radioactive material in the source;

(e) The initial or current source strength in becquerels (curies);

(f) The date for which the source strength is reported; and

(g) The disassemble date of the source.

(5) Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The waste manifest number;

(d) The container identification with the nationally tracked source.

(e) The date of disposal; and

(f) The method of disposal.

(6) The reports discussed in paragraphs (1) through (5) of this section must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

(a) The on-line National Source Tracking System;

(b) Electronically using a computer-readable format;

(c) By facsimile;

(d) By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

(e) By telephone with followup by facsimile or mail.

(7) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 5

business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by paragraphs (1) through (5) of this section. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

(8) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by November 15, 2007. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by November 30, 2007. The information may be submitted by using any of the methods identified by paragraph (6)(a) through (6)(d) of this section. The initial inventory report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;

(d) The radioactive material in the sealed source;

(e) The initial or current source strength in becquerels (curies); and

(f) The date for which the source strength is reported.

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

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

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

R313-15-1301. Vacating Premises.

Each specific licensee or registrant shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of his activities, notify the Director in writing of intent to vacate. When deemed necessary by the Director, the licensee shall decontaminate the premises in such a manner that the annual total effective dose equivalent to any individual after the site is released for unrestricted use should not exceed 0.1 mSv (0.01 rem)above background and that the annual total effective dose equivalent from any specific environmental source during decommissioning activities should not exceed 0.1 mSv (0.01 rem)above background.

KEY: radioactive materials, contamination, waste disposal, safety
Date of Enactment or Last Substantive Amendment: February 14, 2020
Notice of Continuation: January 17, 2017
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-104

State of Utah
Administrative Rule Analysis
Revised June 2021

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION		
	Title No. - Rule No.	
Utah Admin. Code Ref (R no.):	**R313-21**	**Filing ID: (Office Use Only)**

Agency Information

1. Department:	Environmental Quality	
Agency:	Waste Management and Radiation Control	
Room no.:	Second Floor	
Building:	MASOB	
Street address:	195 N. 1950 W.	
City, state and zip:	Salt Lake City, Utah 84116	
Mailing address:	PO Box 144880	
City, state and 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:

R313-21. General 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 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 section also requires the licensing of all sources of ionizing radiation and allows the Division of Waste Management and Radiation Control to require licensing of radiation sources that constitute a significant health hazard. As part of the state primacy of the radiation control program, the provisions in R313-21 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 general licenses for the possession and use of radioactive material contained in certain items and a general license for ownership of radioactive material. As an Agreement State, this rule maintains the appropriate regulatory compatibility with the NRC. There have been no opposing comments to the rules since the last five-year review in 2017.

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 publication in the *Utah State Bulletin*.

Agency head or designee, and title:	Douglas J. Hansen, Division Director	**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.
R313-21. General Licenses.
R313-21-1. Purpose and Scope.

(1) R313-21 establishes general licenses for the possession and use of radioactive material contained in certain items and a general license for ownership of radioactive material.

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

R313-21-21. General Licenses--Source Material.

(1) A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local government agencies to receive, possess, use and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes in the following forms and quantities:

(a) No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms, for example, gaseous, liquid, powder, etc., at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under Subsection R313-21-21(1) may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year. A person possessing source material in excess of these limits as of October 16, 2017, may continue to possess up to 7 kg (15.4 lb) of uranium and thorium at any one time for one year beyond this date, or until the Director takes final action on a pending application submitted on or before October 16, 2017, for a specific license for this material; and receive up to 70 kg (154 lb) of uranium or thorium in any one calendar year until December 31, 2018, or until the Director takes final action on a pending application submitted on or before October 16, 2018, for a specific license for this material; and

(b) No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under Subsection R313-21-21(1) may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under Subsection R313-21-21(1) unless it is accounted for under the limits of Subsection R313-21-21(1)(a); or

(c) No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under Subsection R313-21-21(1)(a); or

(d) No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under Subsection R313-21-21(1) may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.

(2) Any person who receives, possesses, uses, or transfers source material pursuant to the general license issued in Subsection R313-21-21(1):

(a) Is prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the Director in a specific license.

(b) Shall not abandon this source material. Source material may be disposed of as follows:

(i) A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of Subsection R313-21-21(2) is exempt from the requirements to obtain a license under Rule R313-22 to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued under Rules R313-19, and R313-22; or

(ii) In accordance with Section R313-15-1001.

(c) Is subject to the provisions in 10 CFR 40.2a through 40.4, 10 CFR 40.41(c), 10 CFR 40.46, and 10 CFR 40.61(a) and (b), which are incorporated by reference in Section R313-24-4, Section R313-12-3, Section R313-19-5, Section R313-19-34, Subsection R313-22-34(2), Section R313-19-41, Section R313-19-50, Section R313-15-1111, Sections R313-12-51 through R313-12-53, Section R313-19-61, Rule R313-14, 10 CFR 40.41(d), 10 CFR 40.41(e)(1) and (e)(3), 10 CFR 40.51(b)(6), and 10 CFR 40.56.

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

(e) Shall not export such source material except in accordance with 10 CFR Part 110 (2017).

(3) Any person who receives, possesses, uses, or transfers source material in accordance with Subsection R313-21-21(1) shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the Director using the method stated in Section R313-12-110 about such contamination and may consult with the Director as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in Section R313-15-402.

(4) Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in Subsection R313-21-21(1) is exempt from the provisions of Rules R313-15 and R313-18 to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of Sections R313-15-402

and R313-15-1001 to the extent necessary to meet the provisions of Subsections R313-21-21(2)(b) and R313-21-21(3). However, this exemption does not apply to any person who also holds a specific license issued under Rules R313-19 and R313-22.

(5) No person may initially transfer or distribute source material to persons generally licensed under Subsection R313-21-21(1)(a) or R313-21-21(1)(b), or paragraphs (a)(1) or (a)(2) of 10 CFR 40.22 for a non-Agreement State, or equivalent regulations of an Agreement State, unless authorized by a specific license issued in accordance with Subsection R313-22-54 or 10 CFR 40.54 for a non-Agreement State or equivalent provisions of an Agreement State. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally licensed by Subsection R313-21-21(1) before October 16, 2017, without specific authorization may continue for one year beyond this date. 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 on or before October 16, 2018.

(6) A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize a person to receive, possess, deliver, use, or transfer source material.

(7) Depleted uranium in industrial products and devices.

(a) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of R313-21-21(7)(b), (c), (d), and (e), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(b) The general license in R313-21-21(7)(a) applies only to industrial products or devices which have been manufactured or initially transferred, either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to R313-22-75(11) or in accordance with a specific license issued to the manufacturer by the Nuclear Regulatory Commission, an Agreement State, or a Licensing State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

(c)(i) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by R313-21-21(7)(a) shall file form DWMRC-12 "Registration Form-Use of Depleted Uranium Under General License," with the Director. The form shall be submitted within 30 days after the first receipt or acquisition of depleted uranium. The registrant shall furnish on form DWMRC-12 the following information and other information as may be required by that form:

(A) name and address of the registrant;

(B) a statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in R313-21-21(7)(a) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(C) name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in R313-21-21(7)(c)(i)(B).

(ii) The registrant possessing or using depleted uranium under the general license established by R313-21-21(7)(a) shall report in writing to the Director any changes in information previously furnished on form DWMRC-12 "Registration Form - Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of the change.

(d) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by R313-21-21(5)(a):

(i) shall not introduce depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

(ii) shall not abandon depleted uranium;

(iii) shall transfer or dispose of depleted uranium only by transfer in accordance with the provisions of R313-19-41. In the case where the transferee receives the depleted uranium pursuant to the general license established by R313-21-21(7)(a), the transferor shall furnish the transferee a copy of R313-21 and a copy of form DWMRC-12. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the Nuclear Regulatory Commission's or Agreement State's regulation equivalent to R313-21-21(7)(a), the transferor shall furnish the transferee a copy of this rule and a copy of form DWMRC-12 accompanied by a note explaining that use of the product or device is regulated by the Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in R313-21;

(iv) within 30 days of any transfer, shall report in writing to the Director the name and address of the person receiving the depleted uranium pursuant to the transfer;

(v) shall not export depleted uranium except in accordance with a license issued by the Nuclear Regulatory Commission pursuant to 10 CFR Part 110; and

(vi) shall pay annual fees pursuant to R313-70.

(e) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by R313-21-21(7)(a) is exempt from the requirements of R313-15 and R313-18 of these rules with respect to the depleted uranium covered by that general license.

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

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

(1) RESERVED.

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

(a) A general license is hereby issued to a person to acquire, receive, possess, use, or transfer, in accordance with the provisions of

Subsections R313-21-22(2)(b), R313-21-22(2)(c), and R313-21-22(2)(d), radium-226 contained in the following products manufactured prior to November 30, 2007.

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) RESERVED.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(III) the date of the transfer;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) Luminous safety devices for aircraft.

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

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

147; and

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

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

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

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

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

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

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

(7) Calibration and reference sources.

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

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

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

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

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

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

CAUTION - RADIOACTIVE MATERIAL

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

DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

.....

Typed or printed name of the manufacturer or initial transferor

NOTE: *Show the name of the appropriate material.

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

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

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

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

(8) RESERVED.

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

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

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

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

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

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

(iv) hydrogen-3 (tritium), in units not exceeding 1.85 megabecquerel (50 uCi) each;

(v) iron-59, in units not exceeding 740.0 kilobecquerel (20 uCi) each;

(vi) cobalt-57, in units not exceeding 370.0 kilobecquerel (10 uCi) each;

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

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

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

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

(ii) the location of use; and

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

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

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

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

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

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

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

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

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

(i) Except as prepackaged units which are labeled in accordance with the provision of a specific license issued pursuant to R313-22-75(7) or in accordance with the provisions of a specific license issued by the Nuclear Regulatory Commission, or an Agreement State, or before November 30, 2007, in accordance with the provisions of a specific license issued by a State with comparable provisions to 10 CFR 32.71 (2017) which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3(tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under Subsection R313-21-22(9) or its equivalent, and

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

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

.....

Name of Manufacturer"

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

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

(10) Ice Detection Devices.

(a) A general license is hereby issued to own, receive, acquire, possess, use and transfer strontium-90 contained in ice detection

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

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

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

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

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

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

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

KEY: radioactive materials, general licenses, source materials
Date of Enactment or Last Substantive Amendment: October 13, 2017
Notice of Continuation: January 17, 2017
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-104

State of Utah
Administrative Rule Analysis
Revised June 2021

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION		
	Title No. - Rule No.	
Utah Admin. Code Ref (R no.):	**R313-24**	**Filing ID: (Office Use Only)**

Agency Information

1. Department:	Environmental Quality	
Agency:	Waste Management and Radiation Control	
Room no.:	Second Floor	
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Street address:	195 N. 1950 W.	
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Mailing address:	PO Box 144880	
City, state and 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:

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

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 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 section also allows the Board to make rules regarding the possession, use, transfer, or delivery of source and byproduct material and the disposal of byproduct material including establish requirements for the licensing, operation, decontamination, and decommissioning, and the reclamation of sites, structures, and equipment used in conjunction with these activities. As part of the state primacy of the radiation control program, the provisions in R313-24 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 possession and use of source material in milling operations. It also establishes requirements for receipt, possession, and disposal of byproduct material. As an Agreement State, this rule maintains the appropriate regulatory compatibility with the NRC. There have been no opposing comments to the rules since the last five-year review in 2017.

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 publication in the *Utah State Bulletin*.

Agency head or designee, and title:	Douglas J. Hansen, Division Director	**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.
R313-24. Uranium Mills and Source Material Mill Tailings Disposal Facility Requirements.
R313-24-1. Purpose and Authority.

(1) The purpose of this rule is to prescribe requirements for possession and use of source material in milling operations such as conventional milling, in-situ leaching, or heap-leaching. The rule includes requirements for the possession of byproduct material, as defined in Section R313-12-3 (see "byproduct material" definition (b)), from source material milling operations, as well as, possession and maintenance of a facility in standby mode. In addition, requirements are prescribed for the receipt of byproduct material from other persons for possession and disposal. The rule also prescribes requirements for receipt of byproduct material from other persons for possession and disposal incidental to the byproduct material generated by the licensee's source material milling operations.

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

(3) The requirements of Rule R313-24 are in addition to, and not substitution for, the other applicable requirements of Title R313. In particular, the provisions of Rules R313-12, R313-15, R313-18, R313-19, R313-21, R313-22, and R313-70 apply to applicants and licensees subject to Rule R313-24.

(4) See R313-17-4 for special procedures for decisions associated with licenses for activity which results in the production or disposal of byproduct material.

R313-24-2. Scope.

(1) The requirements in Rule R313-24 apply to source material milling operations, byproduct material, and byproduct material disposal facilities.

R313-24-3. Environmental Analysis.

(1) Each new license application, renewal, or major amendment shall contain an environmental report describing the proposed action, a statement of its purposes, and the environment affected. The environmental report shall present a discussion of the following:

(a) An assessment of the radiological and nonradiological impacts to the public health from the activities to be conducted pursuant to the license or amendment;

(b) An assessment of any impact on waterways and groundwater resulting from the activities conducted pursuant to the license or amendment;

(c) Consideration of alternatives, including alternative sites and engineering methods, to the activities to be conducted pursuant to the license or amendment; and

(d) Consideration of the long-term impacts including decommissioning, decontamination, and reclamation impacts, associated with activities to be conducted pursuant to the license or amendment.

(2) Commencement of construction prior to issuance of the license or amendment shall be grounds for denial of the license or amendment.

(3) The Director shall provide a written analysis of the environmental report which shall be available for public notice and comment pursuant to R313-17-2.

R313-24-4. Clarifications or Exceptions.

For the purposes of Rule R313-24, 10 CFR 40.2a through 40.4; 40.12; 40.20(a); 40.21; 40.26(a) through (c); 40.31(h); the introductory paragraph of 40.36 and 40.36(a),(b),(d) and (f); 40.41(c); the introduction to 40.42(k) and 40.42(k)(3)(i); 40.46; 40.61(a) and (b); 40.65; and Appendix A to Part 40 (2015) are incorporated by reference with the following clarifications or exceptions:

(1) The exclusion and substitution of the following:

(a) Exclude 10 CFR 40.26(c)(1) and replace with "(1) The provisions of Sections R313-12-51, R313-12-52, R313-12-53, R313-19-34, R313-19-50, R313-19-61, R313-24-1, Rules R313-14, R313-15, R313-18, and R313-24 (incorporating 10 CFR 40.2a, 40.3, 40.4, and 40.26 by reference)";

(b) In Appendix A to 10 CFR 40, exclude Criterion 5B(1) through 5H, Criterion 7A, Criterion 13, and replace the excluded Criterion with "Utah Administrative Code, R317-6, Ground Water Quality Protection"; and

(c) In Appendix A to 10 CFR 40, exclude Criterion 11A through 11F and Criterion 12;

(2) The substitution of the following:

(a) "10 CFR 40" for reference to "this part" as found throughout the incorporated text;

(b) "Director" for reference to "Commission" in the first and fourth references contained in 10 CFR 40.2a, in 10 CFR 40.3, 40.20(a), 40.26, 40.36(f), 40.41(c), 40.46 (a), 40.61, and 40.65; and "Director" for reference to "NRC" in 10 CFR 40.36(b);

(c) "Rules R313-19, R313-21, or R313-22" for "Section 62 of the Act" as found in 10 CFR 40.12(a);

(d) "Rule R313-15-402" for reference to "10 CFR 20.1402" and "Rule R313-15-403" for reference to "10 CFR 20.1403" in 10 CFR 40.36(d);

(e) "Rule R313-15-1109" for reference to "10 CFR 20.2108" in 10 CFR 40.36(f);

(f) "Rules R313-21 or R313-22" for reference to "the regulations in this part" in 10 CFR 40.41(c);

(g) "Section R313-19-100" for reference to "part 71 of this chapter" as found in 10 CFR 40.41(c);

(h) In 10 CFR 40.42(k)(3)(i), "R313-15-401 through R313-15-406" for reference to "10 CFR part 20, subpart E";

(i) "source material milling" for reference to "uranium milling, in production of uranium hexafluoride, or in a uranium enrichment

facility" as found in 10 CFR 40.65(a);

(j) "Director" for reference to "appropriate NRC Regional Office shown in Appendix D to 10 CFR part 20 of this chapter, with copies to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555," as stated in 10 CFR 65(a)(1);

(k) "require the licensee to" for reference to "require to" in 10 CFR 40.65(a)(1); and

(l) In Appendix A to 10 CFR part 40, the following substitutions:

(i) "R313-12-3" for reference to "Sec. 20.1003 of this chapter" as found in 10 CFR 40.36(f) and in the first paragraph of the introduction to Appendix A;

(ii) "Utah Administrative Code, Rule R317-6, Ground Water Quality Protection" for ground water standards in "Environmental Protection Agency in 40 CFR part 192, subparts D and E" as found in the Introduction, paragraph 4; or "Environmental Protection Agency in 40 CFR part 192, subparts D and E (48 FR 45926; October 7, 1983)" as found in Criterion 5;

(iii) "Director as defined in Subsection 19-5-102(6)" for reference to "Commission" in the definition of "compliance period," in paragraph five of the introduction and in Criterion 5A(3);

(iv) "Director" for reference to "Commission" in the definition of "closure plan", in paragraph five of the introduction, and in Criterions 6(2), 6(4), 6(6), 6A(2), 6A(3), 9, and 10 of Appendix A;

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

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

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

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

(ix) "Director" for reference to "appropriate NRC regional office as indicated in Criterion 8A" as found, Criterion 8, paragraph 2 or for reference to "appropriate NRC regional office as indicated in Appendix D to 10 CFR part 20 of this chapter, or the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555," as stated in Criterion 8A; and

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

KEY: environmental analysis, uranium mills, tailings, byproduct material
Date of Enactment or Last Substantive Amendment: March 15, 2016
Notice of Continuation: January 17, 2017
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-107

State of Utah
Administrative Rule Analysis
Revised June 2021

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION		
	Title No. - Rule No.	
Utah Admin. Code Ref (R no.):	**R313-30**	**Filing ID: (Office Use Only)**

Agency Information

1. Department:	Environmental Quality	
Agency:	Waste Management and Radiation Control	
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Mailing address:	PO Box 144880	
City, state and 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:

R313-30. Therapeutic 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 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 section also allows the Board to make rules necessary for controlling exposure to sources of radiation that constitute a significant health hazard. As part of the state primacy of the radiation control program, the provisions in R313-30 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 requirements for use of therapeutic radiation machines that are in addition to, and not in substitution for, other applicable provisions of the rules found in Title R313. As an Agreement State, this rule maintains the appropriate regulatory compatibility with the NRC. There have been no opposing comments to the rules since the last five-year review in 2017.

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 publication in the *Utah State Bulletin*.

Agency head or designee, and title:	Douglas J. Hansen, Division Director	**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.
R313-30. Therapeutic Radiation Machines.
R313-30-1. Scope and Applicability.

(1) R313-30 establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines. The provisions of R313-30 are in addition to, and not in substitution for, other applicable provisions of these rules.

(2) The use of therapeutic radiation machines shall be by, or under the supervision of, a licensed practitioner of the healing arts who meets the training and experience criteria established by R313-30-3(3).

(3) R313-30 shall only apply to therapeutic radiation machines which accelerate electrons into a target to produce bremsstrahlung or which accelerate electrons to produce a clinically useful electron beam.

R313-30-2. Definitions.

As used in R313-30, the following definitions apply:

"Absorbed dose (D)" means the mean energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is the gray (Gy). The previously used special unit of absorbed dose (rad) is being replaced by the gray.

"Absorbed dose rate" means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

"Accessible surfaces" means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool, or without opening an access panel or door.

"Added filtration" means filtration which is in addition to the inherent filtration.

"Air kerma (K)" means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

"Barrier" See "Protective barrier."

"Beam axis" means the axis of rotation of the radiation head.

"Beam-limiting device" means a field defining collimator which provides a means to restrict the dimensions of the useful beam.

"Beam monitoring system" means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

"Beam scattering foil" means a thin piece of material, usually metallic, placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

"Bent beam linear accelerator" means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

"Changeable filters" means filters, exclusive of inherent filtration, which can be removed from the useful beam through electronic, mechanical, or physical processes.

"Contact therapy system" means a therapeutic radiation machine with a short target to skin distance (TSD), usually less than five centimeters.

"Detector" See "Radiation detector."

"Dose monitor unit (DMU)" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

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

"Field-flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.

"Filter" means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to R313-30-6.

"Gantry" means that part of a therapeutic radiation machine supporting and allowing movements of the radiation head about a center of rotation.

"Gray (Gy)" means the SI unit of absorbed dose, kerma, and specific energy imparted equal to 1 joule per kilogram. The previous unit of absorbed dose (rad) is being replaced by the gray. Note that 1 Gy equals 100 rad.

"Half-value layer (HVL)" means the thickness of a specified material which attenuates x-radiation or gamma radiation to the extent that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-half of the value measured without the material at the same point.

"Interlock" means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

"Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

"Irradiation" means the exposure of a living being or matter to ionizing radiation.

"Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

"Kilovolt (kV) or kilo electron volt (keV)" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum. Current convention is to use kV for photons and keV for electrons.

"Lead equivalent" means the thickness of the material in question affording the same attenuation, under specified conditions, as lead.

"Leakage radiation" means radiation emanating from the therapeutic radiation machine except for the useful beam.

"Light field" means the area illuminated by light, simulating the radiation field.

"mA" means milliampere.

"Megavolt (MV) or mega electron volt (MeV)" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. Current convention is to use MV for photons and MeV for electrons.

"Monitor unit (MU)" See "Dose monitor unit."

"Moving beam radiation therapy" means radiation therapy with continuous displacement of one or more mechanical axes relative to the patient during irradiation. It includes arc therapy, skip therapy, conformal therapy and rotational therapy.

"Nominal treatment distance" means:

(a) For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

(b) For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

"Patient" means an individual subjected to machine produced external beam radiation for the purposes of medical therapy.

"Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

"Periodic quality assurance check" means a procedure which is performed to ensure that a previous calibration continues to be valid.

"Phantom" means an object which attenuates, absorbs, and scatters ionizing radiation in the same quantitative manner as tissue.

"Practical range of electrons" corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung x-rays.

"Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been delivered.

"Primary protective barrier" See "Protective barrier."

"Protective barrier" means a barrier of radiation absorbing materials used to reduce radiation exposure. The types of protective barriers are as follows:

(a) "Primary protective barrier" means the material, excluding filters, placed in the useful beam or a barrier which attenuates the primary beam.

(b) "Secondary protective barrier" means the material which attenuates stray radiation.

"Radiation detector" means a device which, in the presence of radiation provides, by either direct or indirect means a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

"Radiation field" See "Useful beam."

"Radiation head" means the structure from which the useful beam emerges.

"Radiation Therapy Physicist" means an individual qualified in accordance with R313-30-3(4).

"Redundant beam monitoring system" means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

"Scattered radiation" means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation.

"Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

"Secondary protective barrier" See "Protective barrier."

"Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

"Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

"Sievert (Sv)" means the SI unit of dose equivalent. The unit of dose equivalent is the joule per kilogram. The previous unit of dose equivalent (rem) is being replaced by the sievert. Note that 1 Sv equals 100 rem.

"Simulator, or radiation therapy simulation system" means an x-ray system intended for localizing the volume to be exposed during radiation therapy and reproducing the position and size of the therapeutic irradiation field.

"Source" means the region or material from which the radiation emanates.

"Source-skin distance (SSD)" See "Target-skin distance."

"Stationary beam radiation therapy" means radiation therapy without displacement of the radiation source relative to the patient during irradiation.

"Stray radiation" means the sum of leakage and scattered radiation.

"Target" means that part of an x-ray tube or particle accelerator onto which is directed a beam of accelerated particles to produce ionizing radiation or other particles.

"Target-skin distance (TSD)" means the distance measured along the beam axis from the center of the front surface of the x-ray target or electron virtual source to the surface of the irradiated object or patient.

"Tenth-value layer (TVL)" means the thickness of a specified material which, x-radiation or gamma radiation to the extent that the

air kerma rate, exposure rate or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

"Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

"Therapeutic radiation machine" means x-ray or electron-producing equipment designed and used for external beam radiation therapy.

"Tube" means an x-ray tube, unless otherwise specified.

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and filament transformers and other appropriate elements that are contained within the tube housing.

"Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the therapeutic radiation machine to produce radiation.

"Virtual source" means a point from which radiation appears to originate.

"Wedge filter" means a filter which effects continuous change in transmission over all or a part of the radiation field.

"X-ray tube" means an electron tube which is designed to be used primarily for the production of x-rays.

R313-30-3. General Administrative Requirements for Facilities Using Therapeutic Radiation Machines.

(1) Administrative Controls. The registrant shall be responsible for directing the operation of the therapeutic radiation machines which have been registered with the Director. The registrant or the registrant's agent shall ensure that the requirements of R313-30 are met in the operation of the therapeutic radiation machines.

(2) A therapeutic radiation machine which does not meet the provisions of these rules shall not be used for irradiation of patients.

(3) Training for External Beam Radiation Therapy Authorized Users. The registrant for a therapeutic radiation machine subject to R313-30-6 or R313-30-7 shall require the authorized user to be a physician who:

(a) Is certified in:

(i) Radiology or therapeutic radiology by the American Board of Radiology; or

(ii) Radiation oncology by the American Osteopathic Board of Radiology; or

(iii) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(iv) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

(i) To satisfy the requirement for instruction, the classroom and laboratory training shall include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Radiation biology.

(ii) To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include:

(A) Review of the full calibration measurements and periodic quality assurance checks;

(B) Preparing treatment plans and calculating treatment times;

(C) Using administrative controls to prevent misadministrations;

(D) Implementing emergency procedures to be followed in the event of the abnormal operation of a external beam radiation therapy unit or console; and

(E) Checking and using radiation survey meters.

(iii) To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

(A) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and limitations and contraindications;

(B) Selecting proper dose and how it is to be administered;

(C) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and

(D) Post-administration follow-up and review of case histories.

(iv) An individual who satisfies the requirements in R313-30-3(b), but not R313-30-3(a), must submit an application to the Director and must satisfy the requirements in R313-30-3(a) within one year of initial application to the Director.

(c) After December 31, 1994, a physician shall not act as an authorized user for a therapeutic radiation machine until the physician's training has been reviewed and approved by the Director.

(4) Training for Radiation Therapy Physicist. The registrant for a therapeutic radiation machine subject to R313-30-6 or R313-30-7 shall require the Radiation Therapy Physicist to:

(a) Satisfy the provisions of R313-16, as a provider of radiation services in the area of calibration and compliance surveys of

external beam radiation therapy units; and

(b) Be certified by the American Board of Radiology in:

(i) Therapeutic radiological physics; or

(ii) Roentgen-ray and gamma-ray physics; or

(iii) X-ray and radium physics; or

(iv) Radiological physics; or

(c) Be certified by the American Board of Medical Physics in Radiation Oncology Physics; or

(d) Be certified by the Canadian College of Medical Physics; or

(e) Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full time training in therapeutic radiological physics and also one year of full time work experience under the supervision of a Radiation Therapy Physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in R313-30-4(1), R313-30-6(16), R313-30-7(19), R313-30-6(17), and R313-30-7(20) under the supervision of a Radiation Therapy Physicist during the year of work experience.

(f) Notwithstanding the provisions of R313-30-3(4)(e), certification pursuant to R313-30-3(4)(b), (c) or (d) shall be required on or before December 31, 1999 for all persons currently qualifying as a Radiation Therapy Physicist pursuant to R313-30-3(4)(e).

(5) Qualifications of Operators.

(a) Individuals who will be operating a therapeutic radiation machine for medical use shall be American Registry of Radiologic Technologists (ARRT) Registered Radiation Therapy Technologists.

(b) The names and training of personnel currently operating a therapeutic radiation machine shall be kept on file at the facility. Information on former operators shall be retained for a period of at least two years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

(6) Written safety procedures and rules shall be developed by a Radiation Therapy Physicist and shall be available in the control area of a therapeutic radiation machine, including restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be familiar with these rules as required in R313-18-12(1)(c).

(7) Individuals shall not be exposed to the useful beam except for medical therapy purposes. Exposure for medical therapy purposes shall be ordered in writing by an authorized user who is specifically identified on the Certificate of Registration. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes.

(8) Visiting Authorized User. Notwithstanding the provisions of R313-30-3(7), a registrant may permit a physician to act as a visiting authorized user under the term of the registrant's Certificate of Registration for up to 60 days per calendar year under the following conditions:

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

(b) The visiting authorized user meets the requirements established for authorized users in R313-30-3(3)(a) and R313-30-3(3)(b); and

(c) The registrant maintains copies of records specified by R313-30-3(8) for five years from the date of the last visit.

(9) Individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the registrant's quality management program. In addition to the requirements of R313-30, these individuals are also subject to the requirements of R313-15-201, R313-15-202, R313-15-205 and R313-15-502.

(10) Information and Maintenance Record and Associated Information. The registrant shall maintain the following information in a separate file or package for therapeutic radiation machines, for inspection by the representatives of the Director:

(a) Report of acceptance testing;

(b) Records of surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by R313-30, as well as the names of persons who performed the activities;

(c) Records of major maintenance and modifications performed on the therapeutic radiation machine after the effective date of these rules, as well as the names of persons who performed the services; and

(d) Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

(11) Records Retention. Records required by R313-30 shall be retained until disposal is authorized by the Director unless another retention period is specifically authorized in R313-30. Required records shall be retained in an active file from at least the time of generation until the next inspection by a representative of the Director. A required record generated prior to the last inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until the Director authorizes final disposal.

