State of Utah

GARY R. HERBERT
Governor

SPENCER J. COX
Lieutenant Governor

Department of
Environmental Quality

Alan Matheson
Executive Director

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

A meeting of the Waste Management and Radiation Control Board has been scheduled for June 13, 2019 at 1:30 p.m. at the Utah Department of Environmental Quality, Multi-Agency State Office Building. This will be a telephonic meeting held in accordance with the Utah Open and Public Meetings Act.

One or more Board members will participate telephonically. (Audio Conferencing Access Number: 1-877-820-7831; Passcode Number: 853610#)

The anchor location of this Board meeting will be the Utah Department of Environmental Quality, Multi-Agency State Office Building, Red Rocks Conf. Room #3132, 195 North 1950 West, SLC.

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 May 9, 2019 Board Meeting (**Board Action Item**).

V. Underground Storage Tanks Update.

VI. Radioactive Materials.

A. Approval to proceed with formal rulemaking and 30-day public comment period for proposed rule changes to R313-19-34, R313-22-75, and R313-32 of the Radiation Control Rules to incorporate changes promulgated by the Nuclear Regulatory Commission and published in the July 16, 2018 *Federal Register* (83 FR 33046) with an additional proposed change to R313-32-2(5) **(Board Action Item)**.

VII. Other Business.

a. Misc. Information Items.
b. Scheduling of next Board meeting.

VIII. Adjourn.

In compliance with the Americans with Disabilities Act, individuals with special needs (including auxiliary communicative aids and services) should contact Kimberly Diamond-Smith, Office of Human Resources at (801) 536-4285, Telecommunications Relay Service 711, or by email at “kdiamondsmith@utah.gov”.

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Waste Management and Radiation Control Board Meeting
Utah Department of Environmental Quality
195 North 1950 West (Conference Room #1015) SLC, Utah
May 9, 2019
1:30 p.m.

Board Members Present: Brett Mickelson (Chair), Dennis Riding (Vice-Chair), Scott Baird, Deputy Director (Acting for Alan Matheson), Richard Codell, Mark Franc, Jeremy Hawk, Steve McIff, Shawn Milne, Nathan Rich and Shane Whitney

Board Members Telephonic Participation: Danielle Endres and Vern Rogers

Board Members Absent/Excused: Alan Matheson

Staff Members Present: Ty Howard, Therron Blatter (Acting for Brent Everett), Tom Ball, Edward Costomiris, Deborah Ng, Arlene Lovato, Rusty Lundberg, Tina Mercer, Allan Moore, Rick Page, Alma Rosas, Elisa Smith, Raymond Wixom and Otis Willoughby

Others Present: William Simmons, Melissa Scales, Tyler Lee, Tim Orton
Others Telephonic Participation: David Cronshaw

I. Call to Order.

Brett Mickelson (Chair) welcomed all in attendance and called the meeting to order at 1:30 p.m. Board members Danielle Endres and Vern Rogers participated via telephonically.

II. Public Comments. – None.

III. Declarations of Conflict of Interest.

Jeremy Hawk declared a conflict of interest and informed the Board that he is one of the individuals requesting the Board's approval to be certified as a Mammography Imaging Medical Physicists and will abstain from voting on Agenda Item VI. A.

Shane Whitney declared a conflict of interest and will abstain from voting on Agenda Item VII. A.

Vern Rogers declared a conflict of interest and will abstain from voting on Agenda Item VIII. A.

IV. Approval of Meeting Minutes for the February 14, 2019 Board Meeting (**Board Action Item**).

It was moved by Shane Whitney and seconded by Jeremy Hawk and UNANIMOUSLY CARRIED to approve the April 11, 2019 Board Meeting minutes.

V. Underground Storage Tanks Update.

Therron Blatter, Underground Storage Tank Branch Manager 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 March 2019 was $13,826,130.00. The preliminary estimate for the cash balance of the PST Trust Fund for the end of April 2019 is $13,764,148.00. The PST Trust Fund is managed on a cash balance basis to ensure sufficient coverage for known claims that have been reported. The DERR continues

to watch the cash balance closely, as we have, particularly with the passage of House Bill 120, which increased the coverage under the fund from $990,000.00 to $1,990,000.00.

VI. X-Ray Program.

A. Approval of Mammography Imaging Medical Physicists (MIMPs) in accordance with UCA 19-6-104(2)(b) (Board Action Item).

Tom Ball, Planning and Technical Support Section Manager of the Division of Waste Management and Radiation Control, reviewed the request for the Board's approval of qualified Mammography Imaging Medical Physicists (MIMPs). Mr. Ball stated that individuals referred to as MIMPs must submit an application for review of qualifications to be certified by the Board annually. These physicists perform radiation surveys and evaluate the quality control programs of the facilities in Utah providing mammography examinations.

In April 2019, sixteen individuals filed applications to be recertified as a MIMP. Fifteen of the applicants are renewals and one new application was received this year. Division staff has reviewed the applicants' qualifications. All applicants meet the requirements detailed in R313-28-140 of the Utah Administrative Code. A list of the applicants was included in the Board's packet.

The Director of the Division of Waste Management and Radiation Control recommends the Board issue a certificate of approval for the sixteen applicants presented to the Board.

Tom Ball clarified that the current rules require MIMPs to submit their application annually to be recertified. However, a new applicant can submit an application at any time throughout the year and then will be added to the group submitted to the Board for their yearly approval. The rule would have to be amended to allow for any flexibility regarding approving timeframes other than the annual renewal, etc.

It was moved by Shawn Milne and seconded by Dennis Riding and UNANIMOUSLY CARRIED to approve the Mammography Imaging Medical Physicists (MIMPs) in accordance with UCA 19-6-104(2)(b).

VII. Hazardous Waste Section.

A. Approval of proposed Stipulation and Consent Order between the Board and Clean Harbors, Aragonite (Board Action Item).

Deborah Ng, Hazardous Waste Section Manager of the Division of Waste Management and Radiation Control, provided an overview of the Stipulation and Consent Order (SCO) No. 1410021 to resolve Notice of Violation No. 1401002 issued to Clean Harbors Aragonite, LLC (CHA) on April 17, 2014, and violations discovered during inspections of the facility or violations reported by CHA during fiscal years 2014 through 2018 (FY2014 through FY2018). This item was presented to the Board as an information item in the April 11, 2019 Board meeting.

A tolling agreement has been established between the Director and CHA to allow for the continued negotiations while preserving CHA rights to appeal. The inspections conducted in 2014 through 2018 had similar violations as found during the inspection in 2013. The Director and CHA felt it was in the best interest of both parties to combine all violations into one SCO for resolution. The proposed SCO includes a penalty of $330,000.00 for the violations identified during the time period of FY2013 through FY2018.

The 30-day public comment period for this SCO began on March 19, 2019 and ended on April 18, 2019. No comments were received. This is a Board Action Item and the Director recommends approval of the proposed SCO.

Representatives from Clean Harbors were in attendance at the meeting to answer any questions.

Dennis Riding questioned if the violations were all the same during the six year period and whether the Division anticipates the violations will continue. Ms. Ng stated the violations were very similar and CHA has hired a new General Manager, Mr. William Simmons, who could provide better insight regarding future facilities operations.

Mr. William Simmons, Clean Harbors Facility General Manager, informed the Board that he has been employed by Clean Harbors for approximately eleven years and has recently moved to Utah to manage CHA. Mr. Simmons mentioned the elements he anticipates will benefit the facility's operations. Mr. Simmons thanked the Division staff and feels good about the progress that is being achieved and from his perspective, CHA is seeing a significant reduction in repeat violations. Mr. Simmons indicated there has been a tremendous amount of staff training and he is now holding them accountable for their actions.

Mr. Rich questioned what the specific violations were and whether the SCO included anything besides the penalty assessed. Ms. Ng stated that part of the initial settlement negotiation discussions included the facility performing supplemental environmental projects. However, during negotiations it was agreed that the proposed settlement would be a monetary penalty.

Mark Franc questioned the amount of the penalty and what considerations were made in determining it. Mr. Franc stated that one intent of a penalty is its deterrent factor and although $330,000.00 seems like a lot of money, if you break it down it equals roughly $50,000.00 a year, and questioned if some less than scrupulous businesses would consider that just a cost of doing business.

Rusty Lundberg, Deputy Director of the Division of Waste Management and Radiation Control, stated that Mr. Franc's question is a valid one. Mr. Lundberg informed the Board that penalties are negotiated with a company, unless the courts are directly involved. The first option of the Division is to work with the facility to negotiate an agreement for an appropriate penalty. The Division considers an amount that would be a deterrent as well as allows for the corrective actions the facility needs to make to stay in compliance. Mr. Lundberg also stated the Division looks at other factors and briefly discussed them. Mr. Lundberg stated that this SCO is different than those the Board has approved in the past, as different aspects were looked at during the negotiation process than is normally used.

Mr. Franc asked if the Division felt that this penalty amount is sufficient to act as deterrent for CHA. Mr. Lundberg stated that with the hiring of the new manager, facility and employee commitment and their willingness to work with Division staff, it is anticipated that it will benefit the overall operations at the facility and help them operate in a compliant manner.

Shawn Milne stated that he appreciates the comments made from Board member Mr. Franc. Mr. Milne reviewed his history regarding his commitment to CHA in Tooele County. Mr. Milne stated that when he sticks out his neck for CHA and finds out about situations like this, it is an embarrassment to him and brings shame upon the community as a whole. Mr. Milne stated that he agrees with Mr. Franc and feels that $330,000 penalty is fairly diminutive and felt he needed to express his opinion as he represents the affected community. Mr. Milne described a situation dealing with a repeat offender in his county and his desire that something be done that benefits the community he serves. Mr. Milne asked that in the future if the Division staff could work with the local community, local jurisdiction, etc. Mr. Milne acknowledged that CHA is a good corporate citizen by and large, but when offenses are made that bring shame to the community he

would appreciate being informed and to discuss the matters as a community partner. Mr. Milne stated that depending on what this is, and the infraction details, it may be rather diminutive and just the cost of doing business that a company is willing to absorb, but he doesn't want to ever be in the position to have to defend this type of matter within his jurisdiction.

Mr. Lundberg stated that Commissioner Milne's statements are valid points and the Division looks for a balance for the community impacted and that is why a supplemental environment projects are often negotiated. Mr. Lundberg further stated that the overall intent is to look at what other options are valid other than just a cash penalty settlement. Ms. Ng stated that negotiation discussions included options for supplemental environmental projects, such as a household hazardous waste collection project. Commissioner Milne stated that type of event would be well received, as it would benefit the local community.

Dennis Riding asked if a supplemental environmental project was discussed during the settlement agreements. Mr. Lundberg stated that yes, environmental projects were considered however, CHA felt that if they could dedicate more to a "cash" penalty and move forward with new management, a fresh start, then they would consider incorporating supplemental environmental projects if futures violations occur.

Mr. Simmons stated that CHA does not condone being in noncompliance or tolerant violating the rules. Clean Harbor's has the highest expectations from him, the facility and his team. These issues are at CHA not at a corporate level. The corporate level made the change with him and he could not be more proud of the company he works for. Mr. Simmons described the collection of household waste community event that recently took place in the area and reiterated that Clean Harbors has a definitive affection for being a good community member and that he is here to support that. CHA is holding community events, including providing funds back to the community, and this is not only to try support the community, but it is to also get their company name out to the community, as they want to be known as a good employer, etc. At the corporate level Clean Harbors has the highest expectations and the lowest tolerance for violations. CHA has over $8 million in projects they are currently working on and several Class III modifications have been submitted to the State.

It was moved by Mark Franc and seconded by Shawn Milne and UNANIMOUSLY CARRIED to approve the proposed Stipulation and Consent Order between the Board and Clean Harbors, Aragonite.

VIII. Low-Level Radioactive Waste Section.

A. Approval of Energy*Solutions*' request for a site-specific treatment variance from the Utah Administrative Code. Energy*Solutions* seeks authorization to treat waste containing High-Subcategory Mercury by stabilization (Board Action Item).

Otis Willoughby, Environmental Scientist, Low Level Radioactive Waste Section of the Division of Waste Management and Radiation Control, reviewed Energy*Solutions*' request submitted on March 25, 2019, for a site specific treatment variance from the Utah Administrative Code to treat by stabilization, waste containing High-Subcategory Mercury. This agenda item was presented to the Board as an information item in the April 11, 2019 Board meeting.

Energy*Solutions* requested approval to receive and dispose, in Energy*Solutions*' Mixed Waste Landfill Cell, waste containing the D009 or U151 High Mercury-Organic Subcategory and High Mercury-Inorganic Subcategory hazardous waste codes that has been treated using stabilization/amalgamation technologies.

The 30-day public comment period for this variance began April 2, 2019 and ended May 2, 2019. No public comments were received.

The Director recommended approval of this variance based on the following findings: the proposed alternative treatment method meets the regulatory basis for a variance, will be as safe to human health and the environment as the required method, and the required method would create additional waste, and require waste handling that could possibly expose workers to unnecessary contact with the waste. This treatment is recommended by the USEPA and Energy*Solutions* has successfully treated similar waste streams in the past using this approach.

Dennis Riding asked if this is a new variance. Mr. Willoughby stated that this is the sixteenth time Energy*Solutions* has requested similar site-specific treatment variances for High Mercury Subcategory waste. This variance request consists of waste that may be shipped to Energy*Solutions* over the next year. To date, Energy*Solutions* has disposed of approximately 11,100 cubic feet of treated High Mercury Subcategory waste. From knowledge of the current market of High Mercury Subcategory waste requiring treatment or disposal, and from past experience receiving this type of waste, Energy*Solutions* anticipates less than 500 cubic feet of additional High Mercury Subcategory waste for disposal in the next year under this treatment variance.

It was moved by Dennis Riding and seconded by Richard Codell and UNANIMOUSLY CARRIED to approve Energy*Solutions*' request for a site-specific treatment variance from the Utah Administrative Code. Energy*Solutions* seeks authorization to treat waste containing High-Subcategory Mercury by stabilization.

IX. Presentation on the Utah Waste Tire Recycling Act Reauthorization.

Allan Moore, Solid Waste Section Manager of the Division of Waste Management and Radiation Control, informed the Board that the Utah Waste Tire Recycling Act Reauthorization presentation will also be presented to the Natural Resource, Agriculture and Environment Legislative Interim Committee in the near future. The Waste Tire Recycling Act will sunset next year and the Division has been asked to present information to the committee. (A copy of the PowerPoint is available with the meeting minutes).

Mark Franc asked about the goals of the fund, i.e., is the intent to eliminate used tire piles and to accommodate recycling of those tires? He had questions regarding the availability of those funds to the counties.

Mr. Moore stated that the intent is to eliminate used tire piles and if a county has a tire pile, the Division will work with them to access funds for cleanup. The funds are available for abandoned tire piles as well as landfill tire piles. Mr. Franc asked if a private entity has tire piles, could they work with their county to obtain the funds to clean up the tire piles? Mr. Moore stated, yes, and the Division will work with the local government entity to distribute the funds, etc. Ty Howard clarified a "tire pile" is defined in the rules as a collection of over 1,000 tires.

Brett Mickelson stated that the methodology in small rural landfills is to bury the tires and asked if the Division anticipates any of those small facilities piling up 1,000 tires to try to take advantage of this funding option. Mr. Moore stated that now many of the landfills do not bury tires, but, instead have large tire piles because they collect them rather than dispose of them. Mr. Moore stated that the recent audit pointed out that landfills should not be creating tire piles. Mr. Mickelson asked if this issue will be reflected in permit renewals etc. to clarify some of these issues. Mr. Moore stated that, yes, there will be some changes made to permits. Mr. Franc stated that the solid waste rules allow for incidental tires within the waste stream and in attempt to be a good citizen some landfill operators pull them out, but from a regulatory standpoint it might

be preferable to leave those incidental tires in the landfill. As a result you may see tires in the landfill, which wouldn't mean they are accepting tires other than those incidental tires. Mr. Moore reviewed the tire pile incident/cleanup of the hundreds of tires illegally dumped at the Lee Kay Ponds.

Mr. Rich questioned if it wouldn't be more efficient to help landfills accept tires and then have them recycled rather than waiting for a tire pile to be created, which would eventually cost the fund to recycle them. Mr. Moore stated that is a difficult question to answer as that was debated with the legislative auditors over management of tires specifically in rural landfills. A viable solution is needed to manage tires in rural Utah. In rural Utah, if a landfill does not accept tires they will end up in a ravine, etc. Mr. Rich stated that if you have a facility designated to accept and manage tires there should be a way to weave the program to take advantage of that. Mr. Moore stated that the Division will continue to work with legislators to come up with a solution.

Scott Baird, Deputy Director of the Department of Environmental Quality, questioned if these types of issues should be included as part of the presentation that is going to be given at the upcoming Natural Resources, Agriculture and Environment Legislative Interim Committee meeting. Given the legislature is always looking for good ideas to help communities and improve programs. It should not be an issue in moving the reauthorization of the act forward, but it may be an opportunity to raise these issues. Mr. Baird stated that if there are other questions, it would be valuable to have some feedback to present to the Interim Committee. Mr. Baird and Mr. Moore stated that these issues will be incorporated in the presentation with the legislators.

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

Mr. Mickelson informed the Board that each year a board chairman and vice-chairman must be elected. Mr. Mickelson then conducted the election.

Shane Whitney nominated Brett Mickelson to serve as the Board Chairman, Mark Franc seconded the motion. Shawn Milne moved to close the nomination and accept Brett Mickelson by acclamation.

It was moved by Shane Whitney and seconded by Mark Franc and UNANIMOUSLY CARRIED that Brett Mickelson be elected to serve as the Board Chairman.

Steve McIff nominated Dennis Riding to serve as the Board Vice-Chairman, Mark Franc seconded the motion. Shawn Milne moved to close the nomination and accept Dennis Riding by acclamation.

It was moved by Steve McIff and seconded by Mark Franc and UNANIMOUSLY CARRIED that Dennis Riding be elected to serve as the Board Vice-Chairman.

XI. Other Business.

A. Misc. Information Items. – None to Report.
B. Scheduling of next Board.

The next Board meeting will be held on June 13, 2019 at 1:30 p.m. at the Utah Department of Environmental Quality, located at 195 North 1950 West, SLC.

XII. Adjourn.

The meeting adjourned at 2:30 p.m.

UST STATISTICAL SUMMARY
May 1, 2018 -- April 30, 2019

PROGRAM

	May	June	July	August	September	October	November	December	January	February	March	April	(+/-) OR Total
Regulated Tanks	4,066	4,061	4,058	4,067	4,068	4,065	4,072	4,068	4,062	4,067	4,071	4,071	**5**
Tanks with Certificate of Compliance	3,976	3,982	3,986	3,992	3,986	3,989	3,990	3,999	4,002	3,998	4,000	4,004	**28**
Tanks without COC	90	79	72	75	82	76	82	69	60	69	71	67	**(23)**
Cumulative Facilitlies with Registered A Operators	1,264	1,261	1,296	1,300	1,299	1,300	1,302	1,304	1,302	1,300	1,298	1,297	**97.45%**
Cumulative Facilitlies with Registered B Operators	1,306	1,303	1,301	1,304	1,303	1,302	1,304	1,306	1,304	1,302	1,300	1,298	**97.52%**
New LUST Sites	7	6	15	5	7	7	9	4	2	4	3	4	**73**
Closed LUST Sites	13	5	15	16	6	16	4	7	9	4	2	3	**100**
Cumulative Closed LUST Sites	5125	5131	5146	5162	5167	5182	5187	5196	5204	5209	5212	5215	**90**

FINANCIAL

	May	June	July	August	September	October	November	December	January	February	March	April	(+/-)
Tanks on PST Fund	2,698	2,704	2,704	2,703	2,690	2,692	2,696	2,697	2,693	2,689	2,687	2,694	**(4)**
PST Claims (Cumulative)	686	687	688	686	687	688	688	689	689	690	690	692	**6**
Equity Balance	-$14,562,872	-$14,838,728	-$14,362,717	-$14,322,626	-$12,290,504	-$11,828,687	-$11,575,752	-$12,246,462	$12,233,897	$11,795,381	$12,311,881	$12,373,863	**$26,936,735**
Cash Balance	$13,882,024	$13,606,168	$14,082,179	$14,122,270	$13,847,507	$14,309,324	$14,562,259	$13,891,549	$13,904,114	$14,342,630	$13,826,130	$13,764,148	**($117,876)**
Loans	1	0	0	0	0	0	0	0	2	2	0	0	**-1**
Cumulative Loans	113	113	113	113	113	113	113	113	115	117	117	117	**4**
Cumulative Amount	$4,229,887	$4,229,887	$4,229,887	$4,229,887	$4,229,887	$4,229,887	$4,229,887	$4,229,887	$4,253,415	$4,317,727	$4,317,727	$4,317,727	**$87,840**
Defaults/Amount	1	1	1	1	1	1	1	1	1	1	1	1	**0**