R313-30-4. General Technical Requirements for Facilities Using Therapeutic Radiation Machines.

(1) Protection Surveys.

(a) The registrant shall ensure that radiation protection surveys of new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with R313-30-8. The radiation protection survey shall be performed by, or under the direction of, a Radiation Therapy Physicist or a Certified Health Physicist and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation:

(i) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in R313-15-201(1); and

(ii) Radiation levels in unrestricted areas do not exceed the limits specified in R313-15-301(1).

(b) In addition to the requirements of R313-30-4(1)(a), a radiation protection survey shall also be performed prior to subsequent medical use and:

(i) After making changes in the treatment room shielding;

(ii) After making changes in the location of the therapeutic radiation machine within the treatment room;

(iii) After relocation of, or modification of, the therapeutic radiation machine; or

(iv) Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

(c) The survey record shall indicate instances where the facility, in the opinion of the Radiation Therapy Physicist or a Certified Health Physicist, is in violation of applicable radiation protection rules. The survey record shall also include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the therapeutic radiation machine, the instruments used to measure radiation levels, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in areas expressed in microsieverts, millirems, per hour, the calculated maximum level of radiation over a period of one week for restricted and unrestricted areas, and the signature of the individual responsible for conducting the survey;

(d) If the results of the surveys required by R313-30-4(1)(a) or R313-30-4(1)(b) indicate radiation levels in excess of the respective limit specified in R313-30-4(1)(a), the registrant shall lock the control in the "OFF" position and not use the unit:

(i) Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

(ii) Until the registrant has received a written approval from the Director.

(2) Modification of Radiation Therapy Unit or Room Before Beginning a Treatment Program. If the survey required by R313-30-4(1) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by R313-15-301(1) of these rules, before beginning the treatment program the registrant shall:

(a) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with R313-15-301(1) of these rules;

(b) Perform the survey required by R313-30-4(1) again; and

(c) Include in the report required by R313-30-4(4) the results of the initial survey, a description of the modification made to comply with R313-30-4(2)(a), and the results of the second survey; or

(d) Request and receive a registration amendment under R313-15-301(3) of these rules that authorizes radiation levels in unrestricted areas greater than those permitted by R313-15-301(1) of these rules.

(3) Possession of Survey Instruments. Facility locations authorized to use a therapeutic radiation machine in accordance with R313-30-6 and R313-30-7 shall possess appropriately calibrated portable monitoring equipment. As a minimum, the equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 uSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instruments shall be operable and calibrated in accordance with R313-30-8.

(4) Reports of External Beam Radiation Therapy Surveys and Measurements. The registrant for a therapeutic radiation machine subject to R313-30-6 or R313-30-7 shall furnish a copy of the records required in R313-30-4(1) and R313-30-4(2) to the Director within 30 days following completion of the action that initiated the record requirement.

R313-30-5. Quality Management Program.

(1) In addition to the definitions in R313-30-2, the following definitions are applicable to a quality management program:

"Course" means the entire treatment consisting of multiple fractions as prescribed in the written directive.

"Misadministration" means the administration of an external beam radiation therapy dose:

(a) Involving the wrong patient, wrong treatment modality, or wrong treatment site;

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

(c) When the calculated weekly administered dose differs from the weekly prescribed dose by more than 30 percent; or

(d) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose;

"Prescribed dose" means the total dose and dose per fraction as documented in the written directive.

"Recordable event" means the administration of an external beam radiation therapy dose when the calculated weekly administered dose differs by 15 percent or more from the weekly prescribed dose;

"Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation, containing the following information: total dose, dose per fraction, treatment site and overall treatment period.

(2) Scope and Applicability. Applicants or registrants subject to R313-30-6 or R313-30-7 shall establish and maintain a written quality management program to provide high confidence that radiation will be administered as directed by the authorized user. The quality management program shall include written policies and procedures to meet the following specific objectives:

(a) Prior to administration, a written directive is prepared for an external beam radiation therapy dose;

(i) Notwithstanding R313-30-5(2)(a), a written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to administration of the external beam radiation therapy dose or the next external beam radiation therapy fractional dose;

(ii) Notwithstanding R313-30-5(2)(a), if, because of the patient's condition, a delay in order to provide a written revision to an

existing written directive would jeopardize the patient's health, an oral revision to an existing written directive shall be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision;

(iii) Notwithstanding R313-30-5(2)(a), if, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive shall be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared and signed by an authorized user within 24 hours of the oral directive.

(b) Prior to the administration of a course of radiation treatments, the patient's identity is verified, by more than one method, as the individual named in the written directive;

(c) External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives;

(d) An administration is in accordance with the written directive; and

(e) Unintended deviations from the written directive is identified and evaluated, and appropriate action are taken.

(3) Development of Quality Management Program.

(a) An application for registration subject to R313-30-6 or R313-30-7 shall include a quality management program that specifies staff, duties and responsibilities, and equipment and procedures as part of the application required by R313-16 of these rules. The registrant shall implement the program upon issuance of a Certificate of Registration by the Director;

(b) Existing registrants subject to R313-30-6 or R313-30-7 shall submit to the Director a written certification that a quality management program has been implemented by December 31, 1994.

(4) As a part of the quality management program, the registrant shall:

(a) Develop procedures for, and conduct a review of, the quality management program including, since the last review, an evaluation of a representative sample of patient administrations, recordable events, and misadministrations to verify compliance with the quality management program;

(b) Conduct these reviews annually. The intervals should not exceed 12 months and shall not exceed 13 months;

(c) Evaluate these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the requirements of R313-30-5(2); and

(d) Maintain records of these reviews, including the evaluations and findings of the reviews, in a form that can be readily audited, for three years.

(5) The registrant shall evaluate and respond, within 30 days after discovery of the recordable event, to recordable events by:

(a) Assembling the relevant facts including the cause;

(b) Identifying what corrective actions are required to prevent recurrence; and

(c) Retaining a record, in a form that can be readily audited, for three years, of the relevant facts and what corrective actions were taken.

(6) The registrant shall retain:

(a) Written directives; and

(b) A record of administered radiation doses, in a form that can be readily audited, for three years after the date of administration.

(7) The registrant may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased.

(8) The registrant shall evaluate misadministrations and shall take the following actions in response to a misadministration:

(a) Notify the Director by telephone no later than the next calendar day after discovery of the misadministration;

(b) Submit a written report to the Director within 15 days after discovery of the misadministration. The written report shall include: the registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the registrant notified the patient or the patient's responsible relative or guardian, this person will subsequently be referred to as "the patient," and if not, why not; and if the patient was notified, what information was provided to the patient. The report shall not include the patient's name or other information that could lead to identification of the patient;

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

(d) Retain a record of misadministrations for five years. The record shall contain the names of individuals involved; including the prescribing physician, allied health personnel, the patient, and the patient's referring physician; the patient's social security number or identification number if one has been assigned; a brief description of the event; why it occurred; the effect on the patient; what improvements are needed to prevent recurrence; and the actions taken to prevent recurrence; and

(e) If the patient was notified, furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either a copy of the report that was submitted to the Director, or a brief description of both the event and the consequences as they may effect the patient, provided a statement is included that the report submitted to the Director can be obtained from the registrant;

(9) Aside from the notification requirement, nothing in R313-30-5(8) affects the rights or duties of registrants and physicians in

relation to patients, the patient's responsible relatives or guardians, or to others.

R313-30-6. Therapeutic Radiation Machines of Less Than 500 kV.

(1) Leakage Radiation. When the x-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

(a) Systems 5-50 kV. The leakage air kerma rate measured at a position five centimeters from the tube housing assembly shall not exceed 1 mGy (100 mrad) in one hour.

(b) Systems greater than 50 and less than 500 kV. The leakage air kerma rate measured at a distance of one meter from the source in every direction shall not exceed 1 cGy (1 rad) in one hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of five centimeters from the surface of the tube housing assembly shall not exceed 30 cGy (30 rad) per hour.

(2) Permanent Beam Limiting Devices. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

(3) Adjustable or Removable Beam Limiting Devices.

(a) Adjustable or removable beam limiting devices, diaphragms, cones or blocks shall not transmit more than five percent of the useful beam for the most penetrating beam used;

(b) When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

(4) Filter System. The filter system shall be so designed that:

(a) Filters can not be accidentally displaced at every possible tube orientation;

(b) For equipment installed after the effective date of these rules, an interlock system prevents irradiation if the proper filter is not in place;

(c) The air kerma rate escaping from the filter slot shall not exceed 1 cGy (1 rad) per hour at one meter under operating conditions; and

(d) Filters shall be marked as to its material of construction and its thickness.

(5) Tube Immobilization.

(a) The x-ray tube shall be so mounted that it can not accidentally turn or slide with respect to the housing aperture; and

(b) The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

(6) Source Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the source to within five millimeters, and the marking shall be readily accessible for use during calibration procedures.

(7) Beam Block. Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(8) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

(a) A timer which has a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector. The timer shall activate with an indication of "BEAM-ON" and retain its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the timer;

(b) For equipment manufactured after the effective date of these rules, the timer shall be a cumulative timer with an elapsed time indicator. Otherwise, the timer may be a countdown timer;

(c) The timer shall terminate irradiation when a pre-selected time has elapsed, if the dose monitoring system present has not previously terminated irradiation;

(d) The timer shall permit pre-setting and determination of exposure times as short as one second;

(e) The timer shall not permit an exposure if set at zero;

(f) The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

(g) Timer shall be accurate to within one percent of the selected value or to within one second, whichever is greater.

(9) Control Panel Functions. The control panel, in addition to the displays required by other provisions in R313-30-6, shall have:

(a) An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;

(b) An indication of whether x-rays are being produced;

(c) Means for indicating x-ray tube potential and current;

(d) The means for terminating an exposure at any time;

(e) A locking device which will prevent unauthorized use of the therapeutic radiation machine; and

(f) For therapeutic radiation machines manufactured after the effective date of these rules, a positive display of specific filters in the beam.

(10) Multiple Tubes. When a control panel may energize more than one x-ray tube:

(a) It shall be possible to activate only one x-ray tube at a time;

(b) There shall be an indication at the control panel identifying which x-ray tube is activated; and

(c) There shall be an indication at the tube housing assembly when that tube is energized.

(11) Target-to-Skin Distance (TSD). There shall be a means of determining the central axis TSD to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

(12) Shutters. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five seconds after the x-

ray "ON" switch is energized, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel. An indication of shutter position shall appear at the control panel.

(13) Low Filtration X-ray Tubes. Therapeutic radiation machines equipped with a beryllium or other low-filtration window shall have a label clearly marked on the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

(14) Facility Design Requirements for Therapeutic Radiation Machines Capable of Operating in the Range 50 kV to 500 kV. In addition to shielding adequate to meet requirements of R313-30-9, the treatment room shall meet the following design requirements:

(a) Aural Communication. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel;

(b) Viewing Systems. Provision shall be made to permit continuous observation of the patient during irradiation and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(15) Additional Requirements. Treatment rooms which contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

(a) Protective barriers shall be fixed except for entrance doors or beam interceptors;

(b) The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;

(c) Interlocks shall be provided so that entrance doors, including doors to interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by a door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

(d) When a door referred to in R313-30-6(15)(c) is opened while the x-ray tube is activated, the irradiation shall be interrupted either electrically or by the closure of the shutter.

(16) Full Calibration Measurements.

(a) Full calibration of a therapeutic radiation machine subject to R313-30-6 shall be performed by, or under the direct supervision of, a Radiation Therapy Physicist:

(i) Before the first medical use following installation or reinstallation of the therapeutic radiation machine;

(ii) Annually. The intervals should not exceed 12 months and shall not exceed 13 months; and

(iii) Before medical use under the following conditions:

(A) Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be reconciled; and

(B) Following a component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

(iv) Notwithstanding the requirements of R313-30-6(16)(a)(iii):

(A) Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes and energies that are not within their acceptable range; and

(B) If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in R313-30-6(16)(a)(iii)(A).

(v) The registrant shall use the dosimetry system described in R313-30-8(6)(a) to perform the full calibration required in R313-30-6(16)(b);

(b) To satisfy the requirement of R313-30-6(16)(a), full calibration shall include measurements recommended for annual calibration by NCRP Report 69, "Dosimetry of X-Ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV," 1981 ed., which is adopted and incorporated by reference.

(c) The registrant shall maintain a record of calibrations for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the x-ray tube, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the Radiation Therapy Physicist responsible for performing the calibration.

(17) Periodic Quality Assurance Checks.

(a) Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to R313-30-6, which are capable of operation at greater than 50 kV.

(b) To satisfy the requirement of R313-30-6(17)(a), quality assurance checks shall meet the following requirements:

(i) The registrant shall perform quality assurance checks in accordance with written procedures established by the Radiation Therapy Physicist; and

(ii) The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in R313-30-6(16)(a). The acceptable tolerance for parameters measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in R313-30-6(16)(a), shall be stated.

(c) The cause for a parameter exceeding a tolerance set by the Radiation Therapy Physicist shall be investigated and corrected before the system is used for patient irradiation;

(d) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Radiation Therapy Physicist's quality assurance check procedures, the system shall be recalibrated as required in R313-30-6(16)(a);

(e) The registrant shall use the dosimetry system described in R313-30-8(6)(b) to make the quality assurance check required in R313-30-6(17)(b);

(f) The registrant shall have the Radiation Therapy Physicist review and sign the results of radiation output quality assurance checks monthly. The interval should not exceed 30 days and shall not exceed 40 days;

(g) Therapeutic radiation machines subject to R313-30-6 shall have safety quality assurance checks of external beam radiation therapy facilities performed monthly. The interval should not exceed 30 days and shall not exceed 40 days;

(h) Notwithstanding the requirements of R313-30-6(17)(f) and R313-30-6(17)(g), the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by R313-30-6(17)(f) and R313-30-6(17)(g) have been performed within the required interval immediately prior to the administration;

(i) To satisfy the requirement of R313-30-6(17)(g), safety quality assurance checks shall ensure proper operation of:

(i) Electrical interlocks at external beam radiation therapy room entrances;

(ii) Proper operation of the "BEAM-ON" and termination switches;

(iii) Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

(iv) Viewing systems;

(v) If applicable, electrically operated treatment room doors from inside and outside the treatment room;

(j) The registrant shall maintain a record of quality assurance checks required by R313-30-6(17)(a) and R313-30-6(17)(g) for three years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instruments used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

(18) Operating Procedures.

(a) The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of R313-30-6(16) and R313-30-6(17) have been met;

(b) Therapeutic radiation machines shall not be left unattended unless secured pursuant to R313-30-6(9)(e);

(c) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

(d) The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require holding and the peak tube potential of the system does not exceed 50 kV. In these cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;

(e) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

(f) No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, individuals, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of R313-15-201 of these rules.

R313-30-7. Therapeutic Radiation Machines - Photon Therapy Systems (500 kV and Above) and Electron Therapy Systems (500 keV and Above).

(1) Leakage Radiation Outside the Maximum Useful Beam in Photon and Electron Modes.

(a) The absorbed dose rate due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance, that is at the plane of the patient, shall not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose rate on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane;

(b) Except for the area defined in R313-30-7(1)(a), the absorbed dose rate, excluding that from neutrons, at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 percent of the absorbed dose rate on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters;

(c) For equipment manufactured after the effective date of these rules, the neutron absorbed dose outside the useful beam shall be in compliance with applicable acceptance criteria; and

(d) For therapeutic radiation machines, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in R313-30-7(1)(a) through R313-30-7(1)(c) for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by representatives of the Director.

(2) Leakage Radiation Through Beam Limiting Devices.

(a) Photon Radiation.

(i) Adjustable or interchangeable beam limiting devices, such as the collimating jaws or x-ray cones, shall attenuate the useful beam so that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting devices shall not exceed two percent of the maximum absorbed dose on the central axis of the useful beam measured in a ten centimeters by ten centimeters radiation field; and

(ii) Interchangeable beam limiting devices, such as auxiliary beam blocking material, shall attenuate the useful beam so that at the

nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the interchangeable beam limiting device shall not exceed five percent of the maximum absorbed dose on the central axis of the useful beam measured in a ten centimeter by ten centimeter radiation field.

(b) Electron Radiation. Adjustable or interchangeable electron applicators shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, so that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

(i) A maximum of two percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and

(ii) A maximum of ten percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam.

(c) Measurement of Leakage Radiation.

(i) Photon Radiation. Measurements of leakage radiation through the beam limiting devices shall be made with the beam limiting devices closed and residual apertures blocked by at least two tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through the sets of beam limiting devices shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding ten square centimeters;

(ii) Electron Radiation. Measurements of leakage radiation through the electron applicators shall be made with an appropriate radiation detector suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using an appropriate amount of water equivalent build up material for the energies being measured.

(3) Filters and Wedges.

(a) Filters and wedges which are removable from the system shall be clearly marked with an identification number;

(i) For removable wedge filters, the nominal wedge angle shall appear on the wedge, or on the wedge tray if the wedge filter is permanently mounted to the tray.

(ii) If the wedge or wedge tray is damaged, the Radiation Therapy Physicist will decide if the wedge transmission factor shall be redetermined;

(b) For equipment manufactured after the effective date of these rules which utilize a system of wedge filters:

(i) Irradiation shall not be possible until a selection of a wedge filter or a positive selection to use "no wedge filter" has been made at the treatment control panel;

(ii) An interlock system shall be provided to prevent irradiation if the wedge filter selected is not in the correct position;

(iii) A display shall be provided at the treatment control panel showing the wedge filters in use; and

(iv) An interlock shall be provided to prevent irradiation if a wedge filter selection operation, either manual or automatic, carried out in the treatment room does not agree with the wedge filter selection operation carried out at the treatment control panel.

(c) If the absorbed dose rate information required by R313-30-7(8) relates exclusively to operation with a field flattening filter or beam scattering foil in place, the filter or foil shall be removable only by the use of tools. If removable, the filter or foil shall be interlocked to prevent incorrect selection and incorrect positioning.

(d) For equipment manufactured after the effective date of these rules which utilize a system of interchangeable field flattening filters or interchangeable beam scattering foils:

(i) An interlock system shall be provided to prevent irradiation if the appropriate flattening filter for the x-ray energy selected is not in the correct position in the beam;

(ii) An interlock system shall be provided to prevent irradiation if the appropriate beam scattering foil for the electron energy selected is not in the correct position in the beam;

(iii) An interlock system shall be provided to prevent irradiation if no scattering foil is in place for the electron beams, or if no flattening filter is in place for the x-ray beams; and

(iv) A display shall be provided at the treatment control panel showing a fault indicator when the interlock system has prevented irradiation. The fault indicator will identify a filter or foil error.

(4) Stray Radiation in the Useful Beam. For equipment manufactured after the effective date of these rules, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that x-ray stray radiation in the useful electron beam, absorbed dose at the surface during x-ray irradiation and stray neutron radiation in the useful x-ray beam meet applicable acceptance criteria.

(5) Beam Monitors. Therapeutic radiation machines subject to R313-30-7 shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate, and to monitor other beam parameters.

(a) Equipment manufactured after the effective date of these rules shall be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of a common element.

(b) Equipment manufactured on or before the effective date of these rules shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system;

(c) The detector and the system into which that detector is incorporated shall meet the following requirements:

(i) Detectors shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;

(ii) Detectors shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;

(iii) The beam monitoring systems shall be capable of independently monitoring, interrupting, and terminating irradiation; and

(iv) For equipment manufactured after the effective date of these rules, the design of the beam monitoring systems shall ensure that the:

(A) Malfunctioning of one system shall not affect the correct functioning of the secondary system; and

(B) Failure of an element common to both systems which could affect the correct function of both systems shall terminate irradiation or prevent the initiation of radiation.

(v) Beam monitoring systems shall have a legible display at the treatment control panel. For equipment manufactured after the effective date of these rules, displays shall:

(A) Maintain a reading until intentionally reset;

(B) Have only one scale and no electrical or mechanical scale multiplying factors;

(C) Utilize a design so that increasing dose monitor units are displayed by increasing numbers; and

(D) In the event of power failure, the dose monitor units delivered up to the time of failure, or the beam monitoring information required in R313-30-7(5)(c)(v)(C) displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20 minute period of time.

(6) Beam Symmetry.

(a) Bent-beam linear accelerators subject to R313-30-7 shall be provided with auxiliary devices to monitor beam symmetry;

(b) The devices referenced in R313-30-7(6)(a) shall be able to detect field asymmetry greater than ten percent; and

(c) The devices referenced in R313-30-7(6)(a) shall be configured to terminate irradiation if the specifications in R313-30-7(6)(b) can not be maintained.

(7) Selection and Display of Dose Monitor Units.

(a) Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel;

(b) The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation;

(c) After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

(d) For equipment manufactured after the effective date of these rules, after termination of irradiation, it shall be necessary for the operator to reset the preselected dose monitor units before irradiation can be initiated.

(8) Air Kerma Rate and Absorbed Dose Rate. For equipment manufactured after the effective date of these rules, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. The radiation detectors specified in R313-30-7(5) may form part of this system. In addition:

(a) The dose monitor unit dose rate shall be displayed at the treatment control panel;

(b) If the equipment can deliver an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

(c) If the equipment can deliver, under any fault condition, an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 4 Gy (400 rad); and

(d) For therapeutic radiation machines, the registrant shall determine, or obtain from the manufacturer, the maximum values specified in R313-30-7(8)(b) and R313-30-7(8)(c) for the specified operating conditions. Records of these maximum values shall be maintained at the installation for inspection by representatives of the Director.

(9) Termination of Irradiation by the Beam Monitoring System or Systems During Stationary Beam Radiation Therapy.

(a) Primary systems shall terminate irradiation when the preselected number of dose monitor units has been detected by the system;

(b) If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

(c) For equipment manufactured after the effective date of these rules, an indicator on the control panel shall show which monitoring system has terminated irradiation.

(10) Termination Switches. It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

(11) Interruption Switches. If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without a reselection of operating conditions. If a change is made of a pre-selected value during an interruption, irradiation and equipment movements shall be automatically terminated.

(12) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

(a) A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator;

(b) The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

(c) The timer shall terminate irradiation when a preselected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

(13) Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

(a) Irradiation shall not be possible until a selection of radiation type (x-rays or electrons) has been made at the treatment control panel;

(b) The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

(c) An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type which has been selected;

(d) An interlock system shall be provided to prevent irradiation with x-rays, except to obtain a verification film, when electron applicators are fitted;

(e) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and

(f) An interlock system shall be provided to prevent irradiation if selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(14) Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

(a) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

(b) The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation; and

(c) Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location.

(15) Selection of Stationary Beam Radiation Therapy or Moving Beam Radiation Therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

(a) Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;

(b) The mode of operation shall be displayed at the treatment control panel;

(c) An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected;

(d) An interlock system shall be provided to prevent irradiation if a selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

(e) Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement. For equipment manufactured after the effective date of these rules:

(i) An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in increments of ten degrees of rotation or one centimeter of motion differs by more than 20 percent from the selected value;

(ii) Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units shall differ by less than five percent from the dose monitor unit value selected;

(iii) An interlock shall be provided to prevent motion of more than five degrees or one centimeter beyond the selected limits during moving beam radiation therapy;

(iv) For equipment manufactured after the effective date of these rules, an interlock shall be provided to require that a selection of direction be made at the treatment control panel in units which are capable of both clockwise and counter-clockwise moving beam radiation therapy.

(v) Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

(f) Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by R313-30-7(9); and

(g) For equipment manufactured after the effective date of these rules, an interlock system shall be provided to terminate irradiation if movement:

(i) Occurs during stationary beam radiation therapy; or

(ii) Does not start or stops during moving beam radiation therapy unless the stoppage is a preplanned function.

(16) Facility Design Requirements for Therapeutic Radiation Machines Operating above 500 kV. In addition to shielding adequate to meet requirements of R313-30-9, the following design requirements are made:

(a) Protective Barriers. Protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors;

(b) Control Panel. In addition to other requirements specified in R313-30, the control panel shall also:

(i) Be located outside the treatment room;

(ii) Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

(iii) Provide an indication of whether radiation is being produced; and

(iv) Include an access control device which will prevent unauthorized use of the therapeutic radiation machine;

(c) Viewing Systems. Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational;

(d) Aural Communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible;

(e) Room Entrances. Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of access doors, which will indicate when the useful beam is "ON;"

(f) Entrance Interlocks. Interlocks shall be provided so that access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by an access control, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel;

(g) Beam Interceptor Interlocks. If the shielding material in a protective barrier requires the presence of a beam interceptor to ensure compliance with R313-30-301(1), interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barriers;

(h) Emergency Cutoff Switches. At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by R313-30-7(11). Emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control panel without resetting the emergency cutoff switch. Alternatively, power cannot be restarted without pressing a RESET button in the treatment room after resetting the power breaker, and the operator shall check the treatment room and patient prior to turning the power back on;

(i) Safety Interlocks. Safety interlocks shall be designed so that defects or component failures in the safety interlock system prevent or terminate operation of the therapeutic radiation machine; and

(j) Surveys for Residual Radiation. Surveys for residual activity shall be conducted on therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production.

(17) Radiation Therapy Physicist Support.

(a) The services of a Radiation Therapy Physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The Radiation Therapy Physicist shall be responsible for:

(i) Full calibrations required by R313-30-7(19) and protection surveys required by R313-30-4(1);

(ii) Supervision and review of dosimetry;

(iii) Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;

(iv) Quality assurance, including quality assurance check review required by R313-30-7(20)(e) of these rules;

(v) Consultation with the authorized user in treatment planning, as needed; and

(vi) Perform calculations and assessments regarding misadministrations.

(b) If the Radiation Therapy Physicist is not a full-time employee of the registrant, the operating procedures required by R313-30-7(18) shall also specifically address how the Radiation Therapy Physicist is to be contacted for problems or emergencies, as well as the specific actions to be taken until the Radiation Therapy Physicist can be contacted.

(18) Operating Procedures.

(a) No individual, other than the patient, shall be in the treatment room during treatment or during an irradiation for testing or calibration purposes;

(b) Therapeutic radiation machines shall not be made available for medical use unless the requirements of R313-30-4(1), R313-30-7(19) and R313-30-7(20) have been met;

(c) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

(d) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used;

(e) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

(f) When adjustable beam limiting devices or beam limiting devices that do not contact the skin are used, the position and shape of the radiation field shall be indicated by a light field.

(19) Full Calibration Measurements.

(a) Full calibration of a therapeutic radiation machine subject to R313-30-7 shall be performed by, or under the direct supervision of, a Radiation Therapy Physicist:

(i) Before the first medical use following installation or reinstallation of the therapeutic radiation machine;

(ii) Annually. The intervals should not exceed 12 months and shall not exceed 13 months; and

(iii) Before medical use under the following conditions:

(A) Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be easily reconciled; and

(B) Following component replacement, major repair, or modification of components, if the appropriate Quality Assurance checks demonstrate that the characteristics of the radiation beam have been significantly affected as determined by a Radiation Therapy Physicist. The Quality Assurance checks shall be performed by, or under the direct supervision of a Radiation Therapy Physicist. The determination

of the need for a full calibration shall be made by a Radiation Therapy Physicist.

(iv) Notwithstanding the requirements of R313-30-7(19)(a)(iii):

(A) Full calibration of therapeutic radiation machines with multi-energy and multi-mode capabilities is required only for those modes and energies that are not within their range and the difference cannot be easily reconciled; and

(B) If the repair, replacement or modification does not affect all modes and energies, full calibration shall be performed on the effected mode or energy if the Quality Assurance checks demonstrate that the characteristics of the radiation beam have been significantly affected as determined by a Radiation Therapy Physicist. The Quality Assurance checks shall be performed by, or under the direct supervision of, a Radiation Therapy Physicist. The determination of the need for a full calibration shall be made by a Radiation Therapy Physicist. The remaining energies or modes may be validated with quality assurance check procedures against the criteria in R313-30-7(19)(a)(iii)(A).

(b) To satisfy the requirement of R313-30-7(19)(a), full calibration shall include measurements required for annual calibration by American Association of Physicists in Medicine (AAPM) Report 46, "Comprehensive Quality Assurance for Radiation Oncology," 1994 ed., which is adopted and incorporated by reference;

(c) The registrant shall use the dosimetry system described in R313-30-8(6) to measure the radiation output for one set of exposure conditions. The remaining radiation measurements required in R313-30-7(19)(b) may then be made using a dosimetry system that indicates relative dose rates; and

(d) The registrant shall maintain a record of calibrations for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the Radiation Therapy Physicist responsible for performing the calibration.

(20) Periodic Quality Assurance Checks.

(a) Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to R313-30-7. These checks should be performed at intervals not to exceed those intervals recommended in American Association of Physicists in Medicine (AAPM) Report 46, "Comprehensive Quality Assurance for Radiation Oncology," 1994 ed., which is adopted and incorporated by reference.

(i) Determination of parameters for central axis radiation output shall be done at least weekly. The interval shall not exceed ten days.