	May	June	July	August	September	October	November	December	January	February	March	April	TOTAL
Speed Memos	51	31	16	38	20	29	25	0	25	16	28	63	**342**
Compliance Letters	1	7	3	13	7	6	0	1	4	4	10	2	**58**
Notice of Intent to Revoke	0	0	0	0	1	0	0	0	0	0	0	0	**1**
Orders	0	0	0	1	0	0	1	0	0	1	0	2	**5**

WASTE MANAGEMENT AND RADIATION CONTROL BOARD
EXECUTIVE SUMMARY
Proposed Amendments to Radiation Control Rules
R313-19-34, Terms and Conditions of Licenses, R313-22-75, Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices Which Contain Radioactive Material and R313-32, Medical Use of Radioactive Material
June 13, 2019

What is the issue before the Board?	Board approval to initiate formal rulemaking and receive public comment on proposed changes to R313-19-34, *Terms and Conditions of Licenses*, R313-22-75, *Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices Which Contain Radioactive Material.*, and R313-32, *Medical Use of Radioactive Material*, of the radiation control rules to incorporate federal regulatory changes promulgated by the Nuclear Regulatory Commission (NRC) and published in the *Federal Register* on July 16, 2018 (83 FR 33046). The Director is also requesting the addition of the following wording to the requirements in 10 CFR 35.92. The wording is being added to address anticipated variance requests from the Board due to the use of a new radioactive drug at medical facilities: (b) The Director may approve a radioactive material with a physical half-life of greater than 120 days but less than 175 days for decay-in-storage before disposal without regard to its radioactivity on a case by case basis if the licensee: (1) Requests an amendment to the licensee's radioactive materials license for the approval; (2) Can demonstrate that the radioactive waste will be safely stored, and accounted for during the decay-in-storage period and that the additional radioactive waste will not exceed the licensee's radioactive waste storage capacity; and (3) Commits to monitor the waste before disposal as stated in paragraphs (a)(1) and (a)(2) of this section before the waste is disposed."
What is the historical background or context for this issue?	On July 16, 2018, the NRC amended the federal radioactive materials regulations regarding the medical use of radioactive material. These amendments update the medical use of radioactive materials requirements which were last updated in their entirety in 2002. The proposed rule changes address technological advances, changes to medical procedures, and enhance patient safety. In addition, the NRC amended certain federal requirements for radioactive materials licensees that manufacture and prepare radioactive drugs for distribution to medical use licensees for administration to patients. R313-19-34(8) changes the requirement to include a quality control test for each generator eluate of a molybdenum-99/technitium-99m generator and introduces a requirement for generator users to report test results for

any generator that exceeds the permissible breakthrough concentration.

The proposed changes to R313-22-75 clarifies the requirements for the labels for radioactive drugs and removes the requirement for a written attestation statement for individuals who are board certified by an approved specialty board and who seek to be named on a radioactive materials license as an Authorized Nuclear Pharmacist.

Because R313-32 incorporates by reference 10 CFR Part 35, the date of the incorporation by reference was changed from 2010 to 2019 which includes the changes published by the NRC on July 16, 2018. Some of the major changes included in the revised rules are as follows:

- Written attestation statements will no longer be required to be submitted for individuals who are board certified by an appropriate approved specialty board and are seeking to be named on a radioactive materials license as an authorized user; authorized medical physicist, or authorized nuclear pharmacist;
- The ability to have an Associate Radiation Safety Officer (ARSO) named to the license and requirements related to ARSOs were added;
- The medical event criteria was modified and new requirements for medical events involving permanent brachytherapy implants were added;
- Requires licensees to develop specific procedures;
- An addition of a requirement to providing reports to the DWMRC for breakthrough tests exceeding permissible concentrations; and
- Adds a new training requirement for the use of remote afterloader units, teletherapy devices and gamma stereotactic surgery units;

In addition to the changes to adopt the NRC revisions as stated above, Board approval is requested to add a requirement for an issue not addressed by the NRC. The requirements in 10 CFR 35.92 include specific requirements for holding radioactive waste for "decay-in-storage" (DIS) if the radioactive materials have half-lives of 120 days or less. Radioactive waste containing materials with longer half-lives is required to be disposed as low-level radioactive waste (LLRW). Recently, a new radioactive drug using Lutetium-177 (Lu-177) was introduced into use at medical facilities. It has been determined that this drug contains a very small quantity of a radioactive impurity that has a half-life of about 161 days. If the impurity is detected in the radioactive waste, the waste created from the administration of Lu-177 would be required to be disposed as LLRW unless a variance from the Board was requested.
In anticipation of the increased use of this radioactive drug, the Director recommends that the proposed requirement allowing the Director to approve an amendment for the DIS of radioactive waste with half-lives greater than 120 days but less than 175 days on a case by case basis.
For approval, the licensee would be required to demonstrate that the waste will be secured and safely stored, that the additional waste would not exceed the licensee's storage capacity, and that the licensee will meet the

	survey criteria required for DIS waste with half-lives of 120 days or less. Following this summary, the following documents are provided: • Draft rule analysis forms • Proposed rule changes to R313-19-34, R313-22-75, and R313-32
What is the governing statutory or regulatory citation?	The Board is authorized under Subsection 19-3-104(4)(b) 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 19-6-104(1) to make rules necessary to implement the Radiation Control Act. The proposed rule changes also meet existing DEQ and state rulemaking procedures.
Is Board action required?	Yes, Board action is required to publish the proposed rule changes in the *Utah State Bulletin* and start a 30-day public comment period.
What is the Division Director's recommendation?	The Director recommends that the Board authorize the publication of the proposed rule changes in the *Utah State Bulletin* and commence a 30-day public comment period. With the Board's approval, it is anticipated that the proposed rule changes will be published in the July 1, 2019 issue of the *Utah State Bulletin* with the public comment period beginning on July 1 and ending on July 31, 2019.
Where can more information be obtained?	For questions or additional information, please contact Gwyn Galloway (801-536-4258, ggalloway@utah.gov) or Rusty Lundberg (801-536-4257, rlundberg@utah.gov)

State of Utah
Administrative Rule Analysis

NOTICE OF PROPOSED RULE

* The agency identified below in box 1 provides notice of proposed rule change pursuant to Utah Code Section 63G-3-301.
* Please address questions regarding information on this notice to the agency.
* The full text of all rule filings is published in the Utah State Bulletin unless excluded because of space constraints.
* The full text of all rule filings may also be inspected at the Division of Administrative Rules.

DAR file no:		Date filed:	
State Admin Rule Filing Id:		Time filed:	

		Agency No.		Rule No.		Section No.
Utah Admin. Code Ref (R no.):	**R**	313	-	19	-	34
Changed to Admin. Code Ref. (R no.):	**R**		-		-	

1.

Agency:	Waste Management and Radiation Control
Room no.:	2nd Floor
Building:	Multi-Agency State Office Building (MASOB)
Street address 1:	195 North 1950 West
Street address 2:	
City, state, zip:	Salt Lake City, UT, 84116
Mailing address 1:	PO Box 144880
Mailing address 2:	
City, state, zip:	Salt Lake City, UT, 84114-4880
Contact person(s):	

Name:	Phone:	Fax:	E-mail:
Gwyn Galloway	801-536-4258	801-536-0222	

(Interested persons may inspect this filing at the above address or at the Division of Administrative Rules during business hours)

2. **Title of rule or section** (catchline)**:**

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

3. **Type of notice:**

New ___; Amendment _X_; Repeal ___; Repeal and Reenact ___

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

The rule changes are proposed in order to maintain compatibility with the U.S. Nuclear Regulatory Commission (NRC) requirements and to enhance patient safety. To maintain the authority to regulate the use of certain licensed radioactive materials in the State of Utah, the State must maintain rules that are compatible with NRC requirements. Recent changes to 10 CFR Part 35 and related requirements were adopted by the NRC and published in the July 16, 2018 Federal Register (83 FR 33046). This proposed rule change maintains compatibility with the changes published for the requirements in 10 CFR 30.34(g).

5.	**This change is a response to comments from the Administrative Rules Review Committee.**
	No _X__; Yes ___
6.	**Summary of the rule or change:**
	The proposed rule change incorporates the requirements of 10 CFR 30.34(g) and consequently the requirements of 10 CFR 35.204(a) which requires commercial radiopharmacies to test each eluate from the elution of Molybdenum-99/Technetium (Mo-99/Tc-99m) generators for breakthrough instead of testing only the first eluate from the generator. Additionally, the change requires that results of breakthrough tests that exceed permissible concentrations from all medical generators be reported to the Director of the Division of Waste Management and Radiation Control (DWMRC) and the manufacturer of the generator. The reports must be made within a specified time frame and must be made by telephone and in writing.
7.	**Aggregate anticipated cost or savings to:**
	A) State budget:
	Affected: No ___; Yes _X__
	In the State of Utah there are two State owned entities that provide commercial radiopharmcy services (NAICS# 325412). Only one of these entities uses medical generators to prepare dosages for distribution to other licensees for medical use under the provisions of R313-32. Until 2002, testing each eluate of a Mo-99/Tc-99m medical generator for breakthrough was required. The 2002 revisions of 10 CFR Part 35 eliminated this requirement. Presently, only the initial elution of a Mo-99/Tc-99m medical generator is required to be tested for the breakthrough concentration of a specific impurity. Subsequent elutions are not required to be tested. Even so, radiopharmacy licensees in the State of Utah continued to test every eluate for the breakthrough concentrations. Due to certain incidents that occurred after 2002, the NRC determined that the requirement was necessary for patient safety. The requirement was reinstated in the regulations and a reporting requirement was added. Because the radiopharmacies in the State of Utah continued to test each eluate from the Mo-99/Tc-99m generators, there will be no increase to the number of breakthrough tests that must be conducted. The number of tests that may exceed the permissible concentration limits is not known but is estimated by the NRC to be about seven reports per year based on reports voluntarily made by medical licensees across the nation. The reports must be made by the licensee to the Director of the Division of Waste Management and Radiation Control (DWMRC) and the generator's manufacturer. The licensee's presently report any breakthrough test that exceeds the permissible concentration to the generator's manufacturer, therefore the proposed rule will only add a requirement to make the report to the Director of DWMRC. There are no fees proposed in the rule changes, therefore there are no direct or indirect fiscal impacts associated with the proposed rules. Since no additional breakthrough testing will be required and the required reports are presently made to the generator's manufacturer, the licensee is expected to experience a direct fiscal impact related to reporting breakthrough tests that exceed the permissible concentration to the Director of DWMRC. Using the estimated personnel time required to make the report and the mean hourly wage of a pharmacist to determine the potential costs associated with seven reports for results that exceed the permissible concentration, it is expected that the licensee may experience a direct fiscal impact of about $420. The proposed rule change requires licensees to report the results of medical generator breakthrough tests that exceed permissible concentration limits to the Director of the DWMRC. There are no fees associated with the rule change; therefore. there are no expected direct or indirect fiscal impacts for the revenues or expenditures of the DWMRC. Using the number of reports that may be made to the Director each year by all affected licensees, as estimated by the NRC, the DWMRC may receive about 14 reports annually. Based on the number of reports, the estimated time for processing the

	reports and evaluating the incident, and estimated personnel costs, the DWMRC is expected to experience an indirect fiscal impact of about $2,520 per year.
	B) Local government:
	Affected: No __X_; Yes ___
	The proposed rule changes are not expected to have any fiscal or fiscal impacts on local government revenues or expenditures because interactions due to the proposed rules with government agencies all occur at the State Government level. There is no interaction of local government agencies with either the licensee or the DWMRC with respect to this rule.
	C) Small businesses ("small business" means a business employing fewer than 50 persons)**:**
	Affected: No ___; Yes _X__
	There is one small business in the State of Utah that has been issued a radioactive materials license to provide commercial radiopharmacy services (NAICS# 325412) in the State. The assumptions as stated above in 7.A remain the same for the analysis of the impacts to the small business. The commercial radiopharmacy uses Mo-99/Tc-99m generators and other medical generators to prepare dosages for distribution to other licensees who use radioactive materials for medical use under the provisions of R313-32. The proposed rules will require the licensee to test each eluate from the Mo-99/Tc-99m generator to ensure that the breakthrough does not exceed the permissible concentration; however, the radiopharmacy presently performs this testing and there will be no change to the licensees operations due to the proposed rule. Additionally, the proposed rule requires that a breakthrough test that exceeds the permissible concentration be reported to the State and the manufacturer. Reports are currently made to the manufacturer if a permissible breakthrough concentration limit is exceeded as required by the manufacturer. Based on voluntary reports made to the NRC over the years, the NRC estimates that licensees will report approximately seven tests where the results of breakthrough tests exceed the permissible concentration each year. The licensee is expected to have a direct fiscal impact related to the reporting requirement of about $420 per year. There are no other direct fiscal impacts expected to be experienced by the licensee.
	D) Persons other than small businesses, businesses, 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)**:**
	Affected: No _X__; Yes ___
	It is possible that the 47 medical use radioactive materials licensees could experience an indirect fiscal impact from the proposed rules if the radiopharmacy licensees increase the prices they charge for the dosages they prepare from the Mo-99/Tc-99m eluate due to the increased indirect fiscal costs they will incur; however, the expected costs to the licensee are not significant. Therefore, it is likely that the prices charged to medical use licensees will remain the same. At this time, it is not expected that medical use licensees will experience direct or indirect fiscal impacts due to these proposed changes.
8.	**Compliance costs for affected persons:**
	The affected licensees will experience an estimated total of $420 annually to remain compliant with the proposed rule.
9.	**A) Comments by the department head on the fiscal impact the rule may have on businesses:**
	Although the proposed rule will directly cost the affected licensees about $420 in personnel costs to provide the required reports to the State, the proposed rules are necessary to enhance patient safety. There were a number of cases where a medical generator's eluate exceeded the permissible concentration limit and was found by a licensee that was voluntarily testing the eluates at a greater

	frequency than required. There were also a number of cases where a patient set off a monitoring portal after the medical isotope they had been administered should have decayed to undetectable levels. This was the result of the breakthrough concentration exceeding the permissible concentration at the time of administration to the patient. Since there was no reporting requirement, even though a few of these instances occurred simultaneously in different parts of the nation, the NRC and the Agreement States were not able to quickly identify the issue and address corrective measures. The reporting requirement was proposed to address patient safety and provide a mechanism for tracking and a timely response and solution to address the unnecessary patient exposure to radiation from elevated breakthrough concentrations. Given the small number of expected reports that will be made to the DWMRC, processing the reports will have a minimal impact on the work assigned to DWMRC personnel.
	B) Name and title of department head commenting on the fiscal impacts:
	Alan Matheson, Executive Director, Department of Environmental Quality

10. This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws.
State code or constitution citations (required) (e.g., Section 63G-3-402; Subsection 63G-3-601(3); Article IV) **:**

19-3-104	
19-6-104	

11. 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 Division of Administrative Rules; *if none, leave blank*)**:**

	First Incorporation	Second Incorporation
Official Title of Materials Incorporated (from title page)		
Publisher		
Date Issued		
Issue, or version		
ISBN Number (optional)		
ISSN Number (optional)		
Cost of Incorporated Reference		
Action: Adds, updates, or removes		

(If this rule incorporates more than two items by reference, please attach additional pages)

12. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted until 5:00 p.m. on (mm/dd/yyyy)**:**	July 31, 2019
B) A public hearing (optional) will be held:	

	On (mm/dd/yyyy)**:**	**At** (hh:mm AM/PM)**:**	**At** (place)**:**

13.	**This rule change may become effective on** (mm/dd/yyyy)**:**	August 9, 2019
	NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 12(A) above, the agency must submit a Notice of Effective Date to the Division of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.	
14.	**Indexing information -- keywords** (maximum of four, in lower case, except for acronyms (e.g., "GRAMA") or proper nouns (e.g., "Medicaid"); may not include the name of the agency**:**	
	licenses	reciprocity
	transportation	exemptions
15.	**Attach an RTF document containing the text of this rule change** (filename)**:**	R313-019 Fiscal Tables and Rule

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 AUTHORIZATION

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

Appendix 1: Regulatory Impact Summary Table*

Fiscal Costs	**FY 2020**	**FY 2021**	**FY 2022**
State Government	$2940	$2940	$2940
Local Government	$0	$0	$0
Small Businesses	$420	$420	$420
Non-Small Businesses	$0	$0	$0
Other Person	$0	$0	$0
Total Fiscal Costs:	**$3360**	**$3360**	**$3360**
Fiscal Benefits			
State Government	$0	$0	$0
Local Government	$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:	**-$3360**	**-$3360**	**-$3360**

***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 for State Government, Local Government, Small Businesses and Other Persons are described in the narrative. Inestimable impacts for Non-Small Businesses are described in Appendix 2.**

Appendix 2: Regulatory Impact to Non-Small Businesses

This proposed rule is not expected to have any fiscal impacts on large businesses revenues or expenditures, because there are only two radioactive materials licensees that are affected by the proposed rule and neither licensee is a "Non-Small Business" entity. One licensee is considered to be a State Agency and the other is a small business entity. There are also no manufacturers of the devices affected by the proposed rule that operate in the State of Utah. Therefore, there are no non-small business entities that are affected by the proposed rule.

The Director of the Department of Environmental Quality, Alan Matheson, has reviewed and approved this fiscal analysis.

****"Non-small business" means a business employing 50 or more persons; "small business" means a business employing fewer than 50 persons.**

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.
R313-19. Requirements of General Applicability to Licensing of Radioactive Material.
R313-19-34. Terms and Conditions of Licenses.

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

(2)(a) Licenses issued or granted under Rules R313-21 and R313-22 and rights to possess or utilize radioactive material granted by a license issued pursuant to Rules R313-21 and R313-22 shall not be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of a license to a person unless the Director shall, after securing full information find that the transfer is in accordance with the provisions of the Act now or hereafter in effect, and to all rules, and orders of the Director, and shall give his consent in writing.

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

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

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

(3) Persons licensed by the Director pursuant to Rules R313-21 and R313-22 shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

(4) Licensees shall notify the Director in writing and request termination of the license when the licensee decides to terminate activities involving materials authorized under the license.

(5) Licensees shall notify the Director in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11, Bankruptcy, of the United States Code by or against:

(a) the licensee;

(b) an entity, as that term is defined in 11 USC 101(15), controlling the licensee or listing the license or licensee as property of the estate; or

(c) an affiliate, as that term is defined in 11 USC 101(2), of the licensee.

(6) The notification specified in Subsection R313-19-34(5) shall indicate:

(a) the bankruptcy court in which the petition for bankruptcy was filed; and

(b) the date of the filing of the petition.

(7) Licensees required to submit emergency plans pursuant to Subsection R313-22-32(8) shall follow the emergency plan approved by the Director. The licensee may change the approved plan without the Director's approval only if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the Director and to affected off-site response organizations within six months after the change is made. Proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the Director.

(8) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with Rule R313-32 (incorporating 10 CFR 35.204 by reference). The licensee shall record the results of each test and retain each record for three years after the record is made. The licensee shall report the results of each test that exceeds the permissible concentration listed in R313-32 (incorporating 10 CFR 35.204(a)) at the time of generator elution, in accordance with R313-32 (incorporating 10 CFR 35.3204).

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

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

(b) A licensee authorized under Subsection R313-22-32(9) to produce PET radioactive drugs

for noncommercial transfer to medical use licensees in its consortium shall:

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

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

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

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

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

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

KEY: licenses, reciprocity, transportation, exemptions
Date of Enactment or Last Substantive Amendment: [~~October 13, 2017~~]
Notice of Continuation: July 1, 2016
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-104

State of Utah
Administrative Rule Analysis

NOTICE OF PROPOSED RULE

* The agency identified below in box 1 provides notice of proposed rule change pursuant to Utah Code Section 63G-3-301.
* Please address questions regarding information on this notice to the agency.
* The full text of all rule filings is published in the Utah State Bulletin unless excluded because of space constraints.
* The full text of all rule filings may also be inspected at the Division of Administrative Rules.

DAR file no:		Date filed:	
State Admin Rule Filing Id:		Time filed:	

		Agency No.		Rule No.		Section No.
Utah Admin. Code Ref (R no.):	**R**	313	-	22	-	75
Changed to Admin. Code Ref. (R no.):	**R**		-		-	

1. **Agency:** Waste Management and Radiation Control
Room no.: 2nd Floor
Building: Multi-Agency State Office Building (MASOB)
Street address 1: 195 North 1950 West
Street address 2:
City, state, zip: Salt Lake City, UT, 84116
Mailing address 1: PO Box 144880
Mailing address 2:
City, state, zip: Salt Lake City, UT, 84114-4880
Contact person(s):

Name:	Phone:	Fax:	E-mail:
Gwyn Galloway	801-536-4258	801-536-0222	ggalloway@utah.gov

(Interested persons may inspect this filing at the above address or at the Division of Administrative Rules during business hours)

2. **Title of rule or section** (catchline)**:**

R313-22-75. Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices Which Contain Radioactive Material.