(ii) The interval at which periodic quality assurance checks are to be performed shall be determined by the Radiation Therapy Physicist and shall be documented in the registrant's quality management program. The interval for a specific performance check may be based on the history of that performance check for a particular machine. The interval may be increased above the recommended limits only if the Radiation Therapy Physicist determines the increase is justified based on the history of the performance check for that machine or a machine of the same manufacturer and the same model.

(iii) If the performance check demonstrates a need to decrease the interval, the Radiation Therapy Physicist shall decide if the interval should be decreased. The decreased interval shall be continued until the performance check demonstrates that the decreased interval is not necessary.

(b) To satisfy the requirement of R313-30-7(20)(a), quality assurance checks shall include determination of central axis radiation output and shall include a representative sampling of periodic quality assurance checks contained in American Association of Physicists in Medicine (AAPM) Report 46, "Comprehensive Quality Assurance for Radiation Oncology," 1994 ed., which is adopted and incorporated by reference.

(i) A representative sampling shall include those referenced periodic quality assurance checks necessary to assure that the radiation beam and alignment parameters for all therapy machines and modes of operation are within limits prescribed by AAPM Report 46.

(ii) The intervals for a representative sampling of referenced periodic quality assurance checks should not exceed 12 consecutive months and shall not exceed 13 consecutive months.

(c) The registrant shall use a dosimetry system which has been inter-compared semi-annually. The intervals should not exceed six months and shall not exceed seven months, with a dosimetry system described in R313-30-8(6)(a) to make the periodic quality assurance checks required in R313-30-7(20)(a)(i);

(d) The registrant shall perform periodic quality assurance checks required by R313-30-7(20)(a) in accordance with procedures established by the Radiation Therapy Physicist;

(e) The registrant shall review the results of periodic radiation output checks according to the following procedures:

(i) The authorized user and Radiation Therapy Physicist shall be immediately notified if a parameter is not within its acceptable range. The therapeutic radiation machine shall not be made available for subsequent medical use until the Radiation Therapy Physicist has determined that all parameters are within their acceptable range;

(ii) If periodic radiation output check parameters appear to be within their acceptable range, the periodic radiation output check shall be reviewed and signed by either the authorized user or Radiation Therapy Physicist within two weeks;

(iii) The Radiation Therapy Physicist shall review and sign the results of radiation output quality assurance checks at intervals not to exceed one month; and

(iv) Other Quality Assurance checks shall be reviewed at intervals specified in the Quality Management Program, as required by R313-30-5.

(f) Therapeutic radiation machines subject to R313-30-7 shall have safety quality assurance checks of external beam radiation therapy facilities performed weekly at intervals not to exceed ten days;

(g) To satisfy the requirement of R313-30-7(20)(f), safety quality assurance checks shall ensure proper operation of:

(i) Electrical interlocks at external beam radiation therapy room entrances;

(ii) Proper operation of the "BEAM-ON", interrupt and termination switches;

(iii) Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

(iv) Viewing and aural communication systems;

(v) Electrically operated treatment room doors from inside and outside the treatment room;

(vi) At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, switches shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.

(h) The registrant shall promptly repair a system identified in R313-30-7(20)(g) that is not operating properly; and

(i) The registrant shall maintain a record of quality assurance checks required by R313-30-7(20)(a) and R313-30-7(20)(g) for three years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instruments used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

R313-30-8. Calibration and Check of Survey Instruments and Dosimetry Equipment.

(1) The registrant shall ensure that the survey instruments used to show compliance with R313-30 have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

(2) To satisfy the requirements of R313-30-8(1), the registrant shall:

(a) Calibrate required scale readings up to 10 mSv (1000 mrem) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST);

(b) Calibrate at least two points on the scales to be calibrated. These points should be at approximately 1/3 and 2/3 of scale rating; and

(3) To satisfy the requirements of R313-30-8(2), the registrant shall:

(a) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than ten percent; and

(b) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent if a correction factor or graph is conspicuously attached to the instrument.

(4) The registrant shall retain a record of calibrations required in R313-30-8(1) for three years. The record shall include:

(a) A description of the calibration procedure; and

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

(5) The registrant may obtain the services of individuals licensed by the Director, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations which contain information required by R313-30-8(4) shall be maintained by the registrant.

(6) Dosimetry Equipment.

(a) The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated for by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within 24 months prior to use and after servicing that may have affected system calibration.

(i) For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60;

(ii) For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy or energy range appropriate for the radiation being used.

(b) The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with R313-30-8(6)(a). This comparison shall have been performed within the previous 12 months (six months if the dosimetry system is an ionization chamber) and after servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in R313-30-8(6)(a);

(c) The registrant shall maintain a record of dosimetry system calibration, intercomparison, and comparison for the duration of the license and registration. For calibrations, intercomparisons, or comparisons, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by R313-30-8(6)(a) and R313-30-8(6)(b), the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the calibration, intercomparison, or comparison was performed by, or under the direct supervision of, a Radiation Therapy Physicist.

R313-30-9. Shielding and Safety Design Requirements.

(1) Therapeutic radiation machines subject to R313-30-6 or R313-30-7 shall be provided with the primary and secondary barriers that are necessary to ensure compliance with R313-15-201 and R313-30-301 of these rules.

(2) Facility design information for new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for approval by the Director prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in R313-30-10.

R313-30-10. Information on Radiation Shielding Required for Plan Reviews.

(1) Therapeutic Radiation Machines

(a) Basic facility information including: name, telephone number and registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address, including room number, of the external beam radiation therapy facility. The plan should also indicate whether this is a new structure or a modification to existing structures.

(b) Wall, floor, and ceiling areas struck by the useful beam shall have primary barriers. For an adjacent area that is normally unoccupied, barrier thicknesses may be less than the required thickness, if:

(i) That area where the exposure rates and exposures exceed the limits specified in R313-15-301(1) is permanently fenced or walled to prevent access;

(ii) The appropriate warning signs are posted at appropriate intervals and locations on the fence or wall;

(iii) The exposure rates and exposures outside the fence or wall are less than the limits specified in R313-15-301(1);

(iv) Access to the area is controlled by the operator, and once access is gained, the therapeutic radiation machine cannot be operated until the area has been cleared and access is again controlled by the operator;

(v) The ceiling is of sufficient thickness to reduce exposure due to skyshine, so that the exposure rates and exposures surrounding the facility are less than the limits specified in R313-15-301(1); and

(vi) The primary barrier is of sufficient thickness to ensure that the exposure rates and exposures from the primary beam in spaces in adjacent buildings are less than the limits specified in R313-15-301(1).

(c) Secondary barriers shall be provided in wall, floor, and ceiling areas not having primary barriers.

(2) Therapeutic Radiation Machines up to 150 kV (photons only). In addition to the requirements listed in R313-30-10(1), therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, as a minimum, the following additional information:

(a) Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors.

(b) Maximum design workload for the facility including total weekly radiation output, expressed in gray (rad) or air kerma at one meter, total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

(c) A facility blueprint or drawing indicating: the scale of the blueprint or drawing; direction of North; normal location of the therapeutic radiation machine's radiation ports; the port's travel and traverse limits; general directions of the useful beam; locations of windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the external beam radiation therapy treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with R313-15-101 of these rules.

(d) The structural composition and thickness or the lead or concrete equivalent of walls, doors, partitions, floor, and ceiling of the rooms concerned.

(e) The type of occupancy of adjacent areas inclusive of space above and below the rooms concerned. If there is an exterior wall, show distance to the closest areas where it is likely that individuals may be present.

(f) At least one example calculation which shows the methodology used to determine the amount of shielding required for the physical conditions; that is the primary and secondary or leakage barriers, restricted and unrestricted areas, entry doors; and shielding material in the facility.

(i) If commercial software is used to generate shielding requirements, please also identify the software used and the version or revision date.

(ii) If the software used to generate shielding requirements is not in the open literature, please also submit quality control sample calculations to verify the result obtained with the software.

(3) Therapeutic Radiation Machines over 150 kV. In addition to the requirements listed in R313-30-10(1), therapeutic radiation machine facilities which produce photons with a maximum energy in excess of 150 kV and electrons and protons or other subatomic particles shall submit shielding plans which contain, as a minimum, the following additional information:

(a) Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energies and types of radiation produced, that is photon and electron. The source to isocenter distance shall be specified.

(b) Maximum design workload for the facility including total weekly radiation output, expressed in gray (rad) at one meter, total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

(c) Facility blueprint or drawing, including both floor plan and elevation views, indicating relative orientation of the therapeutic radiation machine; scale; types; thickness and minimum density of shielding materials; direction of North; the locations and size of penetrations through shielding barriers, ceiling, walls and floor; as well as details of the doors and maze.

(d) The structural composition and thickness or concrete equivalent of walls, doors, partitions, floor, and ceiling of the rooms concerned.

(e) The type of occupancy of adjacent areas inclusive of space above and below the rooms concerned. If there is an exterior wall, show distance to the closest areas where it is likely that individuals may be present.

(f) Description of assumptions that were used in shielding calculations including, but not limited to; design energy, for example a room may be designed for 6 MV unit although only a 4 MV unit is currently proposed; workload; presence of integral beam-stop in unit; occupancy and uses of adjacent areas; fraction of time that useful beam will intercept permanent barriers, walls, floor and ceiling; and "allowed" radiation exposure in both restricted and unrestricted areas.

(g) At least one example calculation which shows the methodology used to determine the amount of shielding required for the physical conditions; that is the primary and secondary or leakage barriers, restricted and unrestricted areas, small angle scatter, entry doors and maze; and shielding material in the facility.

(i) If commercial software is used to generate shielding requirements, also identify the software used and the version or revision date.

(ii) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

(4) Neutron Shielding. In addition to the requirements listed in R313-30-10(3), therapeutic radiation machine facilities which are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

(a) The structural composition, thickness, minimum density and location of neutron shielding material.

(b) Description of assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron flux rate, absorbed dose and dose equivalent, due to neutrons, in both restricted and unrestricted areas.

(c) At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for the physical conditions, that is, restricted and unrestricted areas, entry doors and maze and neutron shielding material utilized in the facility.

(i) If commercial software is used to generate shielding requirements, also identify the software used and the version or revision date.

(ii) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

(d) The methods and instrumentation which will be used to verify the adequacy of neutron shielding installed in the facility.

KEY: x-rays, survey, radiation, radiation safety
Date of Enactment or Last Substantive Amendment: March 19, 2013
Notice of Continuation: January 17, 2017
Authorizing, and Implemented or Interpreted Law: 19-3-104

State of Utah
Administrative Rule Analysis
Revised June 2021

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION		
	Title No. - Rule No.	
Utah Admin. Code Ref (R no.):	**R313-34**	**Filing ID: (Office Use Only)**

Agency Information

1. Department:	Environmental Quality	
Agency:	Waste Management and Radiation Control	
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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:

R313-34. Requirements for Irradiators.

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 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 section also requires the licensing of all sources of ionizing radiation and allows the Division Waste Management and Radiation Control to require licensing of radiation sources that constitute a significant health hazard. As part of the state primacy of the radiation control program, the provisions in R313-30 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 licenses authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation that are in addition to, and not in substitution for, other applicable provisions of the rules found in Title R313. As an Agreement State, this rule maintains the appropriate regulatory compatibility with the NRC. There have been no opposing comments to the rules since the last five-year review in 2017.

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 publication in the *Utah State Bulletin*.

Agency head or designee, and title:	Douglas J. Hansen, Division Director	**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.
R313-34. Requirements for Irradiators.
R313-34-1. Purpose and Authority.

(1) Rule R313-34 prescribes requirements for the issuance of licenses authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation.

(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 Rule R313-34 are in addition to, and not in substitution for, the other requirements of these rules.

R313-34-2. Scope.

(1) Rule R313-34 shall apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources; underwater irradiators in which both the source and the product being irradiated are under water; and irradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type.

(2) The requirements of Rule R313-34 shall not apply to self-contained dry-source-storage irradiators in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel, medical radiology or teletherapy, the irradiation of materials for nondestructive testing purposes, gauging, or open-field agricultural irradiations.

R313-34-3. Clarifications or Exemptions.

For purposes of Rule R313-34, 10 CFR 36, 2014 ed., is incorporated by reference with the following clarifications or exceptions:

(1) The exclusion of the following 10 CFR sections: 36.1, 36.5, 36.8, 36.11, 36.17, 36.19(a), 36.91, and 36.93;

(2) The substitution of the following:

(a) Radiation Control Act for Atomic Energy Act of 1954;

(b) Utah Radiation Control Rules for the reference to NRC regulations and the Commission's regulations;

(c) The Director or the Executive Secretary's for the Commission or the Commission's, and NRC in the following 10 CFR sections: 36.13, 36.13(f), 36.15, 36.19(b), 36.53(c), 36.69, and 36.81(a), 36.81(d) and 36.81(e); and

(d) In 10 CFR 36.51(a)(1), Rule R313-15 for NRC;

(3) Appendix B of 10 CFR Part 20 refers to the 2014 ed. of 10 CFR; and

(4) The substitution of Title R313 references for the following 10 CFR references:

(a) Section R313-12-51 for reference to 10 CFR 30.51;

(b) Rule R313-15 for the reference to 10 CFR 20;

(c) Subsection R313-15-501(3) for the reference to 10 CFR 20.1501(c);

(d) Section R313-15-902 for the reference to 10 CFR 20.1902;

(e) Rule R313-18 for the reference to 10 CFR 19;

(f) Section R313-19-41 for the reference to 10 CFR 30.41;

(g) Section R313-19-50 for the reference to 10 CFR 30.50;

(h) Section R313-22-33 for the reference to 10 CFR 30.33;

(i) Section R313-22-210 for the reference to 10 CFR 32.210;

(j) Section R313-22-35 for the reference to 10 CFR 30.35; and

(k) Rule R313-70 for the reference to 10 CFR 170.31.

KEY: irradiators, survey, radiation, radiation safety
Date of Enactment or Last Substantive Amendment: May 5, 2015
Notice of Continuation: January 17, 2017
Authorizing, and Implemented or Interpreted Law: 19-3-104(4); 19-3-104(7)

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION		
	Title No. - Rule No.	
Utah Admin. Code Ref (R no.):	**R313-35**	**Filing ID: (Office Use Only)**

Agency Information

1. Department:	Environmental Quality	
Agency:	Waste Management and Radiation Control	
Room no.:	Second Floor	
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Street address:	195 N. 1950 W.	
City, state and zip:	Salt Lake City, Utah 84116	
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City, state and 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:

R313-35. Requirements for X-Ray Equipment Used for Non-Medical Applications.

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 allows the Waste Management and Radiation Control Board to make rules necessary for controlling exposure to sources of radiation that constitute a significant health hazard.

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 radiation safety requirements for registrants who use electronic sources of radiation for industrial radiographic applications, analytical applications or other non-medical applications that are in addition to, and not in substitution for, other applicable provisions of the rules found in Title R313. There have been no opposing comments to the rules since the last five-year review in 2017.

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 publication in the *Utah State Bulletin*.

Agency head or designee, and title:	Douglas J. Hansen, Division Director	**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.
R313-35. Requirements for X-Ray Equipment Used for Non-Medical Applications.
R313-35-1. Purpose and Scope.

(1) R313-35 establishes radiation safety requirements for registrants who use electronic sources of radiation for industrial radiographic applications, analytical applications or other non-medical applications. Registrants engaged in the production of radioactive

material are also subject to the requirements of R313-19 and R313-22. The requirements of R313-35 are an addition to, and not a substitution for, the requirements of R313-15, R313-16, R313-18 and R313-70.

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

R313-35-2. Definitions.

As used in R313-35:

"Analytical x-ray system" means a group of components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials by either x-ray fluorescence or diffraction analysis.

"Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure, hereinafter termed "cabinet," which, independent of existing architectural structure except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x-radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad and bus terminals, and similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

"Collimator" means a device used to limit the size, shape and direction of the primary radiation beam.

"Direct reading dosimeter" means an ion-chamber pocket dosimeter or an electronic personal dosimeter.

"External surface" means the outside surfaces of cabinet x-ray systems, including the high-voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware and including the plane across an aperture or port.

"Fail-safe characteristics" means design features which cause beam port shutters to close, or otherwise prevent emergence of the primary beam, upon the failure of a safety or warning device.

"Forensics x-ray" means the use of x-ray systems in forensic autopsies of deceased humans, police agency use of x-ray systems for evidence identification and testing, or x-ray system use for arson or questionable origin fire investigations.

"Nondestructive testing" means the examination of the macroscopic structure of materials by nondestructive methods utilizing x-ray sources of radiation.

"Non-medical applications" means uses of x-ray systems except those used for providing diagnostic information or therapy on human patients.

"Normal operating procedures" means instructions necessary to accomplish the x-ray procedure being performed. These procedures shall include positioning of the equipment and the object being examined, equipment alignment, routine maintenance by the registrant, and data recording procedures which are related to radiation safety.

"Open-beam configuration" means a mode of operation of an analytical x-ray system in which individuals could accidentally place some part of the body into the primary beam during normal operation if no further safety devices are incorporated.

"Portable package inspection system" means a portable x-ray system designed and used for determining the presence of explosives in a package.

"Primary beam" means ionizing radiation which passes through an aperture of the source housing via a direct path from the x-ray tube located in the radiation source housing.

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

"X-ray system" means an assemblage of components for the controlled production of x-rays. It includes, minimally, an x-ray high-voltage generator, an x-ray control, a tube housing assembly, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

R313-35-20. Personnel Monitoring.

Registrants using x-ray systems in non-medical applications shall meet the requirements of R313-15-502.

R313-35-30. Locking of X-ray Systems Other Than Veterinary X-Ray Systems.

The control panel of x-ray systems located in uncontrolled areas shall be equipped with a locking device that will prevent the unauthorized use of a x-ray system or the accidental production of radiation. Non-cabinet x-ray systems shall be kept locked with the key removed when not in use.

R313-35-40. Storage Precautions.

X-ray systems shall be secured to prevent tampering or removal by unauthorized personnel.

R313-35-50. Training Requirements.

In addition to the requirements of R313-18-12, an individual operating x-ray systems for non-medical applications shall be trained in the operating procedures for the x-ray system and the emergency procedures related to radiation safety for the facility. Records of training shall be made and maintained for three years after the termination date of the individual.

R313-35-60. Surveys.

In addition to the requirements of R313-15-501, radiation surveys of x-ray systems shall be performed:

(1) upon installation of the x-ray system; and

(2) following change to or maintenance of components of an x-ray system which effect the output, collimation, or shielding effectiveness.

R313-35-70. Radiation Survey Instruments.

Survey instruments used in determining compliance with R313-15 and R313-35 shall meet the following requirements:

(1) Instrumentation shall be capable of measuring a range from 0.02 millisieverts (2 millirem) per hour through 0.01 sievert (1 rem) per hour.

(2) Instrumentation shall be calibrated at intervals not to exceed 12 months and after instrument servicing, except for battery changes.

(3) For linear scale instruments, calibration shall be shown at two points located approximately one-third and two-thirds of full-scale on each scale. For logarithmic scale instruments, calibration shall be shown at mid-range of each decade, and at two points of at least one decade. For digital instruments, calibration shall be shown at three points between 0.02 and 10 millisieverts (2 and 1000 millirems) per hour.

(4) An accuracy of plus or minus 20 percent of the calibration source shall be demonstrated for each point checked pursuant to R313-35-70(3).

(5) The registrant shall perform visual and operability checks of survey instruments before use on each day the survey instrument is to be used to ensure that the equipment is in good working condition. If survey instrument problems are found, the equipment shall be removed from service until repaired.

(6) Results of the instrument calibrations showing compliance with R313-35-70(3) and R313-35-70(4) shall be recorded and maintained for a period of three years from the date the record is made.

(7) Records demonstrating compliance with R313-35-70(5) shall be made when a problem is found. The records shall be maintained for a period of three years from the date the record is made.

R313-35-80. Cabinet X-ray Systems.

(1) The requirements as found in 21 CFR 1020.40, 1996 ed., are adopted and incorporated by reference.

(2) Individuals operating cabinet x-ray systems with conveyor belts shall be able to observe the entry port from the operator's position.

R313-35-90. Portable Package Inspection Systems.

Portable package inspection systems shall be registered in accordance with R313-16 and shall be exempt from inspection by representatives of the Director.

R313-35-100. Analytical X-Ray Systems Excluding Cabinet X-Ray Systems.

(1) Equipment. Analytical x-ray systems not contained in cabinet x-ray systems shall meet all the following requirements.

(a) A device which prevents the entry of portions of an individual's body into the primary x-ray beam path, or which causes the beam to be shut off upon entry into its path, shall be provided for open-beam configurations.

(i) Pursuant to R313-12-55(1), an application for an exemption from R313-35-100(1)(a) shall contain the following information:

(A) a description of the various safety devices that have been evaluated;

(B) the reason that these devices cannot be used; and

(C) a description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

(ii) applications for exemptions to R313-35-100(1)(a) shall be submitted to the Director.

(b) Open-beam configurations shall be provided with a readily discernible indication of:

(i) the "on" or "off" status of the x-ray tube which shall be located near the radiation source housing if the primary beam is controlled in this manner; or

(ii) the "open" or "closed" status of the shutters which shall be located near ports on the radiation source housing, if the primary beam is controlled in this manner.

(c) Warning devices shall be labeled so that their purpose is easily identified and the devices shall be conspicuous at the beam port. On equipment installed after July 1, 1989, warning devices shall have fail-safe characteristics.

(d) Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening. Security requirements will be deemed met if the beam port cannot be opened without the use of tools that are not part of the closure.

(e) Analytical x-ray systems shall be labeled with a readily discernable sign or signs bearing a radiation symbol which meets the requirements of R313-15-901 and the words:

(i) "CAUTION-HIGH INTENSITY X-RAY BEAM," or words having a similar intent, on the x-ray tube housing; and

(ii) "CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near switches that energize an x-ray tube.

(f) On analytical x-ray systems with open-beam configurations which are installed after July 1, 1989, ports on the radiation source

housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

(g) An easily visible warning light labeled with the words "X-RAY ON," or words having a similar intent, shall be located near switches that energize an x-ray tube and near x-ray ports. They shall be illuminated only when the tube is energized.

(h) On analytical x-ray systems installed after July 1, 1989, warning lights shall have fail-safe characteristics.

(i) X-ray generators shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of five centimeters from its surface so that they are not capable of producing a dose equivalent in excess of 2.5 microsieverts (0.25 millirem) in one hour.

(j) The components of an analytical x-ray system located in an uncontrolled area shall be arranged and include sufficient shielding or access control so that no radiation levels exist in areas surrounding the component group which could result in a dose to an individual present therein in excess of the dose limits given in R313-15-301.

(2) Personnel Requirements.

(a) An individual shall not be permitted to operate or maintain an analytical x-ray system unless the individual has received instruction which satisfies the requirements of R313-18-12(1). The instruction shall include:

(i) identification of radiation hazards associated with the use of the analytical x-ray system;

(ii) the significance of the various radiation warnings and safety devices incorporated into the analytical x-ray system, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in these cases;

(iii) proper operating procedures for the analytical x-ray system;

(iv) symptoms of an acute localized exposure; and

(v) proper procedures for reporting an actual or suspected exposure.

(b) Registrants shall maintain records which demonstrate compliance with the requirements of R313-35-100(2)(a) for a period of three years after the termination of the individual.

(c) Normal operating procedures shall be written and available to analytical x-ray system workers. An individual shall not be permitted to operate analytical x-ray systems using procedures other than those specified in the normal operating procedures unless the individual has obtained written approval of the registrant or the registrant's designee.

(d) An individual shall not bypass a safety device unless the individual has obtained the written approval of the registrant or the registrant's designee. Approval shall be for a specified period of time. When a safety device has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING," or words having a similar intent, shall be placed on the radiation source housing.

(3) Personnel Monitoring. In addition to the requirements of R313-15-502, finger or wrist dosimetric devices shall be provided to and shall be used by:

(a) analytical x-ray system workers using equipment having an open-beam configuration and not equipped with a safety device; and

(b) personnel maintaining analytical x-ray systems if the maintenance procedures require the presence of a primary x-ray beam when local components in the analytical x-ray system are disassembled or removed.

(4) Posting. Areas or rooms containing analytical x-ray systems not considered to be cabinet x-ray systems shall be conspicuously posted to satisfy the requirements in R313-15-902.

R313-35-105. Portable, Hand-Held, Non-Medical X-ray Systems.

(1) In addition to compliance to the provisions of Rule R313-35 the following sections are specific to portable, hand-held, non-medical x-ray systems, excluding portable handheld devices that are manufactured to provide inherent operator protection:

(a) 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 while operating the x-ray source;

(b) Each operator of hand-held x-ray systems shall complete a training program supplied by the manufacturer prior to using the x-ray system. Records of training shall be maintained on file for examination by an authorized representative of the Director; and

(c) For hand-held x-ray systems, the provision in Subsection R313-35-110(1)(d) of the length of electrical cord for the dead-man switch is optional.

R313-35-110. Veterinary X-Ray Systems.

(1) Equipment. X-ray systems shall meet the following standards to be used for veterinary radiographic examinations.

(a) The leakage radiation from the diagnostic source assembly measured at a distance of one meter shall not exceed 25.8 uC/kg (100 milliroentgens) in one hour when the x-ray tube is operated at its leakage technique factors.

(b) Diaphragms, cones, or a stepless adjustable collimator shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the diagnostic source housing.

(c) A device shall be provided to terminate the exposure after a preset time or exposure.

(d) A "dead-man type" exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator may stand out of the useful beam and at least six feet from the animal during x-ray exposures.

(e) For stationary or mobile x-ray systems, a method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed six percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(f) For portable x-ray systems, a method shall be provided to align the center of the x-ray field with respect to the center of the image receptor to within six percent of the source to image receptor distance, and to indicate the source to image receptor distance to within six percent.

(2) Structural shielding. For stationary x-ray systems, the wall, ceiling, and floor areas shall provide enough shielding to meet the requirements of R313-15-301.

(3) Operating procedures.

(a) Where feasible, the operator shall stand well away from the useful beam and the animal during radiographic exposures.

(b) In applications in which the operator is not located beyond a protective barrier, clothing consisting of a protective apron having a lead equivalent of not less than 0.5 millimeters shall be worn by the operator and other individuals in the room during exposures.

(c) An individual other than the operator shall not be in the x-ray room while exposures are being made unless the individual's assistance is required.

(d) If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, for example, protective gloves and apron. The individual shall be so positioned that no unshielded part of that individual's body will be struck by the useful beam.

R313-35-120. X-Ray Systems Less than 1 MeV used for Non-Destructive Testing.

(1) Cabinet x-ray systems.

Cabinet x-ray systems shall meet the requirements of R313-35-80.

(2) Fixed Gauges.

(a) Warning Devices. A light, which is clearly visible from all accessible areas around the x-ray system, shall indicate when the x-ray system is operating.

(b) Personnel Monitoring. Notwithstanding R313-15-502(1)(a), individuals conducting x-ray system maintenance requiring the x-ray beam to be on shall be provided with and required to wear personnel monitoring devices.

(3) Industrial and Other X-ray Systems.

(a) Equipment.

(i) The registrant shall perform visual and operability checks of indication lights and warning lights before use on each day the equipment is to be used to ensure that the equipment is in good working condition. If equipment problems are found, the equipment shall be removed from service until repaired.

(ii) Inspection and routine maintenance of x-ray systems, interlocks, indication lights, exposure switches, and cables shall be made at intervals not to exceed six months or before the first use thereafter to ensure the proper functioning of components important to safety. If equipment problems are found, the equipment shall be removed from service until repaired.

(iii) Records demonstrating compliance with R313-35-120(3)(a)(i) shall be made when problems with the equipment are found. These records shall be maintained for a period of three years.

(iv) Records demonstrating compliance with R313-35-120(3)(a)(ii) shall be made. These records shall be maintained for a period of three years.

(b) Controls. X-ray systems which produce a high radiation area shall be controlled to meet the requirements of R313-15-601.

(c) Personnel Monitoring Requirements.

(i) Registrants shall not permit individuals to conduct x-ray operations unless all of the following conditions are met.

(A) Individuals shall wear a thermoluminescent dosimeter or film badge.

(I) Each film badge or thermoluminescent dosimeter shall be assigned to and worn by only one individual.

(II) Film badges shall be replaced at periods not to exceed one month and thermoluminescent dosimeters shall be replaced at periods not to exceed three months.

(B) Individuals shall wear a direct reading dosimeter if conducting non-destructive testing at a temporary job site or in a room or building not meeting the requirements of R313-15-301.

(I) Pocket dosimeters shall have a range from zero to two millisieverts (200 millirem) and must be recharged at the beginning of each shift.

(II) Direct reading dosimeters shall be read and the exposures recorded at the beginning and end of each shift. Records shall be maintained for three years after the record is made.

(III) Direct reading dosimeters shall be checked at intervals not to exceed 12 months for correct response to radiation and the results shall be recorded. Records shall be maintained for a period three years from the date the record is made. Acceptable dosimeters shall read within plus or minus 20 percent of the true radiation exposure.

(IV) If an individual's ion-chamber pocket dosimeter is found to be off scale or if the individual's electronic personnel dosimeter reads greater than 2 millisieverts (200 millirems), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's film badge or thermoluminescent dosimeter shall be sent for processing within 24 hours. In addition, the individual shall not resume work with sources of radiation until a determination of the individual's radiation exposure has been made.