3. **Type of notice:**

New ___; Amendment _X_; Repeal ___; Repeal and Reenact ___

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

A change to 10 CFR Part 35 and changes to related U.S. Nuclear Regulatory Commission (NRC) requirements were adopted by the NRC and published in the July 16, 2018, Federal Register (83 FR 33046). In order to maintain the authority to regulate the use of certain licensed radioactive materials in the State of Utah, the State must maintain rules that are compatible with NRC requirements. The purpose of the proposed rule change is to maintain compatibility with the NRC requirements. These proposed rules maintain compatibility with the changes published for the

	requirements in 10 CFR 32.72(a)(4), 10 CFR 32.72(b)(5)(i), and 10 CFR 32.72(d).
5.	**This change is a response to comments from the Administrative Rules Review Committee.**
	No _X__; Yes ___
6.	**Summary of the rule or change:**
	The proposed rule changes incorporates corresponding federal regulations in 10 CFR 32.72 that clarify the requirements regarding the labeling for radioactive drugs manufactured and prepared by commercial radiopharmacies and manufacturers for distribution to licensees for medical use under R313-32. Additionally, individuals who are certified by an approved specialty board and seek to be named on a radioactive materials license as an Authorized Nuclear Pharmacist (ANP) will no longer be required to submit a written attestation statement regarding their training and experience.
7.	**Aggregate anticipated cost or savings to:**
	A) State budget:
	Affected: No ___; Yes _X__
	There are two commercial radiopharmacies (NAICS# 325412) with radioactive materials licenses operated by the University of Utah that manufacture or prepare radioactive drugs under the supervision of an ANP for transfer or distribution to radioactive materials licensees for medical use under R313-32. Additionally, the Division has regulatory oversight of the radiopharmacy licensees and reviews the training and experience (qualifications) of individuals who are to be named on the radiopharmacy licenses as an ANP. There are no fees assessed by the proposed rules; therefore, there are no direct or indirect fiscal impacts associated with the proposed rule changes for any State Agency, including the commercial radiopharmacies. Additionally, the proposed changes for the labeling requirements are not expected to have direct or indirect non-fiscal impacts on revenues or expenditures for any State Agency or the commercial radiopharmacies. This is because the proposed changes clarify the labeling requirements for radioactive drugs manufactured or prepared by the radiopharmacies and require no changes to the labeling or the labeling procedures currently in use by the radiopharmacies. The proposed rule changes also address changes to documentation required to be submitted for individuals who are board certified by an approved specialty board and who are applying to be named as an ANP on a radioactive materials license. There are three potential pathways in the requirements that an individual can use to qualify to be named as an ANP on a radioactive materials license. Only one of these pathways requires that the individual be board certified by an approved specialty board, but all of the pathways currently require the submission of a written attestation statement. The proposed rule changes remove the submission of the written attestation statement for an application to become an ANP from only one of the three pathways. The written attestation statement will still be required for the other two qualification pathways. The NRC estimates that about 30 % of the individuals that are named on a radioactive materials license as an ANP used the board certification pathway to qualify as an ANP. The employment opportunities for ANPs is very limited. In the State of Utah, there are a total of 10 individuals named as ANPs (seven by State operated radiopharmacies and 3 in a small business radiopharmacy). The number of ANPs in the State has remained stable and no positions have been added or lost for a number of years. Given the limited employment opportunities, once an ANP is named on a radioactive materials license, it has been observed that the ANP will remain employed with that entity until they retire. Therefore, in the State of Utah it has been observed that turnover of ANPs rarely occurs; NRC estimates a turnover rate of 10% for ANPs. There is no expectation that one of the seven ANPs employed by the State operated radiopharmacies will leave employment in the next three years. Because there is no anticipated turnover in the State, the proposed rule changes are not expected to have an actual

impact on the radiopharmacies or other State Agencies. However, for the purposes of this analysis, it will be assumed that one ANP will leave employment annually and the applicant for the ANP's replacement will be board certified each year. Using these assumptions, there is an expectation that the licensee will experience an estimated direct fiscal benefit of approximately $55 per year. There is typically no cost associated with obtaining a written attestation since the individuals receive a copy of a written attestation upon completion of their schooling. However, there may be a small cost associated with copying the written attestation statement for inclusion with the submitted ANP application. Assuming a cost of $ 0.25 per page for copying, there could be a direct fiscal impact of $0.75. The licensee's Radiation Safety Officer (usually an ANP) and one of the pharmacy technologists would prepare and submit the application for the individual to become an ANP in the same way that an application is presently created and submitted. The only difference would be that the individual would not need to locate the written attestation statement he was given when his training was completed and the licensee would not need to review the attestation and make a copy of the attestation statement to include with the ANP application. The change to completing and reviewing the application would result in an estimated direct fiscal benefit of approximately $55. This would offset the direct fiscal impact of $0.75. The application would be submitted to the Division with the oversight of the licensee for ANP review and approval. The review process for the application would proceed in the same manner as presently used by the Division. The difference for the review of the application would be the indirect fiscal benefit realized from the savings in personnel time related to the review of the written attestation. Therefore, the Division would experience a fiscal benefit estimated to be about $45 for the review of the ANP application.

In total, State Agencies would experience an estimated direct fiscal impact of $ 0.75, a direct fiscal benefit of approximately $55, and an estimated indirect fiscal benefit of approximately $45 for each of the ANP applications to name individuals who are board certified by an approved specialty board on a radioactive materials license as an ANP. Assuming one ANP application is received from a commercial radiopharmacy each year, the above stated estimated would be the annual expected impacts to the State's expenditures and revenues.

B) Local government:

Affected:	No _X__; Yes ___

This rule change is not expected to have any impacts on the revenues or expenditures for local governments because it only affects government agencies at a State level. There are no radioactive material licenses issued to local government entities for operation as a commercial radiopharmacy and local governments have no regulatory authority over the use of radioactive materials.

C) Small businesses ("small business" means a business employing fewer than 50 persons)**:**

Affected:	No ___; Yes __X_

There is one commercial radiopharmacy (NAICS# 325412) that qualifies as a small business and has been issued a radioactive materials license that authorizes them to manufacture and prepare radioactive drugs for transfer or distribution to other licensees for medical use under R313-32. As stated above in 7.A, there are no fees associated with the proposed changes. The changes to the labeling requirements will have no impact on the small business licensee since the proposed changes clarify the labeling requirements but do not require the licensee to modify the labels or labeling procedures presently used by the licensee. This radiopharmacy employs a total of three ANPs. As stated above, there are only 10 ANPs employed throughout the State of Utah and turnover is very infrequent. There is no expectation that an ANP will be replaced in the next three years; however, an assumption will be made that one ANP per year will be replaced and the individual applying for the position is board certified by an approved specialty board. The licensee

	will be expected to experience a direct fiscal benefit worth approximately $55 if not required to submit the written attestation statement with the ANP application. This would offset a direct fiscal impact of $0.75 for copying the attestation statement. These impacts would be per ANP application submitted; however, since one ANP application is assumed to be submitted each year, these would also be the annual impacts for the licensee.
	D) Persons other than small businesses, businesses, 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)**:** .
	Affected: No ___; Yes _X__
	Since there are no fees associated with the proposed requirements there are no direct or indirect fiscal impacts of the proposed rule changes for the expenditures or revenues of any "person" as defined above. Licensees are responsible for applying to have individuals named on their radioactive materials licenses as ANPs. Therefore, the impact on a person, as defined above, is minimal. The proposed rule changes will impact a person only if the person is board certified by an approved specialty board and is being added to a radioactive materials license as an ANP. The potential impact for a person would involve the amount of time it would take the person to locate their copy of the written attestation statement they were given upon completion of their training and providing a copy of the attestation statement to the licensee. If it is assumed that the person was paid for the time to gather his attestation statement, bring it to the licensee's facility, make a copy of the statement on the licensee's equipment and provide the copy to the licensee, the person could experience an indirect fiscal benefit worth about $30. This would be a one-time benefit for the person. If the person was to be added to a different radioactive materials license as an ANP in the future, a different pathway for qualification as an ANP would be used
8.	**Compliance costs for affected persons:**
	This proposed rule change does not result in additional compliance costs for the affected persons other than those stated in Item 7.
9.	**A) Comments by the department head on the fiscal impact the rule may have on businesses:**
	Since the proposed changes to the labeling requirements do not require changes to the current labels or labeling procedures used by radiopharmacy licensees for radioactive drugs that are manufactured or prepared and distributed to other medical use licensees for use under R313-32, this portion of the rule change has no direct or indirect fiscal impact for the affected entities. The other portion of the proposed rule change will only impact a licensee if a new board certified individual is to be added to the licensee's radioactive materials license. There are a number of conditions that would need to be met before this proposed rule change would apply to a licensee or the State Agency that would review the qualifications of the proposed ANP. Because all of the conditions would have to be met at the same time for the rule to be applicable, it is highly unlikely that the proposed rule would be applied in the next few years. If the conditions were all met it would be unlikely that more than one ANP would be replaced. Therefore, the potential direct fiscal benefits would be minimal for the savings that would result from not being required to submit a written attestation statement with an application for a new ANP.
	B) Name and title of department head commenting on the fiscal impacts:
	Alan Matheson, Executive Director, Department of Environmental Quality
10.	**This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws.** **State code or constitution citations (required)** (e.g., Section 63G-3-402; Subsection 63G-3-601(3); Article IV) **:**

	19-3-104	19-6-104

11. **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 Division of Administrative Rules; *if none, leave blank*)**:**

	First Incorporation	**Second Incorporation**
Official Title of Materials Incorporated (from title page)		
Publisher		
Date Issued		
Issue, or version		
ISBN Number (optional)		
ISSN Number (optional)		
Cost of Incorporated Reference		
Action: Adds, updates, or removes		

(If this rule incorporates more than two items by reference, please attach additional pages)

12. **The public may submit written or oral comments to the agency identified in box 1.** (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted until 5:00 p.m. on (mm/dd/yyyy)**:**	July 31, 2019

B) A public hearing (optional) will be held:

On (mm/dd/yyyy)**:**	**At** (hh:mm AM/PM)**:**	**At** (place)**:**

13. **This rule change may become effective on** (mm/dd/yyyy)**:** August 9, 2019

NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 12(A) above, the agency must submit a Notice of Effective Date to the Division of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.

14. **Indexing information -- keywords** (maximum of four, in lower case, except for acronyms (e.g., "GRAMA") or proper nouns (e.g., "Medicaid"); may not include the name of the agency**:**

specific licenses	decommissioning
broad scope	radioactive materials

15.	**Attach an RTF document containing the text of this rule change** (filename)**:**	R313-022 Fiscal Tables and Rule

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 AUTHORIZATION

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

Appendix 1: Regulatory Impact Summary Table*

Fiscal Costs	**FY 2020**	**FY 2021**	**FY 2022**
State Government	$0.75	$0.75	$0.75
Local Government	$0	$0	$0
Small Businesses	$0.75	$0.75	$0.75
Non-Small Businesses	$0	$0	$0
Other Person	$0	$0	$0
Total Fiscal Costs:	**$1.50**	**$1.50**	**$1.50**
Fiscal Benefits			
State Government	$100	$100	$100
Local Government	$0	$0	$0
Small Businesses	$55	$55	$55
Non-Small Businesses	$0	$0	$0
Other Persons	$0	$0	$0
Total Fiscal Benefits:	**$155**	**$155**	**$155**
Net Fiscal Benefits:	**$153.50**	**$153.50**	**$153.50**

***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 for State Government, Local Government, Small Businesses and Other Persons are described in the narrative. Inestimable impacts for Non-Small Businesses are described in Appendix 2.**

Appendix 2: Regulatory Impact to Non-Small Businesses

This proposed rule is not expected to have any fiscal impacts on large businesses revenues or expenditures, because there are only two radioactive materials licensees that are affected by the proposed rule and neither licensee is a "Non-Small Business" entity. Two licensees are considered to be a State Agencies and the other is a small business entity (NAICS 325412). There are also no manufacturers of medical devices affected by the proposed rule that operate in the State of Utah. Therefore, there are no non-small business entities that are affected by the proposed rule.

The Director of the Department of Environmental Quality, Alan Matheson, has reviewed and approved this fiscal analysis.

****"Non-small business" means a business employing 50 or more persons; "small business" means a business employing fewer than 50 persons.**

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.
R313-22. Specific Licenses.
R313-22-75. Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices Which Contain Radioactive Material.

(1) Licensing the introduction of radioactive material in exempt concentrations into products or materials, and transfer of ownership or possession of the products and materials.

(a) The authority to introduce radioactive material in exempt concentrations into equipment, devices, commodities or other products may be obtained only from the Nuclear Regulatory Commission, Washington, D.C. 20555; and

(b) The manufacturer, processor or producer of equipment, devices, commodities or other products containing exempt concentrations of radioactive materials may obtain the authority to transfer possession or control of the equipment, devices, commodities, or other products containing exempt concentrations to persons who are exempt from regulatory requirements only from the Nuclear Regulatory Commission, Washington, D.C. 20555.

(2) Licensing the distribution of radioactive material in exempt quantities. Authority to transfer possession or control by the manufacturer, processor or producer of equipment, devices, commodities or other products containing byproduct material whose subsequent possession, use, transfer, and disposal by other persons who are exempted from regulatory requirements may be obtained only from the Nuclear Regulatory Commission, Washington, D.C. 20555.

(3) Reserved

(4) Licensing the manufacture and distribution of devices to persons generally licensed under Subsection R313-21-22(4).

(a) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under Subsection R313-21-22(4) or equivalent regulations of the Nuclear Regulatory Commission, an Agreement State or a Licensing State will be approved if:

(i) the applicant satisfies the general requirements of Section R313-22-33;

(ii) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(A) the device can be safely operated by persons not having training in radiological protection,

(B) under ordinary conditions of handling, storage and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that a person will receive in one year, a dose in excess of ten percent of the annual limits specified in Subsection R313-15-201(1), and

(C) under accident conditions, such as fire and explosion, associated with handling, storage and use of the device, it is unlikely that a person would receive an external radiation dose or dose commitment in excess of the following organ doses:

TABLE

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	150.0 mSv (15 rems)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter	2.0 Sv (200 rems)
Other organs	500.0 mSv (50 rems); and

(iii) each device bears a durable, legible, clearly visible label or labels approved by the Director, which contain in a clearly identified and separate statement:

(A) instructions and precautions necessary to assure safe installation, operation and servicing of the device; documents such as operating and service manuals may be identified in the label and used to provide this information,

(B) the requirement, or lack of requirement, for leak testing, or for testing an "on-off" mechanism and indicator, including the maximum time interval for testing, and the identification of radioactive material by radionuclide, quantity of radioactivity, and date of determination of the quantity, and

(C) the information called for in one of the following statements, as appropriate, in the same or substantially similar form:

(I) "The receipt, possession, use and transfer of this device, Model No. ....., Serial No. ....., are subject to a general license or the equivalent, and the regulations of the Nuclear Regulatory Commission or a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited." The label shall be printed with the words "CAUTION -RADIOACTIVE MATERIAL" and the name of the manufacturer or distributor shall appear on the label. The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

(II) "The receipt, possession, use and transfer of this device, Model No. ....., Serial No. ....., are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited." The label shall be printed with the words "CAUTION - RADIOACTIVE MATERIAL" and the name of the manufacturer or distributor shall appear on the label. The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

(iv) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, "Caution-Radioactive Material," the radiation symbol described in Section R313-15-901, and the name of the manufacturer or initial distributor.

(v) Each device meeting the criteria of Subsection R313-21-22(4)(c)(xiii)(A), bears a permanent label, for example, embossed, etched, stamped, or engraved, affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in Section R313-15-901.

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

(b) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that a longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Director will consider information which includes, but is not limited to:

(i) primary containment, or source capsule;

(ii) protection of primary containment;

(iii) method of sealing containment;

(iv) containment construction materials;

(v) form of contained radioactive material;

(vi) maximum temperature withstood during prototype tests;

(vii) maximum pressure withstood during prototype tests;

(viii) maximum quantity of contained radioactive material;

(ix) radiotoxicity of contained radioactive material; and

(x) operating experience with identical devices or similarly designed and constructed

devices.

(c) In the event the applicant desires that the general licensee under Subsection R313-21-22(4), or under equivalent regulations of the Nuclear Regulatory Commission, an Agreement State or a Licensing State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with this activity or activities, and basis for these estimates. The submitted information shall demonstrate that performance of this activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of ten percent of the annual limits specified in Subsection R313-15-201(1).

(d)(i) If a device containing radioactive material is to be transferred for use under the general license contained in Subsection R313-21-22(4), each person that is licensed under Subsection R313-22-75(4) shall provide the information specified in Subsections R313-22-75(4)(d)(i)(A) through (E) to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(A) a copy of the general license contained in Subsection R313-21-22(4); if Subsections R313-21-22(4)(c)(ii) through (iv) or R313-21-22(4)(c)(xiii) do not apply to the particular device, those paragraphs may be omitted;

(B) a copy of Sections R313-12-51, R313-15-1201, and R313-15-1202;

(C) a list of services that can only be performed by a specific licensee;

(D) Information on acceptable disposal options including estimated costs of disposal; and

(E) An indication that the Director's policy is to issue civil penalties for improper disposal.

(ii) If radioactive material is to be transferred in a device for use under an equivalent general license of the Nuclear Regulatory Commission, an Agreement State, or Licensing State, each person that is licensed under Subsection R313-22-75(4) shall provide the information specified in Subsections R313-22-75(4)(d)(ii)(A) through (D) to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(A) A copy of an Agreement State's or Licensing State's regulations equivalent to Sections R313-12-51, R313-15-1201, R313-15-1202, and Subsection R313-21-22(4) or a copy of 10 CFR 31.5, 10 CFR 31.2, 10 CFR 30.51, 10 CFR 20.2201, and 10 CFR 20.2202. If a copy of the Nuclear Regulatory Commission regulations is provided to a prospective general licensee in lieu of the Agreement State's or Licensing State's regulations, it shall be accompanied by a note explaining that use of the device is regulated by the Agreement State or Licensing State; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted;

(B) A list of services that can only be performed by a specific licensee;

(C) Information on acceptable disposal options including estimated costs of disposal; and

(D) The name or title, address, and phone number of the contact at the Nuclear Regulatory Commission, Agreement State, or Licensing State from which additional information may be obtained.

(iii) An alternative approach to informing customers may be proposed by the licensee for approval by the Director.

(iv) Each device that is transferred after February 19, 2002 must meet the labeling requirements in Subsection R313-22-75(4)(a)(iii).

(v) If a notification of bankruptcy has been made under Section R313-19-34 or the license is to be terminated, each person licensed under Subsection R313-22-75(4) shall provide, upon request, to the Director, the Nuclear Regulatory Commission, or an appropriate Agreement State or Licensing State, records of final disposition required under Subsection R313-22-75(4)(d)(vii)(H).

(vi) Each person licensed under Subsection R313-22-75(4) to initially transfer devices to generally licensed persons shall comply with the requirements of Subsections R313-22-75(4)(d)(vi)

and (vii).

(A) The person shall report all transfers of devices to persons for use under the general license under Subsection R313-21-22(4) and all receipts of devices from persons licensed under Subsection R313-21-22(4) to the Director. The report must be submitted on a quarterly basis on Form 653, "Transfers of Industrial Devices Report" as prescribed by the Nuclear Regulatory Commission, or in a clear and legible report containing all of the data required by the form.

(B) The required information for transfers to general licensees includes:

(I) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternative address for the general licensee shall be submitted along with information on the actual location of use.

(II) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(III) The date of transfer;

(IV) The type, model number, and serial number of device transferred; and

(V) The quantity and type of radioactive material contained in the device.

(C) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate persons.

(D) For devices received from a Subsection R313-21-22(4) general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(E) If the licensee makes changes to a device possessed by a Subsection R313-21-22(4) general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(F) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(G) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(H) If no transfers have been made to or from persons generally licensed under Subsection R313-21-22(4) during the reporting period, the report must so indicate.

(vii) The person shall report all transfers of devices to persons for use under a general license in the Nuclear Regulatory Commission's, an Agreement State's, or Licensing State's regulations that are equivalent to Subsection R313-21-22(4) and all receipts of devices from general licensees in the Nuclear Regulatory Commission's, Agreement State's, or Licensing State's jurisdiction to the Nuclear Regulatory Commission, or to the responsible Agreement State or Licensing State agency. The report must be submitted on Form 653, "Transfers of Industrial Devices Report" as prescribed by the Nuclear Regulatory Commission, or in a clear and legible report containing all of the data required by the form.

(A) The required information for transfers to general licensee includes:

(I) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternative address for the general licensee shall be submitted along with information on the actual location of use.

(II) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(III) The date of transfer;

(IV) The type, model number, and serial number of the device transferred; and

(V) The quantity and type of radioactive material contained in the device.

(B) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate persons.

(C) For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device

received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(D) If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(E) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(F) The report must clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.

(G) If no transfers have been made to or from a Nuclear Regulatory Commission licensee, or to or from a particular Agreement State or Licensing State licensee during the reporting period, this information shall be reported to the Nuclear Regulatory Commission or the responsible Agreement State or Licensing State agency upon request of the agency.