(d) Controls. In addition to the requirements of R313-15-601, barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified in accordance with R313-15-902.

(e) Surveillance. During non-destructive testing applications conducted at a temporary job site or in a room or building not meeting the requirements of R313-15-301, the operator shall maintain continuous direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area.

R313-35-130. X-Ray Systems Greater than 1 MeV used for Non-Destructive Testing.

(1) Equipment.

(a) Individuals shall not receive, possess, use, transfer, own, or acquire a particle accelerator unless it is registered pursuant to R313-16-231.

(b) The registrant shall perform visual and operability checks of indication lights and warning lights before use on each day the equipment is to be used to ensure that the equipment is in good working condition. If equipment problems are found, the equipment shall be removed from service until repaired.

(c) Inspection and routine maintenance of x-ray systems, interlocks, indication lights, exposure switches, and cables shall be made at intervals not to exceed three months or before the first use thereafter to ensure the proper functioning of components important to safety. If equipment problems are found, the equipment shall be removed from service until repaired.

(d) Records demonstrating compliance with R313-35-130(1)(b) shall be made when problems with the equipment are found. These records shall be maintained for a period of three years.

(e) Records demonstrating compliance with R313-35-130(1)(c) shall be made. These records shall be maintained for a period of three years.

(f) Maintenance performed on x-ray systems shall be in accordance with the manufacturer's specifications.

(g) Instrumentation, readouts and controls on the particle accelerator control console shall be clearly identified and easily discernible.

(h) A switch on the accelerator control console shall be routinely used to turn the accelerator beam off and on. The safety interlock system shall not be used to turn off the accelerator beam, except in an emergency.

(2) Shielding and Safety Design Requirements.

(a) An individual who has satisfied a criterion listed in R313-16-292, shall be consulted in the design of a particle accelerator's installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.

(b) Particle accelerator installations shall be provided with primary or secondary barriers which are sufficient to assure compliance with R313-15-201 and R313-15-301.

(c) Entrances into high radiation areas or very high radiation areas shall be provided with interlocks that shut down the machine under conditions of barrier penetration.

(d) When a radiation safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls first at the position where the interlock has been tripped, and then at the main control console.

(e) Safety interlocks shall be on separate electrical circuits which shall allow their operation independently of other safety interlocks.

(f) Safety interlocks shall be fail-safe. This means that they must be designed so that defects or component failures in the interlock system prevent operation of the accelerator.

(g) The registrant may apply to the Director for approval of alternate methods for controlling access to high or very high radiation areas. The Director may approve the proposed alternatives if the registrant demonstrates that the alternative methods of control will prevent unauthorized entry into a high or very high radiation area, and the alternative method does not prevent individuals from leaving a high or very high radiation area.

(h) A "scram" button or other emergency power cutoff switch shall be located and easily identifiable in high radiation areas or in very high radiation areas. The cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

(i) Safety and warning devices, including interlocks, shall be checked for proper operation at intervals not to exceed three months, and after maintenance on the safety and warning devices. Results of these tests shall be maintained for inspection at the accelerator facility for three years.

(j) A copy of the current operating and emergency procedures shall be maintained at the accelerator control panel.

(k) Locations designated as high radiation areas or very high radiation areas and entrances to locations designated as high radiation areas or very high radiation areas shall be equipped with easily observable flashing or rotating warning lights that operate when radiation is being produced.

(l) High radiation areas or very high radiation areas shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of the high radiation area or the very high radiation area. Warning devices shall be clearly discernible in high radiation areas or in very high radiation areas. The registrant shall instruct personnel in the vicinity of the particle accelerator as to the meaning of this audible warning signal.

(m) Barriers, temporary or otherwise, and pathways leading to high radiation areas or very high radiation areas shall be identified in accordance with R313-15-902.

(3) Personnel Requirements.

(a) Registrants shall not permit individuals to act as particle accelerator operators until the individuals have complied with the following:

(i) been instructed in radiation safety; and

(ii) been instructed pursuant to R313-35-50 and the applicable requirements of R313-15.

(iii) Records demonstrating compliance with R313-35-130(3)(a)(i) and R313-35-130(3)(a)(ii) shall be maintained for a period of three years from the termination date of the individual.

(b) Registrants shall not permit an individual to conduct x-ray operations unless the individual meets the personnel monitoring requirements of R313-35-120(3)(c).

(4) Radiation Monitoring Requirements.

(a) At particle accelerator facilities, there shall be available appropriate portable monitoring equipment which is operable and has been calibrated for the radiations being produced at the facility. On each day the particle accelerator is to be used, the portable monitoring equipment shall be tested for proper operation.

(b) When changes have been made in shielding, operation, equipment, or occupancy of adjacent areas, a radiation protection survey shall be performed and documented by an individual who has satisfied a criterion listed in R313-16-292 or the individual designated as being responsible for radiation safety.

(c) Records of radiation protection surveys, calibrations, and instrumentation tests shall be maintained at the accelerator facility for inspection by representatives of the Director for a period of three years.

R313-35-140. Duties and Authorities of a Radiation Safety Officer.

Facilities operating x-ray systems under R313-35-130 shall appoint a Radiation Safety Officer. The specific duties and authorities of the Radiation Safety Officer include, but are not limited to:

(1) establishing and overseeing all operating, emergency, and ALARA procedures as required by R313-15;

(2) ensuring that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the registrant's program;

(3) overseeing and approving the training program for radiographic personnel, ensuring that appropriate and effective radiation protection practices are taught;

(4) ensuring that required radiation surveys are performed and documented in accordance with the R313-35-130(4);

(5) ensuring that personnel monitoring devices are calibrated and used properly by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by R313-15-1203; and

(6) ensuring that operations are conducted safely and to assume control for instituting corrective actions including stopping of operations when necessary.

KEY: industry, x-rays, veterinarians, surveys
Date of Enactment or Last Substantive Amendment: May 22, 2015
Notice of Continuation: January 17, 2017
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-107

State of Utah
Administrative Rule Analysis
Revised June 2021

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION		
	Title No. - Rule No.	
Utah Admin. Code Ref (R no.):	**R313-37**	**Filing ID: (Office Use Only)**

Agency Information

1. Department:	Environmental Quality	
Agency:	Waste Management and Radiation Control	
Room no.:	Second Floor	
Building:	MASOB	
Street address:	195 N. 1950 W.	
City, state and zip:	Salt Lake City, Utah 84116	
Mailing address:	PO Box 144880	
City, state and 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:

R313-37. Physical Protection of Category 1 and Category 2 Quantities 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 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 section also allows the Waste Management and Radiation Control Board to make rules necessary for controlling exposure to sources of radiation that constitute a significant health hazard. As part of the state primacy of the radiation control program, the provisions in R313-37 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 physical protection of radioactive materials for a licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material. The requirements are in addition to, and not in substitution for, other applicable provisions of the rules found in Title R313. As an Agreement State, this rule maintains the appropriate regulatory compatibility with the NRC. There have been no opposing comments to the rules since the last five-year review in 2017.

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 publication in the *Utah State Bulletin*.

Agency head or designee, and title:	Douglas J. Hansen, Division Director	**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.

R313-37. Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.

R313-37-1. Purpose and Authority.

(1) The rules in Rule R313-37 prescribe requirements for the physical protection program for a licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material.

(2) The rules set forth herein are adopted pursuant to the provisions of Subsections 19-3-103.1(1)(a), 19-3-104(4) and 19-3-104(7).

(3) The requirements of Rule R313-37 are in addition to, and not in substitution for, the other requirements of these rules.

R313-37-2. Scope.

These requirements provide reasonable assurance of the security of category 1 and category 2 quantities of radioactive material by protecting these materials from theft or diversion. Specific requirements for access to material, and use, transfer, and transportation of material are included.

R313-37-3. Clarifications or Exceptions.

For purposes of Rule R313-37, 10 CFR 37.5, 37.11(c), 37.21 through 37.43(d)(8), 37.45 through 37.103, and Appendix A to 10 CFR 37 (2020), are incorporated by reference with the following clarifications or exceptions:

(1) The exclusion of the following:

(a) In 10 CFR 37.5, exclude definitions for "Act", "Agreement State", "Becquerel", "Byproduct Material", "Commission", "Curie", "Government Agency", "License", "License issuing authority", "Lost or missing licensed material", "Person", "State", and "United States".

(2) The substitution of the following wording:

(a) "Utah Radiation Control Rule" for references to:

(i) "Commission regulation" in 10 CFR 37.101; and

(ii) "regulation" in 10 CFR 37.103;

(b) "Utah Radiation Control Rules" for reference to:

(i) "regulations and laws" in 10 CFR 37.31(d);

(ii) "Commission requirements" in 10 CFR 37.43(a)(3) and 37.43(c)(1)(ii); and

(iii) "regulations in this part" in 10 CFR 37.103;

(c) "Director" for references to:

(i) "appropriate NRC regional office listed in Section 30.6(b)(2) of this Chapter" in 10 CFR 37.45(b);

(ii) "Commission" in 10 CFR 37.103;

(iii) "NRC" in 10 CFR 37.31(d), 37.43(c)(3)(iii), 37.57(a) (second instance of NRC) and (c), 37.77, and 37.77(a)(1) (first instance) and (3), and 37.81(g);

(iv) "NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 29555-0001" in 10 CFR 37.77(c)(2) and 37.77(d);

(v) "NRC's Director of Nuclear Security, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 29555-0001" in 10 CFR 37.77(c)(1);

(vi) "NRC's Operations Center" in 10 CFR 37.81(a) and (b);

(vii) "NRC's Operations Center (301-816-5100)" in 10 CFR 37.57(a) and (b) and 37.81(a) through (f);

(viii) "NRC regional office specified in section 30.6 of this chapter" in 10 CFR 37.41.(a)(3); and

(ix) "Director, Office of Nuclear Material Safety and Safeguards in 10 CFR 37.23(b)(2)".

(d) "Director, the U.S. Nuclear Regulatory Commission, or an Agreement State" for references to "Commission or an Agreement State" in 10 CFR 37.71 and 37.71(a) and (b);

(e) "U.S. Nuclear Regulatory Commission's Security Orders or the legally binding requirement issued by Agreement States" for references to "Security Orders" in 10 CFR 37.21(a)(3), 37.25(b)(2), and 37.41(a)(3);

(f) "mail, hand delivery, or electronic submission" for references to "an appropriate method listed in section 37.7" in 10 CFR 37.57(c) and 37.81(g); and

(g) "shall, by mail, hand delivery, or electronic submission," for reference to "shall use an appropriate method listed in section 37.7 to" in 10 CFR 37.27(c).

(3) The substitution of the following rule references:

(a) "R313-19-41(4)" for reference to "section 30.41(d) of this chapter." In 10 CFR 37.71;

(b) "R313-19-100 (incorporating 10 CFR 71.97 by reference)" for reference to "section 71.97 of this chapter" in 10 CFR 37.73(b);

(c) "R313-19-100 (incorporating 10 CFR 71.97(b) by reference)" for reference to "section 71.97(b) of this chapter" in 10 CFR 37.73(b); and

(d) "10 CFR 73" for references to "part 73 of this chapter" in 10 CFR 37.21(c)(4), 37.25(b)2), and 37.27(a)(4).

KEY: radioactive materials, security, fingerprinting, transportation
Date of Enactment or Last Substantive Amendment: January 15, 2021
Notice of Continuation: January 17, 2017
Authorizing, and Implemented or Interpreted Law: 19-3-103; 19-3-104

State of Utah
Administrative Rule Analysis
Revised June 2021

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION		
	Title No. - Rule No.	
Utah Admin. Code Ref (R no.):	**R313-38**	**Filing ID: (Office Use Only)**

Agency Information

1. Department:	Environmental Quality	
Agency:	Waste Management and Radiation Control	
Room no.:	Second Floor	
Building:	MASOB	
Street address:	195 N. 1950 W.	
City, state and zip:	Salt Lake City, Utah 84116	
Mailing address:	PO Box 144880	
City, state and 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:

R313-38. Licenses and Radiation Safety Requirements for Well Logging.

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 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 section also requires the licensing of all sources of ionizing radiation and allows the Waste Management and Radiation Control Board to make rules necessary for controlling exposure to sources of radiation that constitute a significant health hazard. As part of the state primacy of the radiation control program, the provisions in R313-37 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 a license authorizing the use of licensed materials including sealed sources, radioactive tracers, radioactive markers, and uranium sinker bars in well logging. This rule also prescribes radiation safety requirements for persons using licensed materials in these operations. The requirements are in addition to, and not in substitution for, other applicable provisions of the rules found in Title R313. As an Agreement State, this rule maintains the appropriate regulatory compatibility with the NRC. There have been no opposing comments to the rules since the last five-year review in 2017.

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 publication in the *Utah State Bulletin*.

Agency head or designee, and title:	Douglas J. Hansen, Division Director	**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.
R313-38. Licenses and Radiation Safety Requirements for Well Logging.
R313-38-1. Purpose and Authority.

(1) Rule R313-38 prescribes requirements for the issuance of a license authorizing the use of licensed materials including sealed sources, radioactive tracers, radioactive markers, and uranium sinker bars in well logging in a single well. This rule also prescribes radiation safety requirements for persons using licensed materials in these operations.

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

(3) The provisions and requirements of Rule R313-38 are in addition to, and not in substitution for, the other requirements of these rules. In particular, the provisions of Rules R313-15, R313-18, R313-19, and R313-22 apply to applicants and licensees subject to these rules.

R313-38-2. Scope.

(1) The requirements of Rule R313-38 do not apply to the issuance of a license authorizing the use of licensed material in tracer studies involving multiple wells, such as field flooding studies, or to the use of sealed sources auxiliary to well logging but not lowered into wells.

R313-38-3. Clarifications or Exceptions.

For purposes of Rule R313-38, 10 CFR 39 (2013), is incorporated by reference with the following clarifications or exceptions:

(1) The exclusion of the following 10 CFR sections: 39.1, 39.5, 39.8, 39.11, 39.101, and 39.103;

(2) The exclusion of the following 10 CFR references within 10 CFR 39: Sec. 40.32, and Sec. 70.23;

(3) The exclusion of "licensed material" in 10 CFR 39.2 definitions;

(4) The substitution of the following wording:

(a) License for reference to NRC license;

(b) Utah Radiation Control Rules for the references to:

(i) The Commission's regulations;

(ii) The NRC regulations;

(iii) NRC regulations; and

(iv) Pertinent Federal regulations;

(c) Director for reference to Commission, except as stated in Subsection R313-38-3(4)(d);

(d) Representatives of the Director for the references to the Commission in:

(i) 10 CFR 39.33(d);

(ii) 10 CFR 39.35(a);

(iii) 10 CFR 39.37;

(iv) 10 CFR 39.39(b); and

(v) 10 CFR 39.67(f);

(e) Director for references to:

(i) NRC in:

(A) 10 CFR 39.63(l);

(B) 10 CFR 39.77(c)(1)(i) and (ii); and

(C) 10 CFR 39.77(d)(9); and

(ii) Appropriate NRC Regional Office in:

(A) 10 CFR 39.77(a);

(B) 10 CFR 39.77(c)(1); and

(C) 10 CFR 39.77(d);

(iii) Appropriate NRC Regional Office listed in appendix D of part 20 of this chapter in:

(A) 10 CFR 39.35(d)(2)

(f) Director, the U.S. Nuclear Regulatory Commission or an Agreement State for the references to:

(i) Commission or an Agreement State in:

(A) 10 CFR 39.35(b); and

(B) 10 CFR 39.43(d) and (e); and

(ii) Commission pursuant to Sec. 39.13(c) or by an Agreement State in:

(A) 10 CFR 39.43(c); and

(B) 10 CFR 39.51;

(g) In 10 CFR 39.35(d)(1), persons specifically licensed by the Director, the U.S. Nuclear Regulatory Commission, or an Agreement State for the reference to an NRC or Agreement State licensee that is authorized;

(h) In 10 CFR 39.75(e), a U.S. Nuclear Regulatory Commission or an Agreement State for the reference to the Agreement State;

(5) The substitution of the following Title R313 references for specific 10 CFR references:

(a) Section R313-12-3 for the reference to Sec. 20.1003 of this chapter;

(b) Section R313-12-54 for the reference to 10 CFR 39.17;

(c) Subsection R313-12-55(1) for the reference to 10 CFR 39.91;
(d) Rule R313-15 for references to:
(i) Part 20; and
(ii) Part 20 of this chapter;
(e) Subsection R313-15-901(1) for the reference to Sec. 20.1901(a);
(f) Section R313-15-906 for the reference to Sec. 20.1906 of this chapter;
(g) Sections R313-15-1201 through R313-15-1203 for the references to:
(i) Secs. 20.2201-20.2202; and
(ii) Sec. 20.2203;
(h) Rule R313-18 for the reference to part 19;
(i) Section R313-19-30 for the reference to Sec. 150.20 of this chapter;
(j) Section R313-19-50 for the references to:
(i) Sec. 30.50; and
(ii) Part 21 of this chapter;
(k) Section R313-19-71 for the reference to Sec. 30.71;
(l) Section R313-19-100 for the references to:
(i) 10 CFR Part 71; and
(ii) Sec. 71.5 of this chapter; and
(m) Section R313-22-33 for the reference to 10 CFR 30.33;
(n) Rules R313-15, R313-18, and R313-38 for corresponding references to:
(i) Parts 19, 20, and 39 of this chapter;
(ii) A copy of parts 19, 20, and 39 of NRC regulations.

KEY: radioactive materials, well logging, surveys, subsurface tracer studies
Date of Enactment or Last Substantive Amendment: March 17, 2015
Notice of Continuation: January 17, 2017
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-107

WASTE MANAGEMENT AND RADIATION CONTROL BOARD
Executive Summary
Public Comment - Proposed Rule Changes
Hazardous Waste Rule UAC R315-101
October 14, 2021

What is the issue before the Board?	Approval from the Board to proceed with formal rulemaking and public comment on proposed changes to UAC R315-101 of the Hazardous Waste Rules amending the rule to include the most up-to-date methods and procedures being used by industry to conduct cleanups of contaminated sites and risk assessments based on EPA guidance.
What is the historical background or context for this issue?	Rule R315-101 establishes information requirements to support risk-based cleanup and closure standards at sites for which remediation or removal of hazardous constituents to background levels is not the remediation objective. The procedures in Rule R315-101 also provide for continued management of sites for which risk-based clean closure standards are not met. The current rule contains limited information and is not clear in its' requirements resulting in confusion and inconsistent interpretations. The revised rule provides consistency in interpretations and requirements needed to conduct risk assessments. The changes to the rule are summarized below. The amended rule provides several available approaches for conducting risk assessments allowing regulated entities to choose the approach that best fits their situation. The rule is being amended to adequately address groundwater at all contaminated sites. The amended rule spells out a hierarchy of toxicological sources that are scientifically defensible for use in risk assessment evaluation. The amended rule provides more details, requirements and information resources that are needed to conduct an acceptable ecological risk assessment. The amended rule defines what an acceptable risk assessment needs to contain and provides clear risk management options available depending on the level of risk. The amended rule provides a well-defined interpretation of the term No Further Action (NFA) with regards to the level of risk at a site and the land use exposure scenario. The requirements for drafting a site management plan (SMP) as well as termination are clearly provided.

	There is a section in the amended rule that contains a list of guidance documents and other resources that are incorporated by reference into the rule and a section that provides clear definitions of terms used in the rule. The Rule Analysis Form with proposed changes to R315-101 follow this Executive Summary.
What is the governing statutory or regulatory citation?	The Board is authorized under Subsection 19-6-105 to make rules that establish minimum standards for protection of human health and the environment. The rule changes also meet existing DEQ and state rulemaking procedures.
Is Board action required?	Yes. Board approval is necessary to begin the formal rulemaking process by filing the appropriate documents with the Office of Administrative Rules for publishing the proposed rule changes in the *Utah State Bulletin* and conducting a public comment period.
What is the Division Director's recommendation?	The Director recommends the Board approve proceeding with formal rulemaking and public comment by publishing in the November 1, 2021, *Utah State Bulletin* the proposed changes to UAC R315-101 and conducting a public comment period from November 1 to December 1, 2021.
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 June 2021

NOTICE OF PROPOSED RULE		
TYPE OF RULE: New ___; Amendment _X__; Repeal ___; Repeal and Reenact ___		
	Title No. - Rule No. - Section No.	
Utah Admin. Code Ref (R no.):	**R315-101**	**Filing ID (Office Use Only)**
Changed to Admin. Code Ref. (R no.):	**R**	

Agency Information

1. Department:	Environmental Quality	
Agency:	Waste Management and Radiation Control	
Room no.:		
Building:	MASOB	
Street address:	195 N. 1950 W.	
City, state and zip:	Salt Lake City, Utah 84116	
Mailing address:	P.O. Box 144880	
City, state and 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 or section catchline:

R315-101. Cleanup Action and Risk-Based Closure Standards.

3. Purpose of the new rule or reason for the change (Why is the agency submitting this filing?)**:**

Rule R315-101 is being amended to include the most up-to-date methods and procedures being used by industry to conduct cleanups of contaminated sites and risk assessments based on EPA guidance.

4. Summary of the new rule or change (What does this filing do? If this is a repeal and reenact, explain the substantive differences between the repealed rule and the reenacted rule)**:**

The current rule contains limited information and is not clear in its' requirements resulting in confusion and inconsistent interpretations. The revised rule provides consistency in interpretations and requirements needed to conduct risk assessments. The rule is being amended to provide several available approaches for conducting risk assessments allowing regulated entities to choose the approach that best fits their situation.
Contaminated groundwater is not adequately addressed in the current rule. The rule is being amended to adequately address groundwater at all contaminated sites.
The amended rule spells out a hierarchy of toxicological sources that are scientifically defensible for use in risk assessment evaluation.
The amended rule provides more details, requirements and information resources that are needed to conduct an acceptable ecological risk assessment.
The amended rule defines what DEQ considers to be an acceptable risk range and the target risk considered to be the point of departure. The amended rule also provides clear risk management options available depending on the level of risk. The interpretation of the term No Further Action (NFA) is well defined with regards to the level of risk at a site and the land use exposure scenario. The requirements for drafting a site management plan (SMP) as well as termination are clearly provided.
There is a section in the amended rule that contains a list of guidance documents and other resources that are incorporated by reference into the rule and a section that provides clear definitions of terms used in the rule.

Fiscal Information

5. Provide an estimate and written explanation of the aggregate anticipated cost or savings to:

A) State budget:

It is not anticipated that there will be any cost or savings to the state budget due to this rule amendment. There will be no change to the procedures and manpower used by the State to review risk assessments and cleanup plans that are based on the amended rule. Any State agencies that may be or may need to perform cleanups or risk assessments would be required to do so under the existing rule. This amendment does not add any requirements to the rule that would increase costs, nor does it remove any requirements that would decrease costs.

B) Local governments:

It is not anticipated that there will be any cost or savings to local governments due to this rule amendment. Any local governments that may be or may need to perform cleanups or risk assessments would be required to do so under the existing rule. This amendment does not add any requirements to the rule that would increase costs, nor does it remove any requirements that would decrease costs.

C) Small businesses ("small business" means a business employing 1-49 persons)**:**

It is not anticipated that there will be any cost or savings to small businesses due to this rule amendment. Any small businesses that may be or may need to perform cleanups or risk assessments would be required to do so under the existing rule. This amendment does not add any requirements to the rule that would increase costs, nor does it remove any requirements that would decrease costs.

D) Non-small businesses ("non-small business" means a business employing 50 or more persons)**:**

It is not anticipated that there will be any cost or savings to non-small businesses due to this rule amendment. Any non-small businesses that may be or may need to perform cleanups or risk assessments would be required to do so under the existing rule. This amendment does not add any requirements to the rule that would increase costs, nor does it remove any requirements that would decrease costs.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an ***agency***)**:**

It is not anticipated that there will be any cost or savings to persons other than small businesses, non-small businesses, state, or local government entities due to this rule amendment. Any persons other than small businesses, non-small businesses, state, or local government entities that may be or may need to perform cleanups or risk assessments would be required to do so under the existing rule. This amendment does not add any requirements to the rule that would increase costs, nor does it remove any requirements that would decrease costs.

F) Compliance costs for affected persons (How much will it cost an impacted entity to adhere to this rule or its changes?)**:**

Because this is an amendment to an existing rule and the changes to the rule do not significantly change how cleanups and risk assessments are conducted under the rule it is not anticipated that the compliance costs for affected persons will change due to the rule amendments.

G) Comments by the department head on the fiscal impact this rule may have on businesses (Include the name and title of the department head):

It is not anticipated that this rule amendment will have any additional fiscal impact on any businesses that are currently complying with the rule beyond the current costs of compliance. The changes that are being made include the most up-to-date methods and procedures being used by industry to conduct cleanups of contaminated sites and risk assessments.
Kimberly D. Shelley, Executive Director

6. A) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory Impact Table

Fiscal Cost	**FY2022**	**FY2023**	**FY2024**
State Government	$0	$0	$0
Local Governments	$0	$0	$0
Small Businesses	$0	$0	$0
Non-Small Businesses	$0	$0	$0
Other Persons	$0	$0	$0
Total Fiscal Cost	**$0**	**$0**	**$0**
Fiscal Benefits			
State Government	$0	$0	$0
Local Governments	$0	$0	$0
Small Businesses	$0	$0	$0
Non-Small Businesses	$0	$0	$0
Other Persons	$0	$0	$0
Total Fiscal Benefits	**$0**	**$0**	**$0**

Net Fiscal Benefits	**$0**	**$0**	**$0**

B) Department head approval of regulatory impact analysis:

The head of the Department of Environmental Quality, Kimberly D. Shelley, has reviewed and approved this fiscal analysis.

Citation Information

7. Provide citations to the statutory authority for the rule. If there is also a federal requirement for the rule, provide a citation to that requirement:

19-6-105	19-6-106	

Incorporations by Reference Information

(If this rule incorporates more than two items by reference, please include additional tables.)