(H) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by Subsection R313-22-75(4)(d)(vii). Records required by Subsection R313-22-75(4)(d)(vii)(H) must be maintained for a period of three years following the date of the recorded event.

(5) Special requirements for the manufacture, assembly or repair of luminous safety devices for use in aircraft. An application for a specific license to manufacture, assemble or repair luminous safety devices containing tritium or promethium-147 for use in aircraft for distribution to persons generally licensed under Subsection R313-21-22(5) will be approved if:

(a) the applicant satisfies the general requirements of Section R313-22-33; and

(b) the applicant satisfies the requirements of 10 CFR 32.53 through 32.56 (2015) or their equivalent.

(6) Special requirements for license to manufacture or initially transfer calibration sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under Subsection R313-21-22(7). An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under Subsection R313-21-22(7) will be approved if:

(a) the applicant satisfies the general requirements of Section R313-22-33; and

(b) the applicant satisfies the requirements of 10 CFR 32.57 through 32.59, and 10 CFR 70.39 (2015), or their equivalent.

(7) Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license. An application for a specific license to manufacture or distribute radioactive material for use under the general license of Subsection R313-21-22(9) will be approved if:

(a) the applicant satisfies the general requirements specified in Section R313-22-33;

(b) the radioactive material is to be prepared for distribution in prepackaged units of:

(i) iodine-125 in units not exceeding 370 kilobecquerel (ten uCi) each;

(ii) iodine-131 in units not exceeding 370 kilobecquerel (ten uCi) each;

(iii) carbon-14 in units not exceeding 370 kilobecquerel (ten uCi) each;

(iv) hydrogen-3 (tritium) in units not exceeding 1.85 megabecquerel (50 uCi) each;

(v) iron-59 in units not exceeding 740.0 kilobecquerel (20 uCi) each;

(vi) cobalt-57 in units not exceeding 370 kilobecquerel (ten uCi) each;

(vii) selenium-75 in units not exceeding 370 kilobecquerel (ten uCi) each; or

(viii) mock iodine-125 in units not exceeding 1.85 kilobecquerel (0.05 uCi) of iodine-129 and 1.85 kilobecquerel (0.05 uCi) of americium-241 each;

(c) prepackaged units bear a durable, clearly visible label:

(i) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 370 kilobecquerel (ten uCi) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 1.85 megabecquerel (50 uCi) of hydrogen-3 (tritium); 740.0 kilobecquerel (20 uCi) of iron-59; or Mock Iodine-125 in units not exceeding 1.85 kilobecquerel (0.05 uCi) of iodine-129 and 1.85 kilobecquerel (0.05 uCi) of americium-241 each; and

(ii) displaying the radiation caution symbol described in Section R313-15-901 and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in

Humans or Animals";

(d) one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

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

.....

Name of Manufacturer"

(ii) "This radioactive material shall be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a Licensing State.

.....

Name of Manufacturer"

(e) the label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source shall also contain directions to the licensee regarding the waste disposal requirements set out in Section R313-15-1001.

(8) Licensing the manufacture and distribution of ice detection devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under Subsection R313-21-22(10) will be approved if:

(a) the applicant satisfies the general requirements of Section R313-22-33; and

(b) the criteria of 10 CFR 32.61, 32.62, 2015 ed. are met.

(9) Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under R313-32.

(a) An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to Rule R313-32 will be approved if:

(i) the applicant satisfies the general requirements specified in Section R313-22-33;

(ii) the applicant submits evidence that the applicant is at least one of the following:

(A) registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

(B) registered or licensed with a state agency as a drug manufacturer;

(C) licensed as a pharmacy by a State Board of Pharmacy; or

(D) operating as a nuclear pharmacy within a medical institution; or

(E) registered with a State Agency as a Positron Emission Tomography (PET) drug production facility.

(iii) the applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

(iv) the applicant [~~satisfies~~]commits to the following labeling requirements:

(A) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs

with a half life greater than 100 days, the time may be omitted.

(B) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(b) A licensee described by Subsections R313-22-75(9)(a)(ii)(C) or (D):

(i) May prepare radioactive drugs for medical use, as defined in Rule R313-32 (incorporating 10 CFR 35.2 by reference), provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in Subsections R313-22-75(9)(b)(ii) and (iv), or an individual under the supervision of an authorized nuclear pharmacist as specified in Rule R313-32 (incorporating 10 CFR 35.27 by reference).

(ii) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(A) this individual qualifies as an authorized nuclear pharmacist as defined in Rule R313-32 (incorporating 10 CFR 35.2 by reference);

(B) this individual meets the requirements specified in Rule R313-32 (incorporating 10 CFR 35.55(b) and 10 CFR 35.59 by reference) and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(C) this individual is designated as an authorized nuclear pharmacist in accordance with Subsection R313-22-75(9)(b)(iv).

(iii) The actions authorized in Subsections R313-22-75(9)(b)(i) and (ii) are permitted in spite of more restrictive language in license conditions.

(iv) May designate a pharmacist, as defined in Rule R313-32 (incorporating 10 CFR 35.2 by reference), as an authorized nuclear pharmacist if:

(A) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator produced radioactive material, and

(B) The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

(v) Shall provide to the Director:

(A) a copy of each individual's certification by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or Agreement State as specified in Rule R313-32 (incorporating 10 CFR 35.55(a) by reference)[~~ with the written attestation signed by a preceptor as required by Rule R313-32 (incorporating 10 CFR 35.55(b)(2) by reference)~~]; or

(B) the Nuclear Regulatory Commission or Agreement State license; or

(C) the permit issued by a licensee or Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

(D) the permit issued by a U.S. Nuclear Commission master materials licensee; or

(E) documentation that only accelerator produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

(F) a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to Subsections R313-22-75(9)(b)(ii)(A) and R313-22-75(9)(b)(ii)(C), the individual to work as an authorized nuclear pharmacist.

(c) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(i) perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(ii) check each instrument for constancy and proper operation at the beginning of each day of

use.

(d) A licensee shall satisfy the labeling requirements in R313-22-75(9)(a)(iv).

([~~d~~]e) Nothing in Subsection R313-22-75(9) relieves the licensee from complying with applicable FDA, or Federal, and State requirements governing radioactive drugs.

(10) Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed under Rule R313-32 for use as a calibration, transmission, or reference source or for the uses listed in Rule R313-32 (incorporating 10 CFR 35.400, 10 CFR 35.500, 10 CFR 35.600, and 35.1000 by reference) will be approved if:

(a) the applicant satisfies the general requirements in Section R313-22-33;

(b) the applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(i) the radioactive material contained, its chemical and physical form and amount,

(ii) details of design and construction of the source or device,

(iii) procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,

(iv) for devices containing radioactive material, the radiation profile of a prototype device,

(v) details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,

(vi) procedures and standards for calibrating sources and devices,

(vii) legend and methods for labeling sources and devices as to their radioactive content, and

(viii) instructions for handling and storing the source or device from the radiation safety standpoint, these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided that instructions which are too lengthy for a label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

(c) the label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the source or device is licensed by the Director for distribution to persons licensed pursuant to Rule R313-32 (incorporating 10 CFR 35.18, 10 CFR 35.400, 10 CFR 35.500, and 10 CFR 35.600 by reference) or under equivalent regulations of the Nuclear Regulatory Commission, an Agreement State or a Licensing State; provided that labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source;

(d) the source or device has been registered in the Sealed Source and Device Registry.

(e) in the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include in the application sufficient information to demonstrate that a longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and

(f) in determining the acceptable interval for test of leakage of radioactive material, the Director shall consider information that includes, but is not limited to:

(i) primary containment or source capsule,

(ii) protection of primary containment,

(iii) method of sealing containment,

(iv) containment construction materials,

(v) form of contained radioactive material,

(vi) maximum temperature withstood during prototype tests,

(vii) maximum pressure withstood during prototype tests,

(viii) maximum quantity of contained radioactive material,

(ix) radiotoxicity of contained radioactive material, and

(x) operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(11) Requirements for license to manufacture and distribute industrial products containing depleted uranium for mass-volume applications.

(a) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to Subsection R313-21-21(7) or equivalent regulations of the Nuclear Regulatory Commission or an Agreement State will be approved if:

(i) the applicant satisfies the general requirements specified in Section R313-22-33;

(ii) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses and potential hazards of the industrial product or device to provide reasonable assurance that possession, use or transfer of the depleted uranium in the product or device is not likely to cause an individual to receive a radiation dose in excess of ten percent of the annual limits specified in Subsection R313-15-201(1); and

(iii) the applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(b) In the case of an industrial product or device whose unique benefits are questionable, the Director will approve an application for a specific license under Subsection R313-22-75(11) only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(c) The Director may deny an application for a specific license under Subsection R313-22-75(11) if the end use of the industrial product or device cannot be reasonably foreseen.

(d) Persons licensed pursuant to Subsection R313-22-75(11)(a) shall:

(i) maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

(ii) label or mark each unit to:

(A) identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

(B) state that the receipt, possession, use and transfer of the product or device are subject to a general license or the equivalent and the regulations of the Nuclear Regulatory Commission or an Agreement State;

(iii) assure that the uranium before being installed in each product or device has been impressed with the following legend clearly legible through a plating or other covering: "Depleted Uranium";

(iv) furnish to each person to whom depleted uranium in a product or device is transferred for use pursuant to the general license contained in Subsection R313-21-21(5) or its equivalent:

(A) a copy of the general license contained in Subsection R313-21-21(7) and a copy of form DWMRC-12; or

(B) a copy of the general license contained in the Nuclear Regulatory Commission's or Agreement State's regulation equivalent to Subsection R313-21-21(7) and a copy of the Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in Subsection R313-21-21(7) and a copy of form DWMRC-12 with a note explaining that use of the product or device is regulated by the Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in Subsection R313-21-21(7);

(v) report to the Director all transfers of industrial products or devices to persons for use under the general license in Subsection R313-21-21(7). The report shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the Director and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within thirty days after the end of the calendar quarter in which the product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under Subsection R313-21-21(7) during the reporting period, the report shall so indicate;

(vi) provide certain other reports as follows:

(A) report to the Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the Nuclear Regulatory Commission general license in 10 CFR 40.25 (2010);

(B) report to the responsible state agency all transfers of devices manufactured and distributed pursuant to Subsection R313-22-75(11) for use under a general license in that state's regulations equivalent to Subsection R313-21-21(7),

(C) reports shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within thirty days after the end of each calendar quarter in which a product or device is transferred to the generally licensed person,

(D) if no transfers have been made to Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the Nuclear Regulatory Commission, and

(E) if no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon the request of that agency; and

(vii) records shall be kept showing the name, address and point of contact for each general licensee to whom the person transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in Subsection R313-21-21(7) or equivalent regulations of the Nuclear Regulatory Commission or an Agreement State. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in the product or device transferred, and compliance with the report requirements of Subsection R313-22-75(11).