8. A) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	First Incorporation
Official Title of Materials Incorporated (from title page)	Groundwater Statistics and Monitoring Compliance
Publisher	Interstate Technology Regulatory Council (ITRC)
Date Issued	December 2013
Issue, or version	

B) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Second Incorporation
Official Title of Materials Incorporated (from title page)	ECO-Risk Database
Publisher	Los Alamos National Laboratory (LANL)
Date Issued	2011
Issue, or version	

C) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Third Incorporation
Official Title of Materials Incorporated (from title page)	Toxicological Benchmarks for Wildlife: 1996 Revision
Publisher	Oakridge National Laboratory (ORNL)
Date Issued	1996
Issue, or version	1996

D) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Fourth Incorporation
Official Title of Materials Incorporated (from title page)	A Guide to the ORNL Ecotoxicological Screening Benchmarks: Background, Development, and Application
Publisher	Oakridge National Laboratory (ORNL)
Date Issued	May 1998
Issue, or version	Revision 1

E) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Fifth Incorporation
Official Title of Materials Incorporated (from title page)	Guidelines for the Health Risk Assessment of Chemical Mixtures
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	1986
Issue, or version	

F) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Sixth Incorporation
Official Title of Materials Incorporated (from title page)	Risk Assessment Guidance for Super Fund Volume 1: Human Health Evaluation Manual (Part A)
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	1989
Issue, or version	Interim Final

G) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Seventh Incorporation
Official Title of Materials Incorporated (from title page)	Risk Assessment Guidance for Super Fund Volume 1: Human Health Evaluation Manual Supplemental Guidance Standard Default Exposure Factors
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	March 25, 1991
Issue, or version	Interim Final

H) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Eighth Incorporation
Official Title of Materials Incorporated (from title page)	Risk Assessment Guidance for Super Fund Volume 1: Human Health Evaluation Manual (Part B Development of Risk-based Preliminary Remediation Goals)
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	December 1991
Issue, or version	Interim Final

I) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Ninth Incorporation
Official Title of Materials Incorporated (from title page)	Wildlife Exposure Factors Handbook, Volume I of II
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	December 1993
Issue, or version	

J) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Tenth Incorporation

Official Title of Materials Incorporated (from title page)	Supplemental Guidance to RAGS: Calculating the Concentration Term
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	May 1992
Issue, or version	

K) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Eleventh Incorporation
Official Title of Materials Incorporated (from title page)	Framework for Ecological Risk Assessment
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	February 1992
Issue, or version	

L) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Twelfth Incorporation
Official Title of Materials Incorporated (from title page)	Wildlife Exposure Factors Handbook, Appendix: Literature Review Database, Volume II of II
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	December 1993
Issue, or version	

M) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Thirteenth Incorporation
Official Title of Materials Incorporated (from title page)	Soil Screening Guidance Technical Background Document
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	May 1996
Issue, or version	

N) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Fourteenth Incorporation
Official Title of Materials Incorporated (from title page)	Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	June 1997
Issue, or version	Interim Final

O) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Fifteenth Incorporation
Official Title of Materials Incorporated (from title page)	Guidelines for Ecological Risk Assessment
Publisher	United States Environmental Protection Agency (US EPA)

Date Issued	April 1998
Issue, or version	

P) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**	
	Sixteenth Incorporation
Official Title of Materials Incorporated (from title page)	Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	August 2000
Issue, or version	

Q) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**	
	Seventeenth Incorporation
Official Title of Materials Incorporated (from title page)	Risk Assessment Guidance for Superfund Volume 1: Human Health Evaluation Manual (Part D, Standardized Planning, Reporting, and Review of Superfund Risk Assessments)
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	2001
Issue, or version	Final

R) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**	
	Eighteenth Incorporation
Official Title of Materials Incorporated (from title page)	EPA Requirements for Quality Management Plans
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	2001
Issue, or version	

S) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**	
	Nineteenth Incorporation
Official Title of Materials Incorporated (from title page)	Risk Assessment Guidance for Superfund: Volume III - Part A, Process for Conducting Probabilistic Risk Assessment
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	December 2001
Issue, or version	

T) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**	
	Twentieth Incorporation
Official Title of Materials Incorporated (from title page)	Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	2002
Issue, or version	

U) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Twenty-first Incorporation
Official Title of Materials Incorporated (from title page)	Guidance for Quality Assurance Project Plans
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	December 2002
Issue, or version	

V) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Twenty-second Incorporation
Official Title of Materials Incorporated (from title page)	Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	December 2002
Issue, or version	December 2002(a)

W) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Twenty-third Incorporation
Official Title of Materials Incorporated (from title page)	Guidance for Developing Ecological Soil Screening Levels
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	November 2003
Issue, or version	February 2005

X) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Twenty-fourth Incorporation
Official Title of Materials Incorporated (from title page)	Human Health Toxicity Values in Superfund Risk Assessment
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	December 2003
Issue, or version	

Y) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Twenty-fifth Incorporation
Official Title of Materials Incorporated (from title page)	User’s Guide for Evaluating Subsurface Vapor Intrusion into Buildings
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	February 2004
Issue, or version	February 22, 2004

Z) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Twenty-sixth Incorporation
Official Title of Materials Incorporated (from title page)	Risk Assessment Guidance for Superfund Volume 1: Human Health Evaluation Model (Part E, Supplemental Guidance for Dermal Risk Assessment)
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	July 2004
Issue, or version	Final

AA) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Twenty-seventh Incorporation
Official Title of Materials Incorporated (from title page)	Guidelines for Carcinogen Risk Assessment
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	March 2005
Issue, or version	March 2005(b)

BB) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Twenty-eighth Incorporation
Official Title of Materials Incorporated (from title page)	Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	March 2005
Issue, or version	March 2005(c)

CC) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Twenty-ninth Incorporation
Official Title of Materials Incorporated (from title page)	Guidance on Systematic Planning Using the Data Quality Objectives Process
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	February 2006
Issue, or version	

DD) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Thirtieth Incorporation
Official Title of Materials Incorporated (from title page)	Risk Assessment Guidance for Superfund Volume 1: Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment)
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	January 2009
Issue, or version	Final

EE) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Thirty-first Incorporation
Official Title of Materials Incorporated (from title page)	Statistical Analysis of Groundwater Monitoring Data at RCRA Facilities, Unified Guidance

Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	March 2009
Issue, or version	Rinal

FF) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Thirty-second Incorporation
Official Title of Materials Incorporated (from title page)	Risk Assessment Guidance for Super Fund Volume 1: Human Health Evaluation Manual (Part C, Risk Evaluation of Remedial Alternatives)
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	December 1991
Issue, or version	Interim

GG) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Thirty-third Incorporation
Official Title of Materials Incorporated (from title page)	Exposure Factors Handbook: 2011 Edition
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	September 2011
Issue, or version	2011

HH) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Thirty-fourth Incorporation
Official Title of Materials Incorporated (from title page)	Superfund Vapor Intrusion FAQs
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	February 2012
Issue, or version	

II) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Thirty-fifth Incorporation
Official Title of Materials Incorporated (from title page)	ProUCL Version 5.1 Technical Guide Statistical Software for Environmental Applications for Data Sets with and without Nondetect Observations
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	October 2015
Issue, or version	

JJ) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Thirty-sixth Incorporation
Official Title of Materials Incorporated (from title page)	Human Health Evaluation Manual, Supplemental Guidance: Update of Standard Default Exposure Factors
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	February 2014

Issue, or version	

KK) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**	
	Thirty-seventh Incorporation
Official Title of Materials Incorporated (from title page)	Vapor Intrusion Screening Level (VISL) Calculator User's Guide
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	May 2014
Issue, or version	

LL) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**	
	Thirty-eighth Incorporation
Official Title of Materials Incorporated (from title page)	OSWER Technical Guide for Assessing and Mitigating the Vapor Intrusion Pathway from Subsurface Vapor Sources to Indoor Air
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	June 2015
Issue, or version	

MM) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**	
	Thirty-ninth Incorporation
Official Title of Materials Incorporated (from title page)	Technical Guide for Addressing Petroleum Vapor Intrusion at Leaking Underground Storage Tank Sites
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	June 2015
Issue, or version	

NN) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**	
	Fortieth Incorporation
Official Title of Materials Incorporated (from title page)	Update of Ecological Soil Screening Level (Eco-SSL) Guidance and Contaminant Specific Documents
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	March 2005
Issue, or version	

OO) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**	
	Forty-first Incorporation
Official Title of Materials Incorporated (from title page)	Guidelines for Mutagenicity Risk Assessment
Publisher	United States Environmental Protection Agency (US EPA)
Date Issued	September 1986
Issue, or version	

Public Notice Information

9. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. See Section 63G-3-302 and Rule R15-1 for more information.)		
A) Comments will be accepted until (mm/dd/yyyy)**:**		12/01/2021
B) A public hearing (optional) will be held:		
On (mm/dd/yyyy)**:**	**At** (hh:mm AM/PM)**:**	**At** (place)**:**

10. This rule change MAY become effective on (mm/dd/yyyy)**:**	12/13/2021
NOTE: The date above is the date the agency anticipates making the rule or its changes effective. It is NOT the effective date. To make this rule effective, the agency must submit a Notice of Effective Date to the Office of Administrative Rules on or before the date designated in Box 10.	

Agency Authorization Information

To the agency: Information requested on this form is required by Sections 63G-3-301, 302, 303, and 402. Incomplete forms will be returned to the agency for completion, possibly delaying publication in the *Utah State Bulletin* and delaying the first possible effective date.			
Agency head or designee, and title:	Douglas J. Hansen, Division Director	**Date** (mm/dd/yyyy)**:**	

R315. Environmental Quality, Waste Management and Radiation Control, Waste Management.
R315-101. Cleanup Action and Risk-Based Closure Standards.
R315-101-1. Purpose, Applicability.

(a) Purpose. Rule R315-101 establishes information requirements to support risk-based cleanup and closure standards at sites for which remediation or removal of hazardous constituents to background levels [~~will not be achieved~~]is not the remediation objective. The procedures in [~~this rule~~]Rule R315-101 also provide for continued management of sites for which [~~minimal~~]risk-based clean closure standards [~~cannot be~~]are not met.

(b) Applicability.

(1) Rule R315-101 [~~is applicable~~]applies to any responsible party, or other interested party on a voluntary basis such as a prospective purchaser, a lending institution or land developer, involved in management of a site contaminated with hazardous waste,[~~or~~] hazardous constituents, or other contaminants as determined by the director. [~~This r~~]RuleR315-101 does not apply to a site that has been or [~~will~~]shall be cleaned to background levels of constituents.

(2) In the event of a release of hazardous waste or material [~~which~~]that, when released, becomes hazardous waste, [~~these~~]the requirements of Rule R315-101 apply if the responsible party fails to clean up [~~all~~]the released material and any residue or contaminated soil, water or other material resulting from the release as required by Section R315-263-31. The requirements of Section R315-263-31 shall be considered met if:

(i) [~~If~~] the level of risk, cumulative, present at the site is [~~below~~]less than or equal to 1×10^{-6} for carcinogens and [~~a~~]the [~~H~~]hazard [~~I~~]index [~~of~~]is less than or equal to one for non-carcinogens based on [~~the~~]a risk assessment conducted [~~in accordance with~~] assuming the land use exposure scenario defined in Subsection R315-101-5[~~.2(b)~~](g)(1);

(ii) [~~and~~] the [~~D~~]director determines that ecological effects are insignificant based on the approved assessment conducted in accordance with Subsection R315-101-5[~~.3(a)(8)~~](j); and

(iii) [~~, the requirements of R315-9-3 shall be considered met~~] the director determines that current and potential future impacts to groundwater are insignificant in accordance with Subsection R315-101-6(f)(3).

(3) [~~The owner or operator of a hazardous waste management facility or a facility subject to interim status requirements shall meet the requirements of 40 CFR 265.110 through 120, incorporated by reference in Rule R315-265, and Sections R315-264-110 through 120 prior to implementation of any activities described in R315-101. The requirements of Subsections R315-270-1(c)(5) and (6) shall be met for a hazardous waste management unit if the level of risk present at the site is below 1 x 10^{-6} for carcinogens and a Hazard Index of less than or equal to one for non-carcinogens based on the risk assessment conducted in accordance with R315-101-5.2(b)(1) and the Director determines that ecological effects are insignificant based on the approved assessment conducted in accordance with R315-101-5.3(a)(8). If these risk exposure criteria are met, a request for a risk-based closure may be submitted to the Director for review.~~]The responsible party of a hazardous waste management site shall meet the requirements of Sections R315-265-110 through R315-265-120 or Sections R315-264-110 through R315-264-120, as applicable, prior to implementation of any activities described in Rule R315-101.

(4) [~~If the risk present at the site is greater than the exposure limit as defined in R315-101-1(b)(2) or (3) or the Director determines that ecological effects may be significant, then a risk-based closure will not be granted and appropriate management will be required and may~~

~~include corrective action, post-closure care, monitoring, deed restrictions, and security of the site. For determinations of appropriate corrective action or management activities at a site, the following criteria shall be considered in order of importance:~~

~~(a) The impact or potential impact of the contamination on the human health;~~

~~(b) The impact or potential impact of the contamination on the environment;~~

~~(c) The technologies available for use in clean up; and~~

~~(d) Economic considerations and cost effectiveness of clean up options~~]The requirements of Subsections R315-270-1(c)(5) and R315-270-1(c)(6) shall be considered met for a hazardous waste management unit or solid waste management unit if:

(i) the level of risk, cumulative, present at the site is less than or equal to 1 x 10^{-6} for carcinogens and a hazard index of less than or equal to one for non-carcinogens based on the risk assessment conducted assuming the land use exposure scenario defined in Subsection R315-101-5(g)(1);

(ii) the director determines that ecological effects are insignificant based on the approved assessment conducted in accordance with Subsection R315-101-5(j); and

(iii) the director determines that current and potential future impacts to groundwater are insignificant in accordance with Subsection R315-101-6(f)(3).

(5) If these risk criteria are met, a request for a risk-based clean closure as defined in Subsections R315-101-(6)(j) or R315-101-6(f) may be submitted to the director for review and approval.

(6) If the level of risk, cumulative, present at the site is greater than the limits defined in Subsections R315-101-1(b)(2) or R315-101-1(b)(4) or the director determines that ecological effects may be significant in accordance with Subsection R315-101-5(j), or current and potential future impact to groundwater is significant in accordance with Subsection R315-101-6(f)(3), then a risk-based clean closure shall not be granted and appropriate site management as defined in Subsection R315-101-12(a)(3) and as determined in Subsection R315-101-6(c) shall be required.

(c) For determination of appropriate corrective action at a site, the following criteria shall be considered in order of importance:

(1) the impact or potential impact of the contamination on human health;

(2) the impact or potential impact of the contamination on the environment;

(3) the technologies available for use in cleanup; and

(4) economic considerations and cost-effectiveness of cleanup options.

(d) The responsible party shall follow applicable Utah and federal risk assessment guidance and other guidance documents and methods approved by the director, as set forth in Rule R315-101.

R315-101-2. Stabilization of Releases.

(a) The responsible party [~~must~~]shall immediately take appropriate action as determined by the director to stabilize the site either through source removal or source control. [~~After the responsible party has attempted to complete the requirements of Sections R315-263-30 through 33 and the Director determines that additional work is needed to stabilize the site, the Director will notify the responsible party that additional work is necessary and provide the responsible party with objectives to be addressed in developing a work plan to further stabilize the site. The work plan shall be submitted to the Director for review and approval within fifteen days of receiving notification that additional work will be necessary to complete the emergency actions required by Sections R315-263-30 through 33. Work plans shall be of a scope commensurate with the work to be performed and site specific characteristics. This work plan shall include a description of the interim measure and how it will meet the criteria of source removal or source control. The implementation of the work plan shall be according to the schedule contained within the approved plan. All interim measures shall be at the expense of the party responsible for the site. If the party responsible for the site fails to take the measures required for stabilizing the site, the Director may request the Executive Director of the Department to take abatement and cost recovery actions as provided in Section 19-6-301, et seq., Utah Hazardous Substances Mitigation Act~~]If the director determines that the remedial action taken is insufficient to meet the requirements of Section R315-263-30, the responsible party shall submit a work plan pursuant to Subsection R315-101-2(b) to the director for approval within 15 days of receiving that written determination.

(b) The work plan shall:

(1) define the scope of work to be performed;

(2) include a description of the interim measures and other corrective actions to be taken; and

(3) include a description of how the plan shall meet the criteria of source removal or source control.

(c) The responsible party shall implement the work plan in accordance with the schedule contained in the approved plan. The responsible party shall implement interim measures or other corrective actions as approved. If the responsible party fails to take the measures required for stabilizing the site, the director may request the executive director of the Department of Environmental Quality to take abatement and cost recovery actions as provided in Sections 19-6-301 to 19-6-326 of the Utah Hazardous Substances Mitigation Act.

R315-101-3. Principle of Non-degradation.

(a) When closing or managing a contaminated site, the responsible party shall to the extent practicable in accordance with Subsection R315-101-1(c) not allow levels of contamination in groundwater, regardless of quality, sediment, surface water, soils, and air to increase beyond the existing levels of contamination at a site at the time the responsible party has defined the nature and extent of contamination pursuant to Section R315-101-4.[~~when site management commences.~~]

(b) The responsible party [~~will~~]shall demonstrate compliance with [~~this policy~~]Subsection R315-101-3(a) by submitting appropriate [~~monitoring data~~]sampling or other data as may be required by the [~~D~~]director.

(c) If at any time the level of contamination increases to a significant level as determined by the director on a case-by-case basis, the responsible party shall take immediate [~~corrective~~]action, as determined by the director, such as source removal or source control, to prevent further degradation of any medium. A work plan addressing interim action and other corrective action to mitigate the situation shall be submitted to the director for review and approval.

R315-101-4. Site Characterization, Data Collection and Documentation.

[~~The following information shall be collected to characterize the site, and define site boundaries and Area(s) of Contamination:~~

~~(a) A legal description of the site;~~

~~(b) Historical land use and ownership of the site;~~

~~(c) Topographical map(s) of sufficient detail, scale, and accuracy to depict and locate all past and current physical structures including all building(s) and waste activities at the site;~~

~~(d) Information and maps of sufficient detail, scale, and accuracy to describe regional, local, and site geology, surface water, and hydrogeological conditions;~~

~~(e) An inventory of all current and past wastestreams managed at the site, including process descriptions and suspected contamination source information;~~

~~(f) Background levels of suspected hazardous constituents based on the inventory as determined in R315-101-4(e) in media of concern, e.g. sediments, soil, groundwater, surface water, and air which are representative of the site; and~~

~~(g) Location and boundaries of all Area(s) of Contamination, including concentrations, types and extent of hazardous constituents. Media to be sampled may include sediments, soil, groundwater, surface water, and air, as applicable.~~]

(a) To define the nature and extent of potential contamination, based on the known or suspected history of past or current operations at the facility, in any environmental media, and prior to the collection of data that shall be used in the risk assessment, the responsible party shall develop and submit a site characterization work plan to the director for review and approval. The site characterization work plan shall include the following:

(1) sampling and analysis plan specifying methods and procedures to be used for data collection and analysis as outlined in Section R315-261-1090, Appendix I, and in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods" EPA Publication SW-846, available at the EPA Hazardous Waste Test Methods/SW-846 website;

(i) Samples shall be analyzed by a Utah certified laboratory using procedures and methods in accordance with "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods" EPA Publication SW-846, available at the EPA Hazardous Waste Test Methods/SW-846 website.

(ii) Documentation for laboratory work shall include the data accompanied by quality assurance and quality control measures taken in accordance with current environmental laboratory standards for a level II data package, or other QA/QC data level as determined by the director on a site-specific basis.

(2) representative proposed media sample locations with depths, sample analytes and justification that the proposed sampling is sufficient to define the nature and extent of contamination;

(3) conceptual site model for a site specific characterization, identifying and showing potential primary source areas, media of concern, contaminant release mechanism, receptors of interest, exposure pathways and possible contaminant migration pathways. Media may include sediments, soil, biota, food chain, groundwater, surface water, and air as applicable based on current site conditions;

(4) data quality objective process steps related to the implementation of the sampling and analysis plan in accordance with "Guidance on Systematic Planning Using the Data Quality Objectives Process," EPA QA/G-4, EPA/240/B-06/001, as incorporated by reference in Section R315-101-11;

(5) quality assurance project plan for field procedures, chain-of-custody and laboratory analytical methods to be used for the sampled media; and

(6) field quality assurance and quality control procedures to characterize and dispose of any investigation derived waste in an appropriate manner, including a plan for decontamination procedures, field instrument calibration procedures, any standard operating procedures and other relevant documentation.

(b) Background levels. Based on the site characterization sampling results, the responsible party may determine or propose background levels of suspected hazardous constituents as defined in Subsection R315-101-12(a)(7). The constituent list may be based on the inventory as determined in Subsection R315-101-4(c)(5) in media of concern, including; sediments, soil, groundwater, surface water, and air that are representative of the site.

(c) Additional information. The following additional information shall be collected to characterize the site, and to define site boundaries and areas of contamination:

(1) a description of the site, including legal boundaries;

(2) historical land use and ownership of the site, including existing aerial photos of the site through time if requested by the director;

(3) topographical and other relevant maps of sufficient detail, scale, and accuracy to depict and locate each past and current physical structure including any buildings and waste activities at the site;

(4) information and maps of sufficient detail, scale, and accuracy to describe regional, local, and site geology, surface water, groundwater and groundwater quality, drainage features and other hydrogeological conditions;

(5) an inventory of each current and past waste stream managed at the site, hazardous waste management units, areas of concern and solid waste management units at the site, including process descriptions, amounts and types of waste generated and disposed and suspected contamination source information;

(6) location and boundaries of areas of concern including any hazardous waste management units and solid waste management units;

(7) any past sampling results, and an inventory of any releases, discharges and spills; and

(8) available information such as reports and data on any previous corrective actions.

(d) Petroleum wastes and total petroleum hydrocarbon.

At sites where petroleum wastes may be present, the media samples shall be analyzed for volatile organic compounds, semi-volatile organic compounds including Poly Aromatic Hydrocarbons (PAHs), and total metals.

(e) The director may also require the impacted media to be analyzed for other constituents that may include Polychlorinated Biphenyls (PCBs), dioxins and furans, Per-and Polyfluoroalkyl Substances (PFAS), and any other contaminant of interest as determined on a case-by-case basis based on the history of the site and activities.

(f) Relevant information gathered in Subsections R315-101-4(a) through R315-101-4(e) shall be submitted in a site characterization report to the director for review and approval. In addition, the site characterization report shall include:

(1) site location, legal description and objectives of the site investigation;

(2) methodology and field activities completed including the handling of any investigation derived wastes;

(3) maps of sufficient detail and accuracy to depict waste management units, areas of contamination, nature and extent of contamination, topography, geology, groundwater quality, and potentiometric surface;

(4) site and regional geological, hydrogeological and hydrological descriptions;

(5) a detailed discussion of any areas of contamination found during the site characterization field work;

(6) listing and concentrations of any historic and current hazardous constituents identified in Section R315-101-4;

(7) background levels of hazardous constituents including details of statistical methods used to analyze the data gathered if applicable;

(8) Subsections R315-101-4(f)(6) and R315-101-4(f)(7) shall be known as contaminants of interest;

(9) descriptions of historic and current releases of hazardous constituents and expected extent of migration from the areas of contamination;

(10) deviations from the approved site characterization work plan and the sampling and analysis plan;

(11) discussion of the evaluated potential exposure pathways including groundwater, surface water, sediments, surface and sub-surface soils and air;

(12) a summary outlining the completion of data quality objectives, completed analytical request forms for each analysis performed reported on dry weight basis, actual sampling locations and depths with justification for variations to the approved sampling and analysis, any statistical analysis performed if completed, and quality assurance and quality control results and analytical data validation report in accordance with current environmental laboratory standards for a level II data package, or other QA/QC data level as determined by the director on a site-specific basis;

(13) revised conceptual site model identified in Subsection R315-101-4(a)(3) based on the information presented in the final site characterization report; and

(14) conclusions and recommendations for additional site work and applicable supporting documentation including figures, tables and appendices.

R315-101-5. Human Health and Ecological Risk Evaluation Criteria[~~,~~] and Risk Assessment.

[~~5.1 REQUIRED STUDY~~]

(a) When conducting the risk assessment, the responsible party [~~will use all applicable site characterization data and shall consider the following parameters~~]shall use the conceptual site model as defined in Subsection R315-101-12(a)(13) and as described in Subsections R315-101-4(a)(3) or R315-101-4(a)(13) as applicable, and shall use applicable site characterization data. For the areas of contamination as defined in Subsection R315-101-12(a)(5), the following shall be included when conducting the risk assessment:

(1) identification, concentration, and distribution of [~~all~~]any suspected hazardous constituents identified in [~~Subs~~]Section R315-101-4[~~(c)~~] and defined as contaminants of interest in Subsection R315-101-4(f)(8);

[~~(2) All area(s) of contamination at the site;~~]

[~~(3)~~](2) fate of contaminants of interest and any pathways [~~of contaminant~~]and transport of contaminants of interest;[~~ and~~]

[~~(4) Potentially exposed populations.~~](3) any potential exposure routes;

(4) human receptors; and

(5) ecological receptors.

[~~5.2~~](b) [~~CHARACTERIZATION AND EVALUATION OF RISK~~]Characterization and Evaluation of Human Health Risk.

[~~(a)~~](1) The responsible party shall conduct a risk assessment [~~which includes the following:~~]for human health following the methodologies described in the "US EPA Risk Assessment Guidance for Superfund Sites," Parts A to F, as incorporated by reference in Section R315-101-11.

(2) The concentration term for each medium for each contaminant of interest identified in Section R315-101-4 and Subsection R315-101-4(f)(8) shall be evaluated using the US EPA ProUCL program, calculating upper confidence limits.

(3) The fate, pathways, and transport of contaminants of interest identified in Section R315-101-4 and defined in Subsection R315-101-4(f)(8) shall be evaluated using the conceptual site model developed pursuant to Subsections R315-101-4(a)(3) or R315-101-4(a)(13) as applicable and approved by the director.

[~~(1) The concentration term "C" for each medium for each hazardous constituent identified in R315-101-5.1(a)(1);~~

~~(2) Evaluation of the fate of contaminants and of all pathways of contaminant transport identified in R315-101-5.1(a)(3);~~

~~(3) Exposure assessment identifying the RME for all exposure pathways, intakes, and identified constituents;~~

~~(4) Current toxicity information for carcinogenic and noncarcinogenic effects;~~

~~(5) Risk characterization identifying carcinogenic risk, individual and multiple substances, and noncarcinogenic hazardous index, individual and multiple substances;~~

~~(6) An ecological evaluation which provides for terrestrial and aquatic processes; and~~

~~(7) Current toxicity information for all the constituents and biological processes relevant to the ecological evaluation.~~

~~(b) The risk assessment shall be conducted using one or both of the standard exposure scenarios listed below, as needed to determine site management options:~~

~~(1) Residential. This exposure scenario includes ingestion of water (must include surface water and ground water regardless of water quality), ingestion of soil and dust, ingestion of contaminated and potentially contaminated food, inhalation of contaminants, dermal contact with chemicals in soil, and dermal contact with chemicals in water for a human being ages zero through 70 years old using the equations and default variable values found in the Risk Assessment Guidance for Superfund, Volume 1: Human Health Evaluation Manual Supplemental Guidance, "Standard Default Exposure Factors", Interim Final, OSWER Directive 9285.6-03, March 25, 1991 or most recent edition;~~

~~(2) Actual land use conditions or potential land use conditions based upon applicable zoning and future land use planning considerations, if potential land use conditions offer a more protective exposure scenario than actual land use conditions. This exposure scenario involves an assessment based on actual site conditions using standard default variable values. The potential land use exposure scenario should include a conceptual model including current site conditions, expected future conditions based upon site specific physical and chemical information, and the assumption that contaminated media will not have undergone any remedial engineering.~~

~~5.3 DATA PRESENTATION~~

~~(a) A risk assessment report shall be submitted to the Director and must include at a minimum the following:~~

~~(1) An executive summary;~~

~~(2) An overview of the site and the areas of contamination;~~

~~(3) A site characterization report which includes:~~

~~(i) Maps of sufficient detail and accuracy to depict areas of contamination, topography, geology, and groundwater contours or potentiometric surface;~~

~~(ii) Site and regional geological and hydrological descriptions;~~

~~(iii) A detailed discussion of areas of contamination;~~

~~(iv) Background levels of hazardous constituents including details of statistical methods used to determine background; and~~

~~(v) Descriptions of releases of hazardous constituents and expected extent of migration from the area of contamination.~~

~~(4) Identification and concentration of hazardous constituents identified in R315-101-5.1(a)(1). A sampling and analysis plan shall be prepared and utilized for the collection of all data. This plan shall be developed using procedures and methods outlined in Section R315-261-1090 and the most current version of "SW-846, Test Methods for Evaluating Solid Waste." It shall contain a summary outlining data quality objectives, completed analytical request forms for all analysis performed, dry weight equivalents, sampling location identification and justification, standard operating procedures used for data collection, all statistical analysis performed, quality assurance and quality control plans (QA/QC plan) and QA/QC results, instrument calibration results, and analytical methods including constituent detection limits;~~

~~(5) Exposure assessment identifying exposure levels for all exposure pathways identified in R315-101-5.2(a)(3). If fate and transport models are used, the users manual, model theory, computer software for the model, installation verification data set for the model and parametric analysis of the input parameters must be provided upon request of the Director;~~

~~(6) Identification of toxicity information gathered for all identified hazardous constituents for carcinogenic, slope factors and weight-of-evidence classification, noncarcinogenic effects, chronic reference doses (RfDs) and critical effects associated with RfDs from, in order of preference, the Integrated Risk Information System (IRIS), Health Effects Assessment Summary Tables (HEAST), Agency for Toxic Substances and Disease Registry (ATSDR) toxicological profiles, Environmental Criteria and Assessment Office (ECAO), or other scientifically accepted listings. The source and date of the toxicological information must be identified and be acceptable to the Director;~~

~~(7) The risk characterization identifying carcinogenic risk, individual and multiple substances, noncarcinogenic hazardous index, individual and multiple substances, chronic hazard quotient, subchronic hazard quotient, uncertainties, and a tabulation of all risk characterization data presented in a format approved by the Director; and~~

~~(8) Unless justification is provided to the Director, and a waiver of this requirement is granted by the Director in writing, an ecological assessment of the site which contains at least the following:~~

~~(i) An inventory of the current biological community;~~

~~(ii) Estimates of ecological effects based on a subset of ecological endpoints;~~

~~(iii) The magnitude and variation of toxic effects; and~~

~~(iv) Identification of extent of effects, specifically from the presence of hazardous waste.~~

~~(b) If the risk assessment report does not contain all required information of sufficient quality and detail, the Director will notify the responsible party in writing of the deficiencies and require resubmittal of the report in a designated time frame.~~

~~(c) If the risk assessment report contains all required information of sufficient quality and detail, the Director will approve the risk assessment report in writing.~~]

(c) The exposure scenarios identified in the exposure model shall be estimated using reasonable maximum exposure parameters and shall be based on both current and potential future anticipated land use and receptors defined in Subsections R315-101-5(g)(1) and R315-

101-5(g)(2).

(d) The exposure model shall include a determination as to whether or not each of the following pathways is complete under both current and anticipated future conditions. Risks shall be quantified for those receptors where exposure pathways have a reasonable potential for being complete unless it may be demonstrated that the risk is less significant when compared to other quantified receptor risks.

(1) Pathways for surficial soils, defined as zero to a maximum of six inches below ground surface or as determined on a case-by-case basis including:

(i) leaching to groundwater and potential use of groundwater;

(ii) leaching to groundwater and subsequent migration to a surface water body; and

(iii) ingestion of soil, dermal contact with soil, inhalation of vapors and particulates emitted by surficial soils.

(2) Pathways for subsurface soils, defined as greater than six inches below ground surface to the water table and as determined on a case-by-case basis including:

(i) leaching or vapor migration to groundwater and potential use of groundwater;

(ii) leaching or vapor migration to groundwater and subsequent migration to a surface water body;

(iii) volatilization and upward migration of vapors from subsurface soil and potential indoor inhalation of these emissions; and

(iv) ingestion of soil, dermal contact, inhalation of vapors and particulates.

(3) Soil pathways applicable to construction worker as defined from the surface down to depth of construction of 12 feet or the top of the water table, or as determined on a case-by-case basis including:

(i) ingestion;

(ii) dermal contact with soil;

(iii) inhalation of vapor emissions; and

(iv) inhalation of particulates from soil.

(4) Groundwater pathways applicable to construction worker including:

(i) ingestion;

(ii) dermal contact with groundwater; and

(iii) inhalation of vapor emissions.

(5) Pathways for groundwater in general including:

(i) volatilization and upward migration of vapors from groundwater and potential indoor inhalation of vapor emissions;

(ii) volatilization and upward migration of vapors from groundwater and potential outdoor inhalation of vapor emissions;

(iii) potable use of groundwater, including ingestion of groundwater, dermal contact with groundwater during showering or bathing, and inhalation of vapors from domestic use of groundwater if pathway is complete; and

(iv) migration to surface water body and potential impacts to surface water and potential exposures to surface water.

(6) Other pathways that may need to be considered on a site specific basis may include the following:

(i) contact with soils and ingestion of soils, sediments, inhalation of vapors and particulates, surface water and groundwater for any other anticipated human contacts such as recreational and trespasser activities;

(ii) ingestion of produce grown in impacted soils;

(iii) use of groundwater for irrigation purposes;

(iv) use of groundwater for industrial purposes;

(v) ingestion of livestock fish or other aquatic organisms that, as a result of media contamination, have bio-accumulated constituents of potential concern through the food chain; and

(vi) swimming.

(e) Human health risk assessment approach. The risk assessment may be performed for impacted media by choosing either a Tier 1, or a Tier 2 risk assessment process, or both. Tier 1 shall be a screening risk assessment and Tier 2 shall be a refined risk assessment that may include site specific exposure assumptions and allowance for alternative approaches, such as a Monte Carlo exposure risk analysis, probabilistic risk assessment. The risk assessment shall be conducted considering current and potential future land-use in accordance with the residential land use exposure scenario as defined in Subsection R315-101-5(g)(1) or the non-residential land use exposure scenario as defined in Subsection R315-101-5(g)(2), or both. The responsible party shall develop a risk assessment work plan for review and approval by the director before commencement of evaluation.

(f) Tier 1 screening risk assessment.

(1) The Tier 1 evaluation shall use one or more of the following screening levels:

(i) US EPA Regional Screening Levels available at the EPA Risk Assessment, Regional Screening Levels (RSLs) website;

(ii) site-specific background 95% upper tolerance limit levels developed in accordance with "Statistical Analysis of Groundwater Monitoring Data at RCRA Facilities, Unified Guidance," US EPA, as incorporated by reference in Section R315-101-11. Director approval is required for the development of background level determination;

(iii) vapor intrusion screening levels calculated using US EPA Vapor Intrusion Screening Level Calculator, as incorporated by reference in Section R315-101-11, available at the EPA Vapor Intrusion Screening Levels Calculator website;

(iv) petroleum vapor intrusion screening guidelines developed in accordance with "Technical Guide for Addressing Petroleum Vapor Intrusion at Leaking Underground Storage Tank Sites," US EPA, as incorporated by reference in Section R315-101-11;

(v) the robust confidence limits established for the site in accordance with "Statistical Analysis of Groundwater Monitoring Data at RCRA Facilities, Unified Guidance," US EPA, as incorporated by reference in Section R315-101-11; or

(vi) in instances where a regional screening level is not available, a responsible party, with the approval of the director, may develop

and calculate a site-specific screening value.

(vii) The regional screening levels, robust confidence limits, site specific background levels, calculated site-specific screening values, and vapor intrusion screening levels shall be known collectively as screening values.

(viii) The documents referenced in Subsections R315-101-5(f)(1)(i) through R315-101-5(f)(1)(vi) and other director approved sources shall be used as sources for obtaining screening values.

(2) Chemical specific screening and Tier 1 screening risk assessment for residential land use.

(i) For inorganic contaminants of interest, the following steps shall be followed for screening.

(A) The maximum detected concentration of each contaminant of interest shall be compared to the site-specific background level 95% upper tolerance limit or the established robust confidence limit. If the maximum detected concentration is less than the background 95% upper tolerance limit or the robust confidence limit, then the inorganic contaminants of interest shall not be considered as a constituent of potential concern.

(B) For those inorganic contaminants of interest whose maximum concentrations are greater than the background level site-specific 95% upper tolerance limits or the robust confidence limits, a test of means hypothesis shall be used to determine if inorganic contaminants of interest are present at elevated levels over background levels.

(C) If the results of the test of means hypothesis indicate the detected inorganic contaminant of interest is elevated over background level, it will be selected as a constituent of potential concern or it will be dropped from further evaluation.

(D) If a test of means hypothesis cannot be performed due to sample size or there is no established site specific background level, the inorganic contaminants of interest shall be selected as a constituent of potential concern.

(E)(I) For further evaluation, the maximum detected concentration of inorganic contaminants of interest shall be selected as the exposure point concentration.

(II) For organic contaminants of interest, the maximum detected concentrations shall be the exposure point concentration. If it is determined that the exposure point concentration of any contaminants of interest is greater than the screening value, the contaminants of interest shall be selected as constituents of potential concern. Otherwise, it will not be selected as a contaminants of potential concern needing further evaluation.

(III) For inorganic and organic contaminants of interest, if the maximum detected concentration results in a cancer risk greater than $1x10^{-6}$ or a hazard quotient greater than one, a 95% upper confidence limit on the mean may be calculated using the USEPA ProUCL program. The lesser of the maximum concentration and the 95% upper confidence limit concentration shall be selected as the exposure point concentration.

(IV) If the minimum required sample size for calculating the 95% upper confidence limit cannot be met, the maximum detected concentration shall be the exposure point concentration.

(V) For additivity responses, if no constituents of potential concern are selected in accordance with Subsections R315-101-5(f)(2)(i)(C), R315-101-5(f)(2)(i)(D) and R315-101-5(f)(2)(ii), an additional screening step shall be performed to determine if cumulative effects screening risks posed by detected contaminants of interest at the site meet the acceptable target risk goal of $1x10^{-6}$ for carcinogenic risk and a hazard index of one for non-carcinogenic risk.

(VI) If the cumulative effects screening cancer risk is less than or equal to $1x10^{-6}$ and hazard index is less than or equal to one, then the cumulative effects screening risks posed by detected contaminants of interest at the site meet the residential land use and the site meets the criteria for no further action or unrestricted land use as identified in Subsections R315-101-6(f) or R315-101-6(h) or R315-101-6(i) or R315-101-6(j) as applicable.

(VII) If the cumulative effects screening cancer risk is greater than $1x10^{-6}$ or the hazard index is greater than one, then the cumulative effects screening risks posed by any detected contaminants of interest at the site do not meet the residential land use standards and further evaluation is required.

(3) Residential land use with selected constituents of potential concern.

(i) For carcinogenic constituents of potential concern, the residential land use cumulative effects screening cancer risk estimate is calculated as the sum of the ratios of exposure point concentrations and screening values for the combined residential land use exposure pathways identified under the conceptual site model developed pursuant to Subsections R315-101-4(a)(3) or R315-101-4(a)(13) as applicable for soil and groundwater media. The sum is then multiplied by $1x10^{-6}$.

(ii) For non-carcinogenic constituents of potential concern, the hazard index is calculated as the sum of the ratios of exposure point concentrations and screening values for the combined residential land use exposure pathways identified under the conceptual site model pursuant to Subsections R315-101-4(a)(3) or R315-101-4(a)(13) as applicable for soil and groundwater media.

(iii) Risks to residents from ingestion of livestock grazing on a contaminated site shall be determined and added to the cumulative effects risk equation if it is determined to be a plausible and complete exposure pathway.

(iv) Vapor intrusion pathway if complete, shall be evaluated and added to the cumulative effects screening risk equation.

(v) Any other relevant exposure pathway consistent with the residential exposure pathway shall be evaluated and added to the cumulative risk.

(vi) The Tier 1 risk assessment evaluation may not be appropriate under circumstances when every complete exposure pathway is not covered by the screening values. The Tier 2 refined risk assessment approach may be more appropriate for evaluation.

(vii) If it is determined that the residential land use cumulative effects screening cancer risk posed by constituents of potential concern is less than or equal to the target cancer risk of $1x10^{-6}$ and the hazard index is less than or equal to one for each combined residential land use exposure pathways, and it is determined that there are no current and potential future impacts to groundwater as determined by "Supplemental Guidance For Developing Soil Screening Levels," US EPA, as incorporated by reference in Section R315-101-11,

Subsections R315-101-5(f)(6) and R315-101-6(s) and ecological impacts are insignificant in accordance with Subsection R315-101-5(j), then the site meets the criteria for no further action or unrestricted land use as identified in Subsections R315-101-6(f), or R315-101-6(h), or R315-101-6(i) or R315-101-6(j) as applicable.

(viii) If it is determined that the residential land use cumulative effects screening cancer risk posed by constituents of potential concern is greater than the target risk of $1x10^{-6}$ or the hazard index is greater than one for each combined residential land use exposure pathways, then further evaluation of the site may be conducted using either the Tier 2 refined risk assessment evaluation approach for a residential land use exposure scenario as defined in Subsection R315-101-5(g)(1) or the non-residential land use exposure scenario as defined in Subsection R315-101-5(g)(2) as applicable, or the responsible party may choose to conduct corrective action as identified in Subsections R315-101-6(m) and R315-101-6(n) to mitigate risks at the site to residential acceptable levels.

(ix) In the Tier 2 refined risk assessment, constituents of potential concern that significantly contribute to a pathway in a land use exposure scenario for a receptor that exceeds a cumulative cancer risk of $1x10^{-4}$ or a non-carcinogenic hazard index greater than one shall be known as contaminants of concern.

(x) An ecological evaluation shall also be completed as part of the screening residential land use risk evaluation as described in Subsection R315-101-5(j).

(xi) A groundwater impact evaluation shall also be completed as part of the screening residential land use risk evaluation as identified in Subsection R315-101-5(f)(6).

(4) Chemical specific screening and Tier 1 screening risk assessment for industrial or commercial land use or both.

(i) For inorganic contaminants of interest, the following steps shall be followed.

(A) The maximum detected concentration of each contaminants of interest shall be compared to the site-specific background levels 95% upper tolerance limit or the established robust confidence limits. If the maximum detected concentration is less than the background 95% upper tolerance limit or the robust confidence limit, then the inorganic contaminant of interest will not be considered as a constituent of potential concern.

(B) For those inorganic contaminants of interest whose maximum concentrations is greater than the background level site-specific 95% upper tolerance limits or the robust confidence limit, a test of means hypothesis shall be used to determine if inorganic contaminants of interest are present at elevated levels over background levels.

(C) If the results of the test of means hypothesis indicate the detected inorganic contaminants of interest are elevated over background level, it will be selected as a constituent of potential concern or it will be dropped from further evaluation.

(D) If a test of means hypothesis cannot be performed due to sample size or there is no established site specific background level, the inorganic contaminants of interest shall be selected as a constituent of potential concern.

(E)(I) For further evaluation, the maximum detected concentration of inorganic contaminants of interest shall be selected as the exposure point concentration.

(II) For organic contaminants of interest, the maximum detected concentration shall be the exposure point concentration. If it is determined that the exposure point concentration of any contaminant of interest is greater than the screening value, the contaminant of interest shall be selected as constituents of potential concern. Otherwise, it will not be selected as a constituent of potential concern needing further evaluation.

(III) For inorganic and organic contaminants of interest, if the maximum detected concentration results in a cancer risk greater than $1x10^{-6}$ or a hazard quotient greater than one, a 95% upper confidence limit on the mean may be calculated using the USEPA ProUCL program. The lesser of the maximum concentration and the 95% upper confidence limit concentration shall be selected as the exposure point concentration.

(IV) If the minimum required sample size for calculating the 95% upper confidence limit cannot be met, the maximum detected concentration shall be the exposure point concentration.

(V) For additivity responses, if no constituents of potential concern are selected in accordance with Subsections R315-101-5(f)(4)(i)(C), R315-101-5(f)(4)(i)(D) and R315-101-5(f)(4)(ii), an additional screening step shall be performed to determine if cumulative effects screening risks posed by detected contaminants of interest at the site meet the acceptable target risk goal of $1x10^{-6}$ for carcinogenic risk and a hazard index of one for non-carcinogenic risk.

(VI) If the cumulative effects screening risk is less than or equal to a cancer risk of $1x10^{-6}$ and hazard index is less than or equal to one, then the cumulative effects screening risks posed by detected contaminants of interest at the site meets the industrial or commercial land use or both and the site meets the criteria for restricted land use as identified in the Subsection R315-101-6(k).

(VII) If the cumulative effects screening risk is greater than cancer industrial risk of $1x10^{-6}$ or hazard index is greater than one, then the cumulative effects screening risks posed by the detected contaminants of interest at the site do not meet the industrial or commercial land use or both and further evaluation is required.

(5) Industrial or commercial land use or both with selected constituents of potential concern.

(i) For carcinogenic contaminants of interest, the industrial or commercial land use or both, cumulative effects screening risk estimate is calculated as the sum of the ratios of exposure point concentrations and screening values for the industrial or commercial land use or both exposure pathways combined for soil, groundwater and other media, as applicable. The sum is then multiplied by $1x10^{-6}$.

(ii) For non-carcinogenic cumulative effects screening risk, the hazard index is calculated as the sum of the ratios of exposure point concentrations and screening values for the industrial or commercial land use or both exposure pathways combined for soil, groundwater and other applicable media.

(iii) Exposure scenarios not covered in the screening values shall be evaluated separately and added to the cumulative effects risks. Evaluations may include the vapor intrusion pathway if determined to be complete using the vapor intrusion screening levels.

(iv) Other receptors relevant to the industrial or commercial land use or both scenario, such as construction worker, trespasser, recreational user, shall be evaluated.

(v) The Tier 1 risk assessment evaluation approach may not be appropriate under circumstances when the complete exposure pathways or receptors are not covered by the screening values. A Tier 2 refined risk assessment approach may be more appropriate for evaluation.

(vi) If it is determined that the industrial or commercial land use or both cumulative effects screening risk posed by constituents of potential concern is greater than the target cancer risk of $1x10^{-6}$ or the hazard index is greater than one for the industrial or commercial land use or both exposure pathways combined, then a site management plan or corrective action shall be required as identified in Subsections R315-101-6(k), R315-101-6(m) and R315-101-6(n) as applicable.

(vii) If it is determined that the industrial or commercial land use or both cumulative effects screening cancer risk posed by constituents of potential concern is less than or equal to the target cancer risk of $1x10^{-6}$ and the hazard index is less than or equal to one for the industrial or commercial land use or both exposure pathways combined, then the site qualifies for a restricted land use as identified in Subsection R315-101-6(k).

(viii) If it is determined that the industrial or commercial land use or both cumulative effects screening cancer risk posed by constituents of potential concern is greater than the target cancer risk of $1x10^{-6}$ or the hazard index is greater than one for the combined industrial or commercial land use or both exposure pathways, then further evaluation of the site may be conducted using the Tier 2 refined risk assessment evaluation approach using the non-residential land use exposure scenario as defined in Subsection R315-101-5(g)(2), or the responsible party may choose to conduct corrective action as identified in Subsections R315-101-6(m) and R315-101-6(n) to mitigate risks at the site to non-residential and acceptable levels.

(ix) In the Tier 2 refined risk assessment, constituents of potential concern that significantly contribute to a pathway in a land use exposure scenario for a receptor that exceeds a cumulative cancer risk of $1x10^{-4}$ or a non-carcinogenic hazard index greater than one shall be known as contaminants of concern.

(x) An ecological evaluation, as identified in Subsection R315-101-5(j), shall also be completed as part of the screening industrial or commercial land use or both risk evaluation.

(xi) A groundwater impact evaluation, as identified in Subsection R315-101-5(f)(6), shall also be completed as part of the screening industrial or commercial land use or both risk evaluation.

(6) For evaluation of potential future impacts to groundwater one or more of the following steps shall be used:

(i) Step 1. Compare the maximum detected constituents of potential concern in soil to the US EPA Regional Screening Levels, groundwater protection soil screening level based on a dilution attenuation factor of 20, unless it may be demonstrated that background levels for the contaminants of concern at the site exceed the applicable soil screening levels. If the maximum detected concentrations exceed the US EPA Soil Screening Levels for groundwater protection, the potential exists for future impacts to groundwater. The groundwater protection soil screening level value shall be based on the maximum contaminant level. If the maximum contaminant level value is not available, the responsible party shall use the risk-based groundwater protection soil screening level value for evaluation. If the potential for future groundwater contamination exists, the responsible party may choose to take appropriate actions approved by the director to remove or decrease the level of contamination that may pose a future threat to groundwater; or

(ii) Step 2. Compare the calculated 95% upper confidence limit value of soil constituents of potential concern to the value obtained by multiplying the derived site-specific dilution attenuation factor by the groundwater protection soil screening level value. If sufficient data are not available to calculate a 95% upper confidence limit, the maximum constituent of potential concern concentration value shall be used for evaluation or the director may approve an alternate value. The development of the site-specific dilution attenuation factor shall follow "Supplemental Guidance For Developing Soil Screening Levels," US EPA, as incorporated by reference in Section R315-101-11. If the 95% upper confidence limit concentration exceeds the calculated groundwater protection soil screening level, the potential exists for future impacts to groundwater. The groundwater protection soil screening level value shall be based on the maximum contaminant level. If the maximum contaminant level value is not available, the responsible party shall use the risk-based groundwater protection soil screening level value for evaluation. If the potential for future groundwater contamination exists, the responsible party may choose to submit a work plan for approval by the director describing actions that will be taken to protect groundwater from future impacts due to soil contamination. In addition, the work plan shall include a proposal for collection of sufficient monitoring data to evaluate both current and future groundwater conditions; or

(iii) Step 3. The responsible party shall propose an alternate method for evaluating potential future impacts to groundwater due to soil contamination to the director for approval. If it is determined that the potential for future groundwater contamination exists, the responsible party shall submit a work plan for approval by the director describing actions that will be taken to protect groundwater from future impacts due to soil contamination. In addition, the work plan shall include a proposal for collection of sufficient monitoring data to evaluate both current and future groundwater conditions.

(g) A Tier 2 refined risk assessment shall be conducted using one or both of the following standard land use exposure assumption scenarios listed in Subsections R315-101-5(g)(1) and R315-101-5(g)(2):

(1) Residential Land Use.

(i) child receptor; and

(ii) adult receptor

(2) Non-residential Land Use.

(i) commercial or industrial or both; and

(ii) construction or trespassing or recreation as applicable.

(3)(i) The Tier 2 risk assessment shall assume no institutional or engineering controls in place, such as security, signage, pavements,

personal protective equipment, fences or remediation.

(ii) The risk assessment shall use US EPA standard default exposure parameters, variables and equations based on reasonable maximum exposure in the evaluation, unless scientific evidence suggests otherwise. If a US EPA standard default exposure parameter or variable is not available, the responsible party shall use the "Exposure Factors Handbook," US EPA, as incorporated by reference in Section R315-101-11, for default values, or other sources as approved by the director.

(iii) A refined risk assessment may be conducted using site specific exposure parameters and a Monte Carlo simulation in a probabilistic risk analysis with the approval of the director.

(4) Evaluations shall be conducted in accordance with US EPA approved standards and methodologies and may include the following guidance:

(i) "Guidelines for the Health Risk Assessment of Chemical Mixtures", Risk Assessment Forum, EPA/630/R-98/002, as incorporated by reference in Section R315-101-11;

(ii) "Risk Assessment Guidance for Superfund Volume 1: Human Health Evaluation Manual (Parts A-F)," Office of Emergency and Remedial Response EPA/504/1-89/002, Interim Final, as incorporated by reference in Section R315-101-11;

(iii) "Human Health Evaluation Manual, Supplemental Guidance: Update of Standard Default Exposure Factors," US EPA OSWER Directive 9200.1-20, as incorporated by reference in Section R315-101-11;

(iv) "Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures," US EPA, as incorporated by reference in Section R315-101-11;

(v) "Soil Screening Guidance Technical Background Document," US EPA and "Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites," US EPA, as incorporated by reference in Section R315-101-11;

(vi) "Guidelines for Carcinogen Risk Assessment," EPA/630/P-03/001F, as incorporated by reference in Section R315-101-11;

(vii) "Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens," EPA/630/R-03/00F, as incorporated by reference in Section R315-101-11;

(viii) "OSWER Technical Guidance for Assessing and Mitigating the Vapor Intrusion Pathway From Subsurface Vapor Sources to Indoor Air," US EPA OSWER 9200.2-154, as incorporated by reference in Section R315-101-11;

(ix) "Technical Guide For Addressing Petroleum Vapor Intrusion At Leaking Underground Storage Tank Sites," US EPA, as incorporated by reference in Section R315-101-11; and

(x) "Risk Assessment Guidance for Superfund, Part A, Volume III, Process for Conducting Probabilistic Risk Assessment," EPA 540-0R-02-002 OSWER 9285.7-45 PB 2002 963302, as incorporated by reference in Section R315-101-11.

(5) In performing the Tier 2 risk assessment, the responsible party shall use current toxicity information for carcinogenic and non-carcinogenic effects in accordance with Subsections R315-101-5(i) and R315-101-5(j)(7).

(6) Risk characterization shall identify carcinogenic risks and non-carcinogenic risks for the constituents of potential concern.

(7) The age-dependent-adjustment-factors shall be applied to carcinogens with a mutagenic mode of action.

(8) Risk characterization shall be based on cumulative risk effects and assumption of additivity in the absence of adequate evidence of toxicological interactions as follows.

(i) For non-carcinogenic toxicants acting by similar modes of action or affecting common organs, dose addition shall be followed.

(ii) For carcinogenic risks or toxicants acting independently, response addition shall be followed.

(9) Carcinogenic cumulative risk shall be calculated as the sum of the probabilities of each chemical across the exposure pathways for cumulative risks less than 0.01. For cumulative risks greater than 0.01, the One-Hit Model, as specified in "Risk Assessment Guidance for Super Fund Volume 1: Human Health Evaluation Manual," Part A, US EPA, Office of Emergency and Remedial Response EPA/504/1-89/002, Interim Final, as incorporated by reference in Section R315-101-11, shall be used.

(10) Non-carcinogenic hazard indices shall be calculated as the sum of the non-carcinogenic effects for each chemical across the exposure pathways. However, if the hazard index is greater than one, the hazard quotients should be summed separately by target organ or mode of action.

(11) If total petroleum hydrocarbon risk assessment is evaluated, it shall be conducted in accordance with Subsections R315-101-5(f), R315-101-5(f)(6), R315-101-5(g), R315-101-5(j), "Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures," EPA/630/R-00/002, as incorporated by reference in Section R315-101-11, and the US DOE Risk Assessment Information System website, and in accordance with other procedures approved by the director.

(i) The cumulative risk of the total petroleum hydrocarbon mixture shall assume additivity, dose addition or response addition, unless there is data suggesting toxicological interaction.

(ii) The risk assessment shall be based on the conceptual site model identified in Subsections R315-101-4(a)(3) or R315-101-4(f)(13) as applicable.

(12) Current and future anticipated land use scenarios evaluation.

(i) The evaluation shall be based on current and reasonably anticipated future uses of the property. Sources of information on land uses may include:

(A) current zoning and comprehensive plan maps and applicable regulations provided by the local jurisdiction for the properties within the locality of the site;

(B) inquiries made and responses as to whether there are regional trends that are relevant to land uses and activities in the locality of the site;

(C) inquiries made of any environmental protection zones or regulations; and

(D)(I) the property owner's planned use of land.

(II) An inactive or vacant, fenced or non-fenced, property with no proposed land use in an area zoned for industrial or commercial land use or both shall be assumed to be reasonably used for industrial or commercial use or both in the future.

(III) An inactive or vacant, fenced or non-fenced, property in an area zoned for residential land use shall be assumed to be reasonably used for residential land use in the future.

(IV) For the protection of human health and the environment, if future anticipated land use conditions offer a more protective exposure scenario than the current land use scenario, the more protective future anticipated land use shall be evaluated.

(V) A summary of the results and conclusions along with supporting documentation as to what the current and reasonably anticipated future land uses are for parcels within the locality of the site shall be submitted with the Tier 2 refined risk assessment for approval.

(h) Data and results presentation.

(1) A risk assessment report shall be submitted to the director for review and approval. It shall include, at a minimum, the following:

(i) an executive summary;

(ii) an overview of the site;

(iii) a detailed discussion of areas of contamination;

(iv) an exposure assessment identifying exposure levels for the exposure pathways identified in Subsections R315-101-5(c) and R315-101-5(j)(3)(i);

(v) if fate and transport models are used, the user's manual, model theory, computer software for the model, installation verification data set for the model and input files for the model runs shall be provided upon request by the director;

(vi) the output results of the model runs;

(vii) source of the equations;

(viii) background levels of identified hazardous constituents including any statistical methods used in evaluation of background data;

(ix) identification and concentration of the contaminants of interest identified in Subsection R315-101-4(f)(8);

(x) a list of constituents of potential concern, contaminants of concern, and contaminants with mutagenic mode of action for human health and constituents of potential ecological concern;

(xi) the toxicity information of identified constituents of potential concern, specifically listing mutagenic constituents of potential concern, including slope factors, inhalation unit risks, weight-of-evidence classification, non-carcinogenic chronic reference doses, age dependent adjustment factors, chronic deference concentrations and critical effects associated with reference doses and reference concentrations, toxicity reference values and any other ecological benchmarks used in the risk assessment;

(xii) a list of identified ecological receptors;

(xiii) a list of identified ecological habitats;

(xiv) risk characterization calculations including data used; and

(xv) the risk characterization identifying carcinogenic risk and non-carcinogenic risk for the constituents of potential concern, ecological hazard indices, uncertainties analysis, and a tabulation of the risk characterization data presented in a format approved by the director.

(2) If the risk assessment report does not contain the required information of sufficient quality and detail, the director will notify the responsible party in writing of deficiencies and shall require resubmittal of the report in a designated time frame.

(3) If the risk assessment report contains the required information of sufficient quality and detail, the director will approve, the risk assessment report in writing.

(i) Identification of sources of toxicity information.

(1) Sources of toxicity information gathered for identified hazardous constituents, weight-of-evidence classification and critical effects associated with reference doses and reference concentrations shall be in order of preference based on the US EPA hierarchy of human health toxicity values tiered system, "Human Health Toxicity Values in Superfund Risk Assessment," EPA OSWER Directive 9285.7-53, as incorporated by reference in Section R315-101-11, as follows.

(i) The Tier 1 source is the US EPA Integrated Risk Information System.

(ii) The Tier 2 source is the US EPA Provisional Peer Reviewed Toxicity Values.

(iii) The Tier 3 source may include additional US EPA and non-US EPA sources of toxicity information with priority given to sources that have been peer reviewed including the following:

(A) California Environmental Protection Agency toxicity values;

(B) Agency for Toxic Substances and Disease Registry Minimal Risk Levels;

(C) US EPA additional sources identified for Tier 3 toxicity values; or

(D) US EPA Health Effects Assessment Summary toxicity data.

(2) US EPA Regional Screening Levels; and

(3) US DOE Risk Assessment Information System website.

(j) Ecological risk assessment.

(1) Prior to conducting the risk assessment, the responsible party shall submit a work plan for approval.

(2) An ecological risk assessment for the site shall include terrestrial and aquatic processes as appropriate using current toxicity information for the constituents and biological processes relevant to the ecological evaluation. This shall include plants, soil invertebrates, benthic invertebrates, wildlife species and other ecological receptors as approved by the director.

(3) A waiver of this requirement may be granted by the director if the responsible party demonstrates that ecological receptors will not be affected by any contamination using any of the following criteria:

(i) conditions at the site may be used to eliminate the need for ecological risk assessment;

(ii) the affected property is not a viable habitat and the site cannot be used by potential ecological receptors as a habitat;

(iii) complete or potentially complete exposure pathways do not exist due to prevailing conditions or property setting; or

(iv) detected chemicals at the site are below the ecological screening bench mark levels.

(4) An ecological risk assessment for a site shall be conducted to include the following information:

(i) a problem formulation, identification of constituents of potential ecological concern, identification of habitats, media sampled, potential ecological effects, relevant ecological receptors, relevant exposure pathways, initial definition of assessment and measurement endpoints, with respect to current and reasonably anticipated future land and water uses as described in a conceptual site model;

(ii) the data quality objectives for the ecological risk assessment shall be based on the conceptual site model, with emphasis on analytical detection limits appropriate for ecological receptors;

(iii) an exposure analysis to include identification and selection of constituents of potential ecological concern, identification and selection of target ecological receptors, an exposure pathway model relating target receptors, exposure routes and measurement endpoints for both current and reasonably anticipated future land and water use scenarios;

(iv) an ecological response analysis including a summary of current information regarding the toxicological effects, ecological effects, bio-concentration potential, bio-accumulation potential, bio-magnification potential, persistence of the identified constituents of potential ecological concern and ecological benchmark values;

(v) a risk characterization presenting the quantitative ecological risks potentially associated with the site, a discussion of any available site-specific ecological studies, a detailed discussion of risks associated with the bio-concentration potential, bio-accumulation potential, bio-magnification potential, and persistence of each contaminant, and consideration of any other available, published and peer-reviewed scientific information on other sources of adverse ecological conditions as appropriate;

(vi) an evaluation of the potential for significant adverse effects on the health or viability of individual ecological receptors or local populations, including a weight-of-evidence analysis or population viability analysis. These evaluations may include field studies, laboratory investigations, appropriate population models, or any combination of these or other methods of evaluation as approved by the director; and

(vii) a quantitative and qualitative uncertainty analysis as appropriate for each element of the risk assessment.

(5) Ecological risk assessment estimates shall be conducted:

(i) at the individual level for species present in the locality of the site if the species is listed as threatened or endangered, or is a state sensitive species; and

(ii) at the population level for any other species of plants or animals in the locality of the site.

(6) Cumulative hazard from multiple hazardous substances shall be assessed by summing the hazards posed separately by individual hazardous substances in the locality of the site, unless it is demonstrated that the summation assumption is not appropriate.

(7) Ecological risk assessment shall be conducted in accordance with the following:

(i) "Framework for Ecological Risk Assessment," EPA/630/R-92/001, as incorporated by reference in Section R315-101-11;

(ii) "Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments Interim Final," EPA 540-R.97-006, OSWER 9285.7-25. PB97-963211, as incorporated by reference in Section R315-101-11;

(iii) "Guidelines for Ecological Risk Assessment," US EPA, as incorporated by reference in Section R315-101-11;

(iv) US EPA "Guidance for Developing Ecological Screening Levels," US EPA, as incorporated by reference in Section R315-101-11; and

(v) any other sources as approved by the director.

(8) Appropriate sources of exposure factor information and toxicological parameters may include the following:

(i) "Wildlife Exposure Factors Handbook," US EPA, as incorporated by reference in Section R315-101-11;

(ii) "Toxicological Benchmarks for Wildlife," Oak Ridge National Laboratory (ORNL), as incorporated by reference in Section R315-101-11;

(iii) Los Alamos National Laboratory (LANL) ECO Risk Database;

(iv) US EPA Ecological Soil Screening Levels;

(v) "Guidance for Developing Ecological Soil Screening Levels," US EPA, as incorporated by reference in Section R315-101-11; and

(vi) any other sources as approved by the director.

(9) In the absence of available and acceptable toxicity information, the director may require the development of site-specific toxicity information.

(10) An ecological risk assessment shall be conducted using a tiered evaluation approach as described in Subsections R315-101-5(j)(10)(i) through R315-101-5(j)(10)(x).

(i) A Tier 1 ecological screening risk assessment shall use conservative assumptions and shall include:

(A) a conceptual site model;

(B) an evaluation of fate and transport mechanisms;

(C) an identification of constituents of potential ecological concern;

(D) a characterization of the ecological setting; and

(E) a selection of toxicity endpoints and receptors of ecological significance.

(ii) Tier 1 ecological screening risk assessment - exposure pathways:

(A) each ecological receptor shall be considered to be exposed to constituents of potential ecological concern in soil in the zero to ten feet below ground surface interval. In addition, burrowing animals and deep rooted plants may be considered to be exposed to constituents

of potential ecological concern in soils deeper than ten feet; and

(B) exposure pathways may include ingestion, inhalation, direct contact for burrowing receptors, exposure through uptake of biota exposed to constituents of potential ecological concern, and plant uptake of constituents of potential ecological concern.

(iii) The exposure assessment for the Tier 1 ecological screening risk assessment shall be conducted by assuming:

(A) the maximum detected concentrations as the exposure point concentration for calculating exposure doses;

(B) the area use factor is equal to one indicating that the home range of the receptor is the entire contaminated area;

(C) that the bioavailability of contaminants is equal to 100%;

(D) the maximum reported ingestion rate from literature;

(E) the dietary composition consists of direct ingestion of 100% of the constituents of potential ecological concern levels in soil;

(F) each calculation is performed on a dry-weight basis; and

(G) minimum receptor body weight.

(iv) The toxicity assessment for the Tier 1 ecological screening risk assessment shall be conducted by assuming:

(A) for wildlife, the dose-based toxicity reference values which are receptor, media, and chemical specific, shall be the applicable protective standards available in peer reviewed literature sources;

(B) the toxicity reference values selected shall be those based on no observed adverse effects levels for evaluation;

(C) the responsible party may use a literature search to determine availability of data for derivation of a toxicity reference value if detected constituents of potential ecological concern have no published toxicity reference values, and shall provide the following:

(I) the responsible party shall provide supporting data to the director for approval of the newly derived toxicity reference value; and

(II) if the responsible party is unable to derive a toxicity reference value based on literature, the detected constituents of potential ecological concern shall be addressed qualitatively in the uncertainty analysis of the ecological risk assessment report;

(D) for plants and other invertebrate receptors, such as soil organisms, benthic organisms and aquatic organisms, concentration-based effects benchmarks shall be used. Concentration levels identified in peer reviewed literature sources shall be used as measurement endpoints for evaluation of chemical effects on receptors;

(E) the effects concentration levels shall be the no observed effects concentrations; and

(F) the responsible party may use a literature search to determine availability of data for derivation of effects concentration levels if detected constituents of potential ecological concern have no published effects concentration levels.

(I) The responsible party shall provide supporting data to the director for approval of the newly derived effects concentration levels; and

(II) If the responsible party is unable to derive effects concentration levels based on literature, the detected constituents of potential ecological concern shall be addressed qualitatively in the uncertainty analysis of the ecological risk assessment report.

(v) The risk characterization for Tier 1 ecological screening risk assessment shall include:

(A) for plants and other invertebrate receptors, a screening hazard quotient, shall be calculated as the maximum detected exposure concentration of constituents of potential ecological concern divided by the no observed effects concentration;

(B) for wildlife, a screening hazard quotient shall be calculated as the estimated exposure dose or contaminant intake divided by the no observed adverse effects level-based toxicity reference value; and

(C) tier 1 screening results.

(I) If the calculated screening hazard quotient is less than or equal to one, no further evaluation is required.

(II) If the calculated screening hazard quotient is greater than one, then there may be the potential for adverse ecological risk from the detected constituents of potential ecological concern at the site. The responsible party shall either conduct corrective action or conduct further evaluation in a Tier 2 refined ecological risk assessment.

(vi) A Tier 2 refined ecological risk assessment shall:

(A) use constituents of potential ecological concern with screening hazard quotients greater than one for a refined problem formulation; and

(B) use site-specific exposure assumptions in Subsections R315-101-5(j)(10)(ii) and R315-101-5(j)(10)(iii) for the refined evaluation.

(vii) The exposure assessment in the Tier 2 refined ecological risk assessment shall include exposure doses calculated utilizing site-specific exposure assumptions as follows:

(A) exposure point concentration:

(I) calculate exposure point concentration as the 95% upper confidence limit if sufficient data are available in accordance with US EPA ProUCL software; and

(II) if sufficient data are not available to calculate the 95% upper confidence limit an alternate value, as approved by the director, shall be used as the exposure point concentration;

(B) estimate the site-specific area use factor for each representative receptor by dividing the receptor's average home range by the area of contamination or area of the solid waste management units. This estimate shall have a value between zero and one;

(C) the bioavailability of constituents of potential ecological concern shall be assumed to be 100%;

(D) the ingestion rate for each representative receptor shall be assumed to be the average reported ingestion rate in reported literature or estimated from average body weight using allometric equations;

(E) the dietary composition shall be based on receptor specific percentages of plant, animal, and soil matter. The non-dietary ingestion of soil shall be assumed to be in addition to the dietary intake rate to add up to 100%, soil and dietary items;

(F) the concentrations of constituents of potential ecological concern in receptor dietary elements, plant and animal matter, shall be

predicted by using bio-uptake and bioaccumulation models;

(G) each calculation shall be performed on a dry-weight basis;

(H) if a bioaccumulation model is not available, 100% uptake factor shall be assumed;

(I) each equation and variables used to estimate constituents of potential ecological concern in plants shall be listed;

(J) the methodologies for determination of bioaccumulation factors for the constituents of potential ecological concern shall be documented; and

(K) exposure doses for wildlife receptors shall be assessed using bio-uptake and bioaccumulation modeling to predict the concentration of constituents of potential ecological concern in animal matter that may be ingested by wildlife receptors.

(viii) The toxicity assessment for a Tier 2 refined ecological risk assessment shall be based on:

(A) the lowest observed adverse effects levels for wildlife receptors and lowest observed effects concentrations for plants and invertebrate receptors; and

(B) the toxicity reference values shall be based on the lowest observed adverse effects levels for each wildlife receptor and shall be based on lowest observed effects concentrations for any other receptors including invertebrates, with the exception of endangered, threatened and sensitive species for which a no observed adverse effects level applies.

(ix) The risk characterization of the Tier 2 refined ecological risk assessment.

(A) For wildlife vertebrate receptors, a hazard quotient shall be calculated as the ratio of the estimated receptor-specific contaminant intake or dose to the lowest observed adverse effects level based toxicity reference value.

(B) For plants and other invertebrate receptors, a qualitative discussion of the potential for adverse effects shall be provided in the assessment. The assessment shall be based on plant hazard quotients as well as site observations that were made during a habitat survey.

(C) Hazard quotients shall be summed for the constituents of potential ecological concern with similar receptor-specific modes of toxicity.

(D) Tier 2 assessment results.

(I) If the hazard index is less than or equal to one, adverse ecological effects are not expected and no further action is needed.

(II) If the hazard index is greater than one, there is potential for adverse ecological effects to occur at the site and the responsible party shall either conduct corrective action or conduct further evaluation in a Tier 3 refined ecological risk assessment as outlined in Subsection R315-101-5(j)(x).

(x) A Tier 3 refined ecological risk assessment shall be conducted based on:

(A) a site-specific ecological evaluation;

(B) uptake factors, bioaccumulation factors, and plant uptake factors determined from the analysis of animal and plant tissue collected at the site;

(C) the evaluation of unique exposure pathways and effects of exposure to various life stages or other assessment endpoints as determined by the director;

(D) the evaluation of habitat suitability including habitat quality; and

(E) the calculation of refined hazard indices for the constituents of potential ecological concern shall take into account information from Subsections R315-101-5(j)(9)(x)(A) through R315-101-5(j)(9)(x)(D).

(xi) Tier 3 refined ecological risk assessment results and possible outcomes.

(A) If the Tier 3 refined evaluation results in an hazard index greater than one, the responsible party, shall, in conjunction with the results of a Tier 2 refined evaluation, use several lines of evidence and a weight-of-evidence approaches to facilitate a final determination regarding the need for corrective action.

(B) Site remediation shall be required when unacceptable or potential significant adverse ecological effects are documented by the risk assessment results.

(C) The director has the discretion to require corrective action at the site based on data and ecological significance as reported.

(11) Results presentation.

An ecological risk assessment report shall be prepared and submitted to the director in accordance with the requirements in Subsection R315-101-5(h).

R315-101-6. Risk Management: Site Management Plan and Closure Equivalency.

(a) A site management plan, which is supported by the findings in the approved risk assessment reports and containing appropriate site management activities, shall be submitted to the [~~D~~]director within 60 days of approval of the [~~risk assessment~~]reports. [~~This~~]The site management [~~plan may be submitted along with the risk assessment report and must~~]shall include a schedule for implementation.

(b) [~~The Director shall review and approve or disapprove of the conclusions of the proposed site management plan. If the Director finds that the site management plan is not adequate for protection of human health and the environment, the responsible party shall then submit a revised site management plan addressing the comments of the Director within an appropriate time frame as specified by the Director. The Director shall review and approve or reject the revised site management plan. Upon draft approval of the site management plan, the Director shall follow the requirements of R315-101-7 prior to issuance of final approval. The approved site management plan shall be implemented according to the approved schedule. If the Director rejects this revised site management plan, the revised plan will be considered deficient for the reasons specified by the Director in a statement of disapproval.~~]The site management plan shall:

(1) encompass any activities, controls and conditions necessary to manage the risk to human health and the environment so that acceptable risk levels are not exceeded under current or reasonably anticipated future land use conditions;

(2) ensure that the assumptions made in the estimation of risk and applicable target risk levels are being met; and

(3) ensure that adverse ecological effects are controlled and managed so that documented hazard indices are less than or equal to one.

(c)[~~(1) The site management plan may contain a no further action option only if the level of risk present at the site is below 1 x 10^{-6} for carcinogens and a Hazard Index of "less than or equal to one" for non-carcinogens based on the approved assessment conducted in accordance with R315-101-5.2(b)(1) and the Director determines that ecological effects are insignificant based on the approved assessment conducted in accordance with R315-101-5.3(a)(8);~~

~~(2) The requirements of Subsections R315-270-1(c)(5) and (6) shall be deemed met for a hazardous waste management unit if the level of risk present at the site is below 1 x 10^{-6} for carcinogens and a Hazard Index of "less than or equal to one" for non-carcinogens based on the risk assessment conducted in accordance with R315-101-5.2(b)(1) and the Director determines that ecological effects are insignificant based on the approved assessment conducted in accordance with R315-101-5.3(a)(8). If this risk exposure criterion is met, a request for a risk-based closure may be submitted; or~~

~~(3) If the risk present at the site is greater than or equal to 1 x 10^{-6} for carcinogens or a Hazard Index of "greater than one" for non-carcinogens based upon the exposure assessment conducted in accordance with R315-101-5.2(b)(1), or the Director determines that ecological effects may be significant based on the approved assessment conducted in accordance with R315-101-5.3(a)(8), a risk based closure will not be granted. The responsible party shall then submit a site management plan fulfilling the requirements of R315-101-6(d) or (e) as applicable.~~] Appropriate site management activities shall be measures and controls taken to manage and reduce risks greater than 1 x 10^{-6} but less than 1x10^{-4} under both current and reasonably anticipated future land use conditions, through land use controls, such as institutional controls and engineering controls, groundwater monitoring, post-closure care, or corrective action as determined by the director on a case-by-case basis in accordance with Subsections R315-101-12(a)(4) and R315-101-1(c).

(d) [~~If the level of risk present at the site is less than 1 x 10^{-4} for carcinogens and a hazard index is "less than or equal to one" for the risk assessment conducted in accordance with R315-101-5.2(b)(2) but greater than or equal to 1 x 10^{-6} for carcinogens or a hazard index is greater than one for a risk assessment conducted in accordance with R315-101-5.2(b)(1) or the Director determines that ecological effects may be significant based on the approved assessment conducted in accordance with R315-101-5.3(a)(8), the site management plan may contain, but is not required to contain, procedures for corrective action. The site management plan shall contain appropriate management activities e.g., monitoring, deed notations, site security, or post-closure care, as determined on a case-by-case basis in accordance with criteria identified in R315-101-1(b)(4).~~]The site management plan shall be reviewed and approved by the director prior to implementation of the plan. Prior to approval, the site management plan shall be subject to the public notice requirements of Section R315-101-9.

(e)[~~The site management plan must contain procedures for corrective action if the level of risk present at the site is greater than or equal to 1 x 10^{-4} for carcinogens or a Hazard Index of "greater than one" for non-carcinogens based on the approved assessment conducted in accordance with R315-101-5.2(b)(2) or the Director concludes that corrective action is required to mitigate ecological effects based on the approved assessment conducted in accordance with R315-101-5.3(a)(8). For determination of appropriate corrective action the criteria identified in R315-101-1(b)(4) shall be considered.~~](1) If the director finds that the site management plan is not adequate for protection of human health and the environment, the responsible party shall re-submit a revised site management plan addressing the comments of the director within an appropriate time frame as specified by the director. The director shall review and approve or reject the revised site management plan. The responsible party shall resubmit the site management plan addressing the deficiencies in a time frame specified by the director.

(2) The site management plan shall be implemented in accordance with the approved schedule.

(f) [~~If hazardous constituents are present only in groundwater at the site, and if the hazardous constituents are listed in Table 1 of Section R315-264-94, the Maximum Concentration Levels listed in Table 1 can be presented in lieu of health risk estimates for those constituents. The RME for Table 1 constituents must be determined in accordance with approved site characterization methods listed in R315-101-4.~~]A determination of no further action shall be approved only if:

(1) the level of risk present at the site is equal to or less than 1 x 10^{-6} as the point of departure for carcinogens and the hazard index is less than or equal to one for non-carcinogens based on the approved risk assessment conducted assuming the land use exposure scenario defined in Subsection R315-101-5(g)(1);

(2) the director determines that ecological effects at the site are insignificant based on the approved assessment conducted in accordance with Subsection R315-101-5(j); and

(3) current impacts to groundwater are insignificant in accordance with Subsection R315-101-6(s) and residual contamination present at the site poses no future threat to groundwater in accordance with Subsection R315-101-5(f)(6) and "Soil Screening Guidance Technical Background Document," US EPA, as incorporated by reference in Section R315-101-11, or groundwater contaminant concentrations have been shown to be below a corrective action level using a statistical corrective action test in accordance with "Statistical Analysis of Groundwater Monitoring Data at RCRA Facilities," US EPA Unified Guidance, as incorporated by reference in Section R315-101-11 or the "Groundwater Statistics and Monitoring Compliance Guidance Document," Interstate Technology Regulatory Council (ITRC) as incorporated by reference in Section R315-101-11, as applicable.

(g) Upon completion of the requirements in Subsection R315-101-6(f), corrective action shall be considered complete without controls and the land is acceptable for unrestricted use.

(h) The requirements of Subsections R315-270-1(c)(5) and R315-270-1(c)(6) shall be deemed met for a hazardous waste management unit or a solid waste management unit or an area of contamination, the site, if:

(1) the level of risk, cumulative, present at the site is less than or equal to 1 x 10^{-6} for carcinogens and the hazard index is less than or equal to one for non-carcinogens based on the risk assessment conducted assuming the land use exposure scenario defined in Subsection R315-101-5(g)(1);

(2) the director determines that ecological effects are insignificant based on the approved assessment conducted in accordance with Subsection R315-101-5(j); and

(3) current and potential future impacts to groundwater are insignificant in accordance with Subsection R315-101-6(f)(3).

(i) If the requirements of Subsections R315-101-6(f) or R315-101-6(h) are met, a request for a risk-based clean closure may be submitted.

(j) The residential land use exposure scenario defined in Subsection R315-101-5(g)(1) shall be evaluated to determine if a site qualifies for a no further action or a risk-based clean closure. Qualification for no further action or risk-based clean closure shall meet the following criteria:

(1) the human health cumulative risk level is less than or equal to 1×10^{-6} for carcinogens and hazard index is less than or equal to one for non-carcinogens under a residential land use exposure scenario using reasonable maximum exposure parameters for evaluation;

(2) there are no current or potential future impacts to groundwater in accordance with Subsection R315-101-6(f)(3); and

(3) constituents of potential concern do not pose significant risks to ecological receptors in accordance with Subsection R315-101-5(j).

(k) A site qualifies for either restricted land use, corrective action complete with controls or a site management plan, or all three if:

(1) the level of risk, cumulative, present at the site is between 1×10^{-4} and 1×10^{-6} for carcinogens and the hazard index is less than or equal to one for non-carcinogens for the risk assessment conducted assuming the land use exposure scenario defined in Subsections R315-101-5(g)(1) or R315-101-5(g)(2); or

(2) the director determines that ecological risks may be significant, but does not require further corrective action based on the approved assessment conducted in accordance with Subsection R315-101-5(j); or

(3) current or potential future impacts to groundwater exist in accordance with Subsection R315-101-6(f)(3), but do not require further corrective action. The site management plan shall contain appropriate site management activities as defined in Subsection R315-101-12(a)(3) and as determined in Subsection R315-101-6(c), and as approved by the director.

(l) A site qualifies for unrestricted land use, corrective action complete without controls, risk based clean closure, no further action, and no site management if the level of risk present at the site is less than or equal to 1×10^{-6} for carcinogens and the hazard index is less than or equal to one for non-carcinogens for the risk assessment conducted assuming the land use exposure scenario defined in Subsection R315-101-5(g)(1). The site shall also meet the requirements of Subsections R315-101-6(f), R315-101-6(h) or R315-101-6(j).

(m) Corrective action is required at a site if:

(1) the level of risk present at the site is greater than 1×10^{-4} for carcinogens and a hazard index greater than one for non-carcinogens for the risk assessment conducted assuming the land use exposure scenario defined in Subsections R315-101-5(g)(1) or R315-101-5(g)(2);

(2) the director determines that ecological effects are significant based on the approved assessment conducted in accordance with Subsection R315-101-5(j); or

(3)(i) groundwater contamination is exceeded in accordance with Subsection R315-101-6(s) or groundwater contaminant concentrations have been shown to be above a corrective action level using a statistical corrective action test in accordance with "Statistical Analysis of Groundwater Monitoring Data at RCRA Facilities" US EPA Unified Guidance, as incorporated by reference in Section R315-101-11, or the "Groundwater Statistics and Monitoring Compliance Guidance Document," Interstate Technology Regulatory Council (ITRC), as incorporated by reference in Section R315-101-11; or

(ii) contamination present at the site poses a potential threat to groundwater in accordance with Subsection R315-101-5(f)(6) and "Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites," US EPA, as incorporated by reference in Section R315-101-11, and "Soil Screening Guidance Technical Background Document," US EPA, as incorporated by reference in Section R315-101-11.

(n) The responsible party shall submit a corrective action plan for review and approval prior to implementation of the corrective action activities at the site. Determination of appropriate corrective action measures shall be made in accordance with criteria identified in Subsection R315-101-1(c).

(o) Upon completion of any corrective action, the responsible party may request from the director, a corrective action completeness determination.

(p) The site management plan shall include a land use control plan that specifies allowable and prohibited use of the site.

(q) Land use controls shall guarantee that pathways of exposure to contaminants of concern remain incomplete for as long as there are hazardous waste or hazardous waste constituents remaining that could pose an unacceptable risk to human health and the environment.

(r) Land use controls shall be reliable, enforceable, and consistent with the risk posed by the contaminants of concern as documented in the approved risk assessment report. Land use controls may include engineering controls such as capping, paving, fencing, signage, site security; and institutional controls such as post-closure care and land use restrictions as determined on a case-by-case basis and approved by the director.

(s) For groundwater impacts due to contaminants of interest at a site, the maximum contaminant level shall be used as trigger for assessing appropriate corrective action levels. In the absence of a maximum contaminant level, the tap water risk-based concentration that assumes standard default residential land use exposure assumptions and a cancer risk of 1×10^{-6} and a hazard index of one shall be the standard. For detected volatile organic compounds in groundwater, the vapor intrusion screening levels shall also be considered in assessing corrective action levels. Any corrective action levels proposed shall be protective of the complete exposure pathways or potentially complete exposure pathways.

(t) In instances where groundwater contamination has migrated off site, and the director determines that the contaminant concentration poses a potential risk exceeding the acceptable risk level for residential land use exposure scenario defined in Subsection R315-101-5(g)(1), the responsible party shall:

(1) Submit a proposed written notice of contamination to the director for approval prior to its distribution to the off-site property owners.

(i) The written notice shall at a minimum, include the following:

(A) names of the contaminants detected above applicable screening levels;

(B) the corresponding screening levels;

(C) the respective detected contaminant concentrations; and

(D) adverse effects on human health and the environment.

(2) Notify the off-site property owners, in writing, within thirty days of director approval of written notice.

(3) Provide the director with a certified mail return receipt, or any other form of delivery that provides confirmation of receipt.

(4) With the property owner's consent, and the approval of the director, conduct corrective action to reduce concentrations of constituents of concern on the property to or below residential land use exposure scenario defined in Subsections R315-101-5(g)(1) or R315-101-6(s) as applicable, if it is determined by the director that the action is necessary for protection of human health and the environment, or that groundwater-use is designated as a drinking water source or is potentially a drinking water source; or

(5) If groundwater contamination has migrated off-site but Subsection R315-101-6(t)(1) through R315-101-6(t)(4) is not applicable, the responsible party shall inform the off-site property owner in writing of the contamination as required by Subsection R315-101-6(t)(1), and with the property owner's consent, and approval by the director, conduct corrective action to reduce concentrations of contaminants of concern on the off-site property to non-residential land use exposure levels consistent with the requirements of Subsection R315-101-5(g)(2) and the designated groundwater-use, and develop a site management plan and record an environmental covenant on the property with the approval of the director and consent of property owner.

(u) If the responsible party is unable to gain access to further characterize the off-site property, or to assess and manage risks, or to conduct corrective action on the off-site property, the responsible party shall:

(1) document each attempt to gain access to the off-site property, and obtain concurrence from the director that the attempts made were reasonable and that no further attempts need to be made;

(2) meet the applicable target risk levels or some approved groundwater protection standards at the boundary of the site; and

(3) with an approved site management plan by the director, take the necessary actions to prevent further migration of contaminants of concern beyond the site boundary.

(v) For impacts to off-site groundwater, surface water bodies and sediments, and other media, the corrective action levels shall be protective of each receptor, human and ecological, for each current and potential future exposure pathways.

(w) The site management plan in Subsections R315-101-6(t)(5) and R315-101-6(u)(3) addressing off-site and site groundwater contamination respectively, shall include the activities and conditions necessary to address current and potential future impacts to groundwater. The proposed controls and measures shall be consistent with Section R315-101-3 and prevent further ground water degradation at the site or off-site property so that risks are controlled, reduced or maintained at levels within the acceptable risk range as defined in Subsection R315-101-12(a)(2).

(x) Once the site management plan as specified in Subsections R315-101-6(k) or R315-101-6(t)(5) or R315-101-6(u)(3) has been approved by the director, the contamination level shall not be allowed to exceed the level of risk specified in the plan. The responsible party has the burden to demonstrate that future levels of contamination at either the site or off-site property or both are either below or within the risk levels specified in the site management plan.

(y) If the responsible party cannot demonstrate that the level of contamination at either the site or off-site property or both is either below or within the risk levels specified in the site management plan, then further corrective action may be required as determined by the director to bring the risk levels to within the acceptable risk range as specified in the site management plan. A revised site management plan may be required by the director.

(z) In instances where contaminated groundwater has been determined by the director as having no complete exposure pathways and there is no migration of the contaminated plume off site, or when the director has approved a claim of technical impracticability for corrective action, then, instead of meeting specific cleanup levels, the acceptable management goals and remedy, shall be the following:

(1) source control of releases of contaminants that may pose a threat to human health and the environment;

(2) protection of human health and the environment from any potential exposure pathways to contaminated groundwater;

(3) long-term plume containment system for protection of human health and the environment, perpetual care obligation;

(4) periodic groundwater monitoring, unless terminated by the director after an evaluation of the site-specific conditions and risk characteristics, to demonstrate that contaminant levels are not increasing and the groundwater plume is stationary; and,

(5) periodic re-evaluation of the technical impracticability decision as part of routine performance monitoring to ensure long-term protection of human health and the environment.

R315-101-7. Contents of a Site Management Plan, Land Use Controls, Environmental Covenants, Restrictions, Controls and Conditions.

(a) The content of the site management plan. The site management plan to be approved by the director shall contain at a minimum:

(1) a legal description of the site including a legal plat map; (2) a summary of the media investigations conducted at the site including the characterization, delineation and listing of identified constituents of potential concern and contaminants of concern;

(3) a summary of the completed human health risk assessment and ecological risk assessment performed in accordance with Section R315-101-5;

(4) an implementation schedule of the site management plan within the site;

(5) a description of the groundwater conditions under the site and within the impacted aquifer, as defined in a site characterization report and including activity and use limitations such as potable, culinary, domestic, process, irrigation or any other use;

(6) a complete list of the persons or entities that have rights of reasonable access to the site at any time after the effective date of the site management plan for activities such as monitoring and compliance with the site management plan, along with any other terms and conditions of the site management plan;

(i) the site management plan shall also indicate that persons with legal interest in land and those subject to the site management plan are required to allow compliance with the site management plan;

(7) provisions that the director, and his authorized officers, employees, or representatives may at any reasonable time and upon presentation of appropriate credentials, have access to the site to monitor, sample or determine compliance with the site management plan or environmental covenant;

(8) a list of the contact names and information for site management plan inquiries; and

(9) a general description of any site-specific groundwater monitoring including:

(i) a general overview of the proposal;

(ii) a summary of site groundwater conditions; and

(iii) the current and potential uses of groundwater and the contaminants of concern.

(b) Activities related to monitoring potential contamination of the groundwater at the site shall be conducted under an approved groundwater monitoring plan. The responsible party shall submit a draft plan to the director and shall not proceed with any portion of the plan until the director has given written approval.

(1) Based on the results of the groundwater monitoring, the potential need for additional site management activities shall be evaluated and implemented, if necessary, to protect human health and the environment. Groundwater monitoring shall be the responsibility of the property owner and its assignees.

(c) If an existing groundwater monitoring well is lost, abandoned, destroyed, or needs to be relocated for development purpose, the owner shall replace the wells in an area that provides the groundwater data required by the site management plan. Any proposal to replace groundwater monitoring wells requires review and approval by the director. If drinking water wells are proposed, the responsible party shall provide prior notice to the director after obtaining either any necessary permits approval or both for the installation of the proposed drinking water wells by the appropriate state, local or other regulatory agencies.

(d) Site management plan modification and termination. The site management plan shall be subject to review and may be terminated or modified as follows.

(1) If groundwater sampling data within the site or off-site property indicates that approved groundwater corrective action levels found in Subsections R315-101-6(n), R315-101-6(s), R315-101-6(t) have been met for the site or off-site, the responsible party may request modification or termination of the groundwater monitoring program, as follows:

(i) groundwater data shall be evaluated using a statistical corrective action test in accordance with the "Statistical Analysis of Groundwater Monitoring Data at RCRA Facilities, Unified Guidance," US EPA, March 2009, or the "Groundwater Statistics and Monitoring Compliance Guidance Document," Interstate Technology Regulatory Council (ITRC), as incorporated by reference in Section R315-101-11;

(ii) groundwater monitoring may be terminated within the site or off-site property only if the groundwater protection standards found in Subsections R315-101-6(n), R315-101-6(s), or R315-101-6(t) have been met, including a demonstration that future levels of contamination will not exceed the approved groundwater corrective action levels; and

(iii) land use controls, either engineering or institutional or both, shall be relied upon to ensure protection of human health and the environment if the approved corrective action levels are in excess of the drinking water standards, maximum contaminant levels.

(2) If soil sampling data, including soil vapor, within the site or off-site indicate corrective action levels as found in Subsection R315-101-6(n) have been met for the soil portion of the site, the owner may request a modification or termination of the section of the site management plan addressing soil management at the site and off-site.

(3) If the owner or responsible party satisfies Subsections R315-101-7(d)(1) and R315-101-7(d)(2) and, in addition, meets the requirements defined in Subsections R315-101-6(f) or R315-101-6(g) or R315-101-6(h) or R315-101-6(j) or R3150101-6(l), as applicable, the owner may request a corrective action complete without controls determination or a no further action determination.

(4) If Subsection R315-101-7(d)(3) is satisfied a request for termination of the site management plan and the environmental covenant may be submitted to the director for approval.

(5) The director may require public comment on any modifications or termination of the approved site management plan and environmental covenant.

(6) The director may require a re-evaluation of the approved risk assessment, the site management plan and the environmental covenant upon receipt of new information or data that brings into question the protectiveness of the existing site management plan.

(e) Land use controls.

(1) The site management plan shall identify land use limitations for the site, such as residential, industrial, commercial, recreational, agricultural or any other comparable use with a similar level of human occupancy and exposure. The site management plan shall also identify the management and engineering controls to be placed upon the site. Any subsequent plans for development of the site shall demonstrate to the director that the level of risk present for the proposed use shall not exceed the applicable risk levels specified in the site management plan.

(2) The site management plan shall contain as many land use controls, institutional and engineering, as is deemed necessary to protect human health and the environment. Controls may include maintaining pavement, capping, soil excavation restrictions, and groundwater use limitations. Each control shall be approved by the director.

(3) The proposed land use controls shall be developed and included in the site management plan.

(4) Land use controls shall be used at any site where cumulative carcinogenic risk exceeds a level of $1x10^{-6}$ but less than $1x10^{-4}$ after cleanup or as indicated by the approved risk assessment report.

(5) Land use controls shall ensure that pathways of exposure to contaminants of concern remain incomplete for as long as there are contaminants of concern remaining that could pose an unacceptable risk to human health or the environment.

(6) Land use controls shall be enforceable pursuant to Section 57-25-111 and consistent with the risks posed by the contaminants of concern reported in the approved risk assessment report. The responsible party, or a subsequent land owner who assumes the responsibility of maintaining land use controls, shall be responsible for reimbursing the agency for any costs associated with periodic administrative oversight to ensure that land use controls are maintained and are in compliance with the site management plan. Costs shall not exceed the authorized statutory rate for technical oversight by the agency at the time of service.

(f) An environmental covenant. An environmental covenant pursuant to Sections 57-25-101 to 57-25-114 shall be required for each site unless it has been documented that any contaminants of interest at the site are at or below background levels or the following requirements have been met:

(1) the level of risk is less than or equal to $1x10^{-6}$ for carcinogens and the hazard index is less than or equal to one for non-carcinogens pursuant to the risk assessment conducted assuming the land use exposure scenario defined in Subsection R315-101-5(g)(1);

(2) the ecological effects have been determined to be insignificant; and

(3) there are no current or potential future impacts to groundwater.

(g) The content of the environmental covenant. The environmental covenant shall contain at a minimum:

(1) a brief narrative description of the contamination and remedy;

(2) a list of the constituents of potential concern and contaminants of concern;

(3) a list of the exposure pathways;

(4) the limits of exposure;

(5) the locations and extent of the contamination;

(6) a brief narrative description of land use limitations for the site;

(7) any groundwater use limitations;

(8) any ground surface use limitations; and

(9) any worker safety limitations.

(h) The environmental covenant shall indicate that persons with legal interest in land and those subject to the site management plan are required to maintain compliance with the site management plan.

(i) The environmental covenant shall include provisions that the director, and his authorized officers, employees, or representatives may at any reasonable time and upon presentation of appropriate credentials, have access to the site to monitor, sample or determine compliance with the site management plan or the environmental covenant.

(j) The terms and conditions of the land use controls established on the property shall be consistent with the environmental covenant recorded on the site.

(k) Within 30 days of the director signing the environmental covenant, the owner shall record the approved environmental covenant with the county recorder's office, and within 30 days of recording shall submit a copy of the recorded document to the director.

(l) Restrictions, controls and conditions. Restrictions, controls and conditions specified in the environmental covenant and the site management plan shall be enforceable by the director under Section 57-25-111 and Rule R315-101.

R315-101-8. Owner Responsibilities.

(a) The owner or responsible party shall ensure compliance with the environmental covenant and the land use restrictions such as groundwater use restrictions, soil removal restrictions, hazard notifications, implementation of the groundwater monitoring program and any other restrictions or conditions cited in the site management plan. Documentation of compliance with the site management plan requirements shall be submitted to the director upon request.

(b) The owner or responsible party shall notify present and future workers at the site of the residual risk at the site and the existence of the site management plan. This includes site workers present for a typical work week and construction workers that may be temporary. If the site management plan specifies controls to prevent workers from exposure, the owner or responsible party shall provide those controls.

(c) Within 48 hours of becoming aware of a deviation from the site management plan the owner or responsible party shall notify the director of the deviation. The owner or responsible party shall submit to the director a written report within 30 days detailing the nature of the deviation and an evaluation of whether the situation and existing site management practices compromise the level of protection afforded by the original site management plan requirements and whether an alternate site management plan is needed to provide a comparable level of protection. Any proposed modification to the site management plan requirements shall require director approval.

(d) The environmental covenant shall run with the land and shall be binding on the current and all subsequent owners. The site management plan requirements shall be imposed and enforced on the current owner through an environmental covenant. Additionally, after the environmental covenant is recorded in the appropriate county recorder's office, each deed, title or other instrument conveying an interest in the property executed by the owner or his successors in title to the property shall include a notice stating that the property is subject to the site management plan and environmental covenant, and shall reference the recorded location of the site management plan and environmental covenant and the restrictions applicable to the property in the site management plan.

R315-101-[~~7~~]9. Public Participation.

(a) The [~~D~~]director may provide for public participation in [~~all~~]each phase[~~s~~] of the cleanup action process, as defined in Sections

R315-101-4 through R315-101-6.[~~ As directed by the Director and based on the circumstances and level of public interest at the site, pertinent work plans shall describe how information will be made available to the public through, for example, fact sheets or information repositories and, where appropriate, contain proposed time frames for public input through, for example, public meetings, hearings, or comment periods.~~]

(b) Prior to approving the site management plan, [~~T~~]the [~~D~~]director shall[~~ also~~] provide public notice[~~, a~~] for public comment periods[~~,~~] and public hearings[~~(s)~~] for the site management plan in accordance with Sections R315-124-10 through R315-124-12 and R315-124-17.

R315-101-[~~8~~]10. [~~Cleanup/Management Action~~]Administrative Oversight.

(a) [~~Upon approval of the site management plan by the Director, all remedial activities at the site shall proceed according to the schedule established in the approved site management plan using the method(s) described therein~~] The director or his representatives shall have access to the site as described in Section R315-260-5 and at any time when activity pursuant to Rule R315-101 is taking place. The director or his representatives may collect environmental samples or document any visit to the site by photographic, or videographic or some other reasonable means.

(b) [~~Cleanup/Management Report. The Cleanup/Management Report shall detail remediation, treatment, and monitoring activities undertaken at the site by the responsible party as required by the approved site management plan. If the Cleanup/Management Report provides analytical data as evidence that levels of contamination at the site meet the requirements established in the site management plan for a risk-based closure or no further action as defined in R315-101-6(c)(2), the responsible party shall submit a certification of completion as outlined in R315-101-8(c), or request risk-based closure as outlined in Subsection R315-270-1(c)(6), whichever is applicable~~]The director shall send an invoice to the responsible party for review of plans submitted, contractor costs, laboratory costs and time spent on correspondence, telephone calls, meetings, field work, and any associated activities to meet the requirements of Rule R315-101.

(c) [~~Certification of Completion. Within 60 days of the completion of all activities documented in the Cleanup/Management Report, a Certification of Completion of Cleanup/Management Action shall be submitted to the Director by registered mail. The certification of completion shall state the site has been managed in accordance with the specifications in the approved Site Management Plan and shall be signed by the responsible party and by an independent Utah registered professional engineer~~]The owner shall pay any invoices it receives from the director in a timely manner.

(d) [~~Oversight.~~

~~(1) The Director or his representatives shall have access to the site as described in Section R315-260-5 and at all times when activity pursuant to R315-101 is taking place. The Director or his representatives may take samples or make records of any visit to the site by photographic, electronic, videotape or any other reasonable means.~~

~~(2) The Director shall bill the responsible party for review of plans submitted to meet the requirements of this Rule.~~

~~(3) The responsible party shall notify the Director at least seven days prior to any sampling event or remediation activity~~]The responsible party shall notify the director at least seven days prior to any field work such as a sampling event or remediation activity.

(e) Any engineering documents submitted to the director shall be signed by the responsible party and by a Utah registered professional engineer.

(f) Any groundwater information submitted to the director shall be signed by the responsible party and by a Utah registered professional geologist.

(g) Any other information submitted to the director shall be signed by the responsible party.

R315-101-11. Documents Incorporated by Reference.

(a) For purposes of Rule R315-101 regarding cleanup action and Risk-Based Closure Standards, the following documents are adopted and incorporated by reference.

(1) Interstate Technology Regulatory Council (ITRC), December 2013, “Groundwater Statistics and Monitoring Compliance" Guidance Document.

(2) Los Alamos National Laboratory (LANL), 2011, “ECO-Risk Database.”

(3) Oakridge National Laboratory (ORNL), 1996, “Toxicological Benchmarks for Wildlife: 1996 Revision." ES/ER/TM-86/R3.

(4) Oakridge National Laboratory (ORNL), May 1998, “A Guide to the ORNL Ecotoxicological Screening Benchmarks: Background, Development, and Application,” ORNL/TM-13615.

(5) United States Environmental Protection Agency (US EPA), 1986, “Guidelines for the Health Risk Assessment of Chemical Mixtures", Risk Assessment Forum, EPA/630/R-98/002.

(6) United States Environmental Protection Agency (US EPA), 1989, “Risk Assessment Guidance for Super Fund Volume 1: Human Health Evaluation Manual (Part A)”, Office of Emergency and Remedial Response EPA/504/1-89/002, Interim Final.

(7) United States Environmental Protection Agency (US EPA), March 25, 1991, “Risk Assessment Guidance for Super Fund Volume 1: Human Health Evaluation Manual Supplemental Guidance Standard Default Exposure Factors.” Interim Final. OSWER Directive 9285.6-03.

(8) United States Environmental Protection Agency (US EPA), December 1991, “Risk Assessment Guidance for Super Fund Volume 1: Human Health Evaluation Manual (Part B, Development of Risk-based Preliminary Remediation Goals),” Office of Emergency and Remedial Response EPA/504/1-89/003, Interim Final.

(9) United States Environmental Protection Agency (US EPA), December 1993, “Wildlife Exposure Factors Handbook, Volume I of II,” EPA/600/R-93/187.

(10) United States Environmental Protection Agency (US EPA), May 1992, "Supplemental Guidance to RAGS: Calculating the Concentration Term," Office of Solid Waste and Emergency Response, Washington, D.C. OSWER Directive 9285.7-081.

(11) United States Environmental Protection Agency (US EPA), February 1992, "Framework for Ecological Risk Assessment," EPA/630/R-92/001.

(12) United States Environmental Protection Agency (US EPA), December 1993, "Wildlife Exposure Factors Handbook, Appendix: Literature Review Database, Volume II of II" EPA/600/ R-93/187.

(13) United States Environmental Protection Agency (US EPA), May 1996, "Soil Screening Guidance Technical Background Document," EPA/540/R95/128.

(14) United States Environmental Protection Agency (US EPA), June 1997, "Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments," Interim Final, EPA 540-R.97-006, OSWER 9285.7-25, PB97-963211.

(15) United States Environmental Protection Agency (US EPA), April 1998, "Guidelines for Ecological Risk Assessment."

(16) United States Environmental Protection Agency (US EPA), August 2000, "Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures," EPA/630/R-00/002, August Risk Assessment Forum Technical Panel.

(17) United States Environmental Protection Agency (US EPA), December 2001, "Risk Assessment Guidance for Superfund: Volume 1 Human Health Evaluation Manual (Part D, Standardized Planning, Reporting, and Review of Superfund Risk Assessments)," Final, OSWER 9285.7-47.

(18) United States Environmental Protection Agency (US EPA), March 2001, "EPA Requirements for Quality Management Plans," EPA QA/R-2, EPA/240/B-01/002.

(19) United States Environmental Protection Agency (US EPA), December 2001, "Risk Assessment Guidance for Superfund: Volume III - Part A, Process for Conducting Probabilistic Risk Assessment," EPA 540-0R-02-002 OSWER 9285.7-45 PB 2002 963302.

(20) United States Environmental Protection Agency (US EPA), December 2002, "Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites," OSWER 9355.4-24.

(21) United States Environmental Protection Agency (US EPA), December 2002, "Guidance for Quality Assurance Project Plans," EPA QA/G-5, EPA/240/R-02/009 , OSWER 2002.

(22) United States Environmental Protection Agency (US EPA), December 2002(a), "Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites."

(23) United States Environmental Protection Agency (US EPA), February 2005, "Guidance for Developing Ecological Soil Screening Levels," Office of Solid Waste and Emergency Response OSWER Directive 9285.7-55.

(24) United States Environmental Protection Agency (US EPA), December 2003, "Human Health Toxicity Values in Superfund Risk Assessment," Office of Solid Waste and Emergency Response, OSWER Directive 9285.7-53.

(25) United States Environmental Protection Agency (US EPA), February 2004, "User's Guide for Evaluating Subsurface Vapor Intrusion into Buildings."

(26) United States Environmental Protection Agency (US EPA), July 2004, "Risk Assessment Guidance for Superfund Volume 1: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)," EPA/540/R/99/005, Final.

(27) United States Environmental Protection Agency (US EPA), March 2005(b), "Guidelines for Carcinogen Risk Assessment," EPA/630/P-03/001F.

(28) United States Environmental Protection Agency (US EPA), March 2005(c), "Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens," EPA/630/R-03/003F.

(29) United States Environmental Protection Agency (US EPA), February 2006, "Guidance on Systematic Planning Using the Data Quality Objectives Process," EPA/240/B-06/001.

(30) United States Environmental Protection Agency (US EPA), January 2009, "Risk Assessment Guidance for Superfund Volume 1: Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment)," EPA/540/R/070/002, OSWER 9285.7-82.

(31) United States Environmental Protection Agency (US EPA), March 2009, "Statistical Analysis of Groundwater Monitoring Data at RCRA Facilities, Unified Guidance," Final, EPA 530/R-09-007.

(32) United States Environmental Protection Agency (US EPA), December 1991, "Risk Assessment Guidance for Super Fund Volume 1: Human Health Evaluation Manual (Part C, Risk Evaluation of Remedial Alternatives)," Office of Emergency and Remedial Response EPA/540/R-92/004, Interim.

(33) United States Environmental Protection Agency (US EPA), September 2011, "Exposure Factors Handbook: 2011 Edition," Office of Research and Development, EPA/600/R-090/052F.

(34) United States Environmental Protection Agency (US EPA), February 2012, "Superfund Vapor Intrusion FAQs."

(35) United States Environmental Protection Agency (US EPA), October 2015, "ProUCL Version 5.1 Technical Guide Statistical Software for Environmental Applications for Data Sets with and without Nondetect Observations", EPA/600/R-07/041.

(36) United States Environmental Protection Agency (US EPA), February 2014, "Human Health Evaluation Manual, Supplemental Guidance: Update of Standard Default Exposure Factors," OSWER Directive 9200.1-20.

(37) United States Environmental Protection Agency (US EPA), May 2014, "Vapor Intrusion Screening Level (VISL) Calculator User's Guide."

(38) United States Environmental Protection Agency (US EPA), June 2015, "OSWER Technical Guide for Assessing and Mitigating the Vapor Intrusion Pathway from Subsurface Vapor Sources to Indoor Air," OSWER 9200.2-154.

(39) United States Environmental Protection Agency (US EPA), June 2015, "Technical Guide for Addressing Petroleum Vapor

Intrusion at Leaking Underground Storage Tank Sites."

(40) United States Environmental Protection Agency (US EPA), March 2005, "Update of Ecological Soil Screening Level (Eco-SSL) Guidance and Contaminant Specific Documents".

(41) United States Environmental Protection Agency (US EPA), September 1986, "Guidelines for Mutagenicity Risk Assessment", EPA/630/R-98/003.

R315-101-12. Definitions.

(a) Terms used in Rule R315-101 regarding cleanup action and Risk-Based Closure Standards are defined as follows:

(1) "95% Upper Confidence Limit or 95% UCL" means an estimate of the arithmetic average concentration for a contaminant and it provides reasonable confidence that the true site average will not be underestimated.

(2) "95% Upper Tolerance Limit or 95% UTL" means a value not to be exceeded of possible background concentration values and so provides a reasonable upper limit on what is likely to be observed in the background with 95% confidence.

(3) "Acceptable Risk Range" means cancer risk greater than 1 x 10-6 but less than or equal 1 x 10-4 or a hazard index less than or equal to one with justifiable, reasonable and practicable measures in place to reduce and control risk within the range.

(4) "Action Level" means the existence of a contaminant concentration in the environment that is high enough to warrant an action or trigger a response action under the National Oil and Hazardous Substances Contingency Plan.

(5) "Adverse Effect" means any effect that causes harm to the normal functioning of plants or animals due to exposure to a chemical contaminant.

(6) "Appropriate Site Management Activities" means measures that are reasonable and practical that will be taken to control and reduce risks greater than 1×10^{-6} and less than 1×10^{-4} for carcinogen and hazard index equal to or less than one for non-carcinogens under both current and reasonably anticipated future land use conditions, for example, institutional controls, engineering controls, groundwater monitoring, post-closure care, or corrective action and ensuring that assumptions made in the estimation of cancer risk and non-cancer hazard in the risk assessment report are not violated.

(7) "Area of Contamination" means a hazardous waste management unit or a solid waste management unit or an area where a release has occurred.

(8) "Assessment Endpoints" means an explicit expression of environmental value that is to be protected. It is the part of the ecosystem that should be protected at a superfund site and it is generally some characteristic of a species of plant or animal, for example, reproduction, growth, that may be described numerically.

(9) "Background" means substances or locations that are not influenced by releases from a site and are naturally occurring in the environment in forms that have not been influenced by human activity or are natural and human-made substances present in the environment as a result of anthropogenic activities and not related to the site.

(10) "The boundary" means the furthest extent where contamination from a defined source has migrated in any medium at the time the release is first identified.

(11) "Cancer Risk" means the probability that an individual with contract cancer after life time exposure to a carcinogen.

(12) "Cleanup" means the range of corrective action activities that occur in the context of addressing environmental contamination at RCRA sites to lower contaminant concentration or decrease chemical toxicity. Activities may include waste removal, contaminated media removal or source reduction, such as excavation or pumping, in-place treatment of waste or contaminated media, such as bioremediation, containment of waste or contaminated media, such as barrier walls, low permeability covers, liners or capping, or various combination of these approaches. Waste cover up is not capping unless it meets some defined performance standards.

(13) "Concentration Term - 95% Upper Confidence Limit" means the intake variable and it is an estimate of the arithmetic average concentration for a contaminant based on a set of site sampling results. Because of the uncertainty associated with estimating the true average concentration at a site, the 95% Upper Confidence Limit of the arithmetic mean is used to represent this variable and provides reasonable confidence that the true site average will not be underestimated.

(14) "Complete Exposure Pathway" means how a contaminant may be traced or expected to travel from a source to a plant or animal that may be affected by that chemical and shall meet the following:

(a) the presence of a source and transport;

(b) exposure point or contact (receptor); and

(c) exposure route. Otherwise exposure is incomplete.

(15) "Conceptual Site Model" means a written, illustrative, or both, representation of a site that documents the physical, chemical and biological processes that control the transport, migration, actual or potential, or both impacts of contamination in soil, air, ground water, surface water, sediments, to human or ecological receptors, or both, exposure pathways, at a site or at a reasonably anticipated site under both current and potential future land use scenarios.

(16) "Contaminate" means to render a medium polluted through the introduction of hazardous waste or hazardous constituents as identified in Section R315-261-1092, which incorporates by reference 40 CFR 261, Appendix VIII.

(17) "Contaminants of Concern" means Constituents of Potential Concern that significantly contribute to a pathway in a land use scenario for a receptor that either exceeds a cumulative cancer risk of $1x10^{-4}$ or exceed a non-cancer hazard index of one.

(18) "Contaminants of Interest" means chemicals detected at the site during the site characterization process that may pose threat to human health or the environment.

(19) "Constituents of Potential Concern" means constituents detected in a medium that are selected to be addressed in the risk assessment process because contact with humans may result in adverse effects.

(20) “Constituents of Potential Ecological Concern” means any constituent that is shown to pose possible ecological risk at a site. It is generally a constituent that may or may not be causing risk or adverse effects to plants and animals at a site.

(21) "Corrective Action" means the cleaning up of environmental problems caused by the mismanagement of wastes, or the cleanup process or program under RCRA and any activities related to the investigation, characterization, and cleanup of release of hazardous waste or hazardous constituents from solid waste management units or hazardous waste management units at a permitted or interim status treatment storage or disposal facilities or voluntary cleanup sites or brownfield sites.

(22) "Corrective Action Complete With Controls" means a condition of a solid waste management unit, a hazardous waste management unit, an area of contamination or a contaminated site where site characterization or risk assessment indicate corrective action is required and completed and the results of the risk assessment meet the closure standards and requirements specified in Subsection R315-101-6(k), or a condition of a solid waste management unit, a hazardous waste management unit, area of contamination or a contaminated site where site characterization or risk assessment indicate corrective action is not required but also meets the closure standards and requirements specified in Subsection R315-101-6(k).

(23) "Corrective Action Complete Without Controls" means a condition of a solid waste management unit, a hazardous waste management unit, area of contamination or a contaminated site where site characterization or risk assessment indicate corrective action is required and completed and the results of the risk assessment meet the closure standards and requirements equivalent to a no further action or meeting the requirements of Subsections R315-101-6(l) or R315-101-6(f) or R315-101-6(j) or a condition of a solid waste management unit, a hazardous waste management unit, area of contamination or a contaminated site when site characterization or risk assessment indicate corrective action is not required but also meets the closure standards and requirements equivalent to a no further action or meeting the requirements of Subsections R315-101-6(l) or R315-101-6(f) or R315-101-6(j).

(24) "Corrective Action Level" means the concentration of a contaminant in a medium after cleanup of a site that is protective of human health and the environment.

(25) “Data Quality Objectives” means qualitative and quantitative statements of the quality of data needed to support specific decisions or regulatory actions.

(26) “Dilution Attenuation Factor” means the ratio of the contaminant concentration in soil leachate to the concentration in groundwater at the receptor point.

(27) "Environment" means the surroundings or conditions in which a person, animal, or plant lives or operates.

(28) “Exposure” means contact of an organism with a chemical or physical agent and it is the amount of the agent available at the exchange boundaries of the organism.

(29) “Exposure Pathway” means the course a chemical or physical agent takes from a source to an exposed organism.

(30) "Exposure Point Concentration" means either a statistical derivation of measured data or modeled data that represents an estimate of the chemical concentration available from a particular medium or route of exposure. The exposure point concentration value is used to quantify potential cancer risks and non-cancer hazards.

(31) "Groundwater Cleanup Levels" means site-specific groundwater chemical concentration levels based on groundwater use designation and exposure pathway established to ensure the protection of human health and the environment when defining groundwater cleanup objectives.

(32) "Groundwater Use" means the current or reasonably expected maximum beneficial use of groundwater that warrants the most stringent cleanup levels, drinking or other uses.

(33) "Hazard Index" means the sum of hazard quotients.

(34) "Hazard Quotient" means the ratio of exposed dose to some reference dose or reference concentration.

(35) “Lowest Observed Adverse Effects Level or Lowest Observed Adverse Effects Concentration” means the lowest level of a chemical stressor evaluated in a toxicity test that shows harmful effects on a plant or animal. A Lowest Observed Adverse Effects Level is based on dose of a chemical ingested while Lowest Observed Adverse Effects Concentration refers to direct exposure to a chemical such as through the skin.

(36) "Maximum Contaminant Level" means the highest level of a contaminant that is allowed in drinking water and are set as close to the "Maximum Contaminant Level Goal" as feasible using the best available treatment technology and taking cost into consideration. Maximum Contaminant Levels are enforceable standards.

(37) "Maximum Contaminant Level Goal” means the level of a contaminant in drinking water below which there is no known or expected risk to health. Maximum Contaminant Level Goals allow for a margin of safety and are non-enforceable public health goals.

(38) “Measures of Effects” means quantitative measurements of effects expressed as statistical or numerical assessment endpoint summaries of the observations that make up the measurement.

(39) “Measurement End Point” means a measurable ecological characteristic that is related to the valued characteristic chosen as the assessment endpoint and it is a measure of biological effects such as death, reproduction, or growth, of a particular species.

(40) "Natural Resources" means land, fish, wildlife, biota, air, water, ground water, drinking water supplies, and other similar resources.

(41) "No Further Action" means the state of a solid waste management unit, a hazardous waste management unit, or a contaminated site at closure meeting the requirements in Subsections R315-101-6(f) or R315-101-6(j) and it is equivalent to corrective action complete without controls if the site was under corrective action activities. No further action is equivalent to unrestricted land use.

(42) “No Observed Adverse Effects Level or No Observed Adverse Effects Concentration” means the highest level of a chemical stressor in a toxicity test that did not cause harmful effect in a plant or animal. A No Observed Adverse Effects Level refers to a dose of chemical that is ingested, while a No Observed Adverse Effects Concentration refers to direct exposure to a chemical such as through the

skin.

(43) "Point of Departure" means the target risk level that risk to an individual is considered insignificant.

(44) "Potentially Complete Exposure Pathway" means a pathway that, due to current site conditions is incomplete, but could become complete at a future time because of changing site practices. For example the ingestion pathway of groundwater from a residential well in a high total dissolved solids aquifer. This pathway could be complete if treatment technologies like reverse osmosis become economically feasible and are observed to be employed successfully in that aquifer.

(45) "Reasonable Maximum Exposure" means the highest exposure that is reasonably expected to occur at a site. Reasonable Maximum Exposure combines upper-bound and mid-range exposure factors so that the result represents an exposure scenario that is both protective and reasonable; not the worst possible case.

(46) "Regional Screening Levels" means risk-based chemical concentrations derived from standardized equations combing exposure assumptions with EPA chemical-specific toxicity values and target risk levels that are used for site screening and initial cleanup goals.

(47) "Release" means spill or discharge of hazardous waste, hazardous constituents, or material that becomes hazardous waste when released to the environment.

(48) "Responsible Party" means the owner or operator of a site, or any other person responsible for the release of hazardous waste or hazardous constituents.

(49) "Risk-Based Clean Closure" means closure of a site where hazardous waste was managed or any medium that has been contaminated by a release of hazardous waste or hazardous constituents, and where hazardous waste or hazardous constituents remain at the site in any medium at concentrations determined, in Rule R315-101, to cause minimal levels of risk to human health and the environment so as to require no further action or monitoring on the part of the responsible party nor any notice of hazardous waste management on the deed to the property.

(50) "Risk Based Concentration" means the concentration of a contaminant the values of which are derived from equations combining toxicity factors with standard exposure scenarios to calculate chemical concentrations corresponding to some fixed levels of risks in any media; such as water, air, fish tissue, sediment, and soil.

(51) "Robust Statistic" means a statistic that is resistant to errors in the results, produced by deviations from assumptions, such as, normality. This means that the limits are not susceptible to outliers, or distributional assumptions. For example, if the limits are centered on the median, instead of on the mean, or on a modified, "robust mean," and constructed with suitable weighting, or influence, function, they could be considered "robust."

(52) "Site" means the area of contamination and any other area that could be impacted by the released contaminants, or could influence the migration of those contaminants, regardless of whether the site is owned by the responsible party.

(53) "Site Specific Screening Value" means contaminant screening values derived for media, such as soil, sediment, water, at a site based on relevant site assumptions and factors.

(54) "Source Control" means a range of actions, for example, removal, treatment in place and containment, designed to protect human health and the environment by eliminating or minimizing migration of or exposure to significant contamination.

(55) "Target Risk" means any acceptable specified risk level. The preferred Target Risk is $1x10^{-6}$ which is at the protective end of the acceptable risk range for screening of contaminants in risk assessment.

KEY: hazardous waste
Date of Enactment or Last Substantive Amendment: April 25, 2013
Notice of Continuation: March 10, 2016
Authorizing, and Implemented or Interpreted Law: 19-6-105; 19-6-106