KEY: specific licenses, decommissioning, broad scope, radioactive materials
Date of Enactment or Last Substantive Amendment: [~~October 13, 2017~~]
Notice of Continuation: July 1, 2016
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-104

State of Utah
Administrative Rule Analysis

NOTICE OF PROPOSED RULE

* The agency identified below in box 1 provides notice of proposed rule change pursuant to Utah Code Section 63G-3-301.
* Please address questions regarding information on this notice to the agency.
* The full text of all rule filings is published in the Utah State Bulletin unless excluded because of space constraints.
* The full text of all rule filings may also be inspected at the Division of Administrative Rules.

DAR file no:		Date filed:	
State Admin Rule Filing Id:		Time filed:	

		Agency No.		Rule No.		Section No.
Utah Admin. Code Ref (R no.):	**R**	313	-	32	-	
Changed to Admin. Code Ref. (R no.):	**R**		-		-	

1.	**Agency:**	Waste Management and Radiation Control		
	Room no.:	2nd Floor		
	Building:	Multi-Agency State Office Building (MASOB)		
	Street address 1:	195 North 1950 West		
	Street address 2:			
	City, state, zip:	Salt Lake City, UT, 84116		
	Mailing address 1:	PO Box 144880		
	Mailing address 2:			
	City, state, zip:	Salt Lake City, UT, 84114-4880		
	Contact person(s):			
	Name:	**Phone:**	**Fax:**	**E-mail:**
	Gwyn Galloway	801-536-4258	801-536-0222	

(Interested persons may inspect this filing at the above address or at the Division of Administrative Rules during business hours)

2. Title of rule or section (catchline)**:**

R313-32. Medical Use of Radioactive Materials.

3. Type of notice:

New ___; Amendment _X_; Repeal ___; Repeal and Reenact ___

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

The purpose of the rule change is to update the medical use of radioactive materials requirements which were last updated in their entirety in 2002. The proposed changes address technological advances, changes to medical procedures, and enhance patient safety. The changes are proposed in order to maintain compatibility with U.S. Nuclear Regulatory Commission (NRC) requirements. To maintain authority to regulate certain licensed radioactive materials in the State of Utah, the State must maintain rules that are compatible with NRC requirements. Recent changes to 10 CFR Part 35 and related NRC requirements were adopted by the NRC and published in the July 16, 2018,

	Federal Register (83 FR 33046). These proposed rule changes maintain compatibility with the changes published for the requirements in 10 CFR Part 35 by incorporating the 2019 version of 10 CFR Part 35 by reference. An additional change is being requested to R313-32 to allow licensees to hold radioactive wastes with half-lives less than 175 days to be disposed using the decay in storage method so that the materials will not be required to be disposed as low level radioactive waste.
5.	**This change is a response to comments from the Administrative Rules Review Committee.**
	No _X__; Yes ___
6.	**Summary of the rule or change:**
	The proposed rule changes address the removal of the requirement for a written attestation statement from proposed authorized users who are board certified by approved specialty boards, adds the ability for licensees to have Associate Radiation Safety Officers, clarifies requirements for the use of sealed sources in diagnostic procedures, clarifies training and experience requirements for unsealed radioactive materials requiring the use of a written directive, includes additional requirements for testing and reporting requirements for the use of generators used for obtaining specific isotopes, includes changes to the medical event requirements, and adds specific medical event reporting requirements for permanent brachytherapy implants. In addition to the above changes to adopt the NRC revisions, a change is being proposed to add a new subparagraph, as stated in R313-32-2(5), to include specific requirements for holding radioactive waste for "decay-in-storage" (DIS) if the radioactive material has a half-life of greater than 120 days, but less than 175 days. Currently, radioactive waste containing materials with half-lives greater than 120 days is required to be disposed as low-level radioactive waste (LLRW). Recently, a new radioactive drug using Lutetium-177 (Lu-177) was introduced into use at medical facilities in the State of Utah. It has been determined that this drug contains a very small quantity of a radioactive impurity that has a half-life of about 161 days. If the impurity is detected in the radioactive waste, the waste created from the administration of Lu-177 is required to be disposed as LLRW unless a variance from the Board is requested and approved. In anticipation of the increased use of this radioactive drug, the proposed change will allow the Director to approve an amendment for the DIS of radioactive waste containing materials with half-lives greater than 120 days but less than 175 days on a case by case basis. For approval, the licensee would be required to demonstrate that the waste will be secured and safely stored, that the additional waste would not exceed the licensee's storage capacity, and that the licensee will meet the survey criteria required for DIS waste with half-lives of 120 days or less.
7.	**Aggregate anticipated cost or savings to:**
	A) State budget:
	Affected: No ___; Yes _X__
	The following are very rough estimates of the possible costs and benefits associated with the proposed changes. The implementation of these proposed requirements is dependent on the uses of radioactive materials by each separate licensee. Licensees in the State that use radioactive materials only for diagnostic purposes may not choose or be required to implement any of the proposed changes or may choose to implement just a few of the proposed changes. Licensees using radioactive materials for the therapeutic treatment of patients will be required to implement certain of the proposed changes, but may choose not to implement other proposed changes. Since each licensee is not required to implement all of the proposed rule changes, licensees may choose to avail themselves of some of the proposed requirements that benefit licensees multiple times in a year, may not implement any of the proposed changes or may implement the proposed changes in a myriad of combinations, an estimate of the costs and benefits to licensees and State Agencies is difficult to determine. However, rough estimates were made for the proposed changes. For the

rough estimates, it was assumed that the 45 medical use licensees could simplistically be separated into businesses that provide both diagnostic and therapeutic treatments with radioactive materials and those licensees that provide only diagnostic services using radioactive materials. It was also assumed that each group would use each of the proposed rule changes possibly applicable to their operations at least once in a year. As an example, it was assumed that businesses performing only diagnostic scans would have no need to add an Associate Radiation Safety Officer (ARSO) to their radioactive materials license since the types of radioactive materials used at these facilities would be limited. Also, since the requirements of R313-32 [incorporating 10 CFR 35.490 or 10 CFR 35.690 by reference] apply only to the therapeutic use of radioactive materials, these requirements would not be applicable to those businesses that only provide diagnostic services. Lastly, for determining the costs or benefits associated with the proposed requirements, all estimates for the number of licensees affected by the proposed requirement was rounded up to the next whole number when calculating the number of impacted licensees.

There are currently 45 licensees authorized to medically use radioactive materials pursuant to R313-32. Therefore, the DWMRC provides regulatory oversight for 45 medical use licensees. Of these, four are operated by a State owned and operated entity. One of these four licensees provides both diagnostic and therapeutic treatments for patients while the other three licensees limit their practices to diagnostic services. There are no fees associated with the proposed rules. The proposed rule changes will result in both direct fiscal impacts and direct fiscal benefits in the form of personnel costs and savings to the State licensees. Using the NRC's regulatory impact analysis associated with the federal regulatory changes to 10 CFR Part 35 (ML16124B034, Secy-16-0080; Enclosure 2) as guidance and using the assumptions stated above, for the four licensees there may be estimated direct fiscal impacts for the implementation of these requirements of approximately $2,963.96. In addition, the four licensees could experience annual direct fiscal impacts of approximately $1,064.49 and direct fiscal benefits of approximately $2,102.45.

In addition to the direct fiscal impacts and benefits, the State may also experience indirect fiscal impacts and benefits related to the regulatory oversight of the licensees. These costs and savings are based on personnel costs and savings and are related to the processing of requests to add authorized users and other changes to the radioactive materials licenses, as well as, responses to reports made to the State due to the proposed changes. The State will incur a one-time indirect fiscal impact of about $6,480.00 to implement the proposed changes and an annual ongoing indirect fiscal impact of about $971.10 for the regulatory oversight of the proposed changes. In addition to the stated indirect fiscal impacts, the State could also experience indirect fiscal benefits of about $3,870.00 annually. These licensees will also be impacted by the requirement proposed for the disposal of certain materials. This requirement will result in a direct benefit to the licensees; however, the benefit cannot be analyzed at this time. The radioactive material in question is from a new medical treatment for certain cancers and it is unknown how many facilities will provide this treatment to patients or how much waste will be created from its use. Therefore, this direct fiscal benefit cannot be estimated.

In total, the State may experience one-time direct fiscal implementation costs of about $2,963.96 and experience ongoing direct fiscal costs of about $1,064.49. Additionally, the State may experience one-time indirect fiscal implementation costs of about $6,480.00 and indirect fiscal costs of about $971.10 annually. The State may also experience direct fiscal benefits of approximately $2,102.45 and indirect fiscal benefits of about $3,870.00 annually.

B) Local government:

Affected:	No __X_; Yes ___

The proposed rule changes are not expected to have any impacts on the revenues or expenditures for local governments because it only affects government agencies at a State level. There are no radioactive material licenses for the medical use of radioactive materials issued to a local government entity. Additionally, local governments have no regulatory authority for the possession and use of radioactive materials.

C) Small businesses ("small business" means a business employing fewer than 50 persons)**:**

Affected:	No ___; Yes _X__

There are 12 small businesses in the State of Utah that have radioactive materials licenses authorizing the medical use of radioactive materials (NAICS # 622111). Of the 12 licensees, five of the licensees provide only diagnostic services to their patients. The remaining seven licensees provide treatment for various cancers and other therapeutic treatments. There are no fees associated with the proposed rule changes. The referenced information and noted assumptions stated in Item 7.A were also used to develop the analysis for this section. As stated above, licensees may experience both one-time and ongoing (annual) direct fiscal impacts associated with the implementation of the proposed requirements. The five licensees limited to providing diagnostic treatments may experience one-time direct fiscal impacts of about $906.75 and ongoing direct fiscal impacts of about $525.92. Additionally, these licensees may experience annual direct fiscal benefits of approximately $1,450.80.

The remaining seven small business licensees, who provide both diagnostic and therapeutic treatments to patients, may incur direct fiscal impacts of about $7,846.12 to implement the proposed changes and annual direct fiscal impacts of about $1,904.18. Licensees providing both diagnostic and therapeutic services using radioactive materials may also experience direct fiscal benefits of about $4,532.30 annually. In total, the licensees considered to be small businesses may experience one-time direct fiscal implementation costs of about $17,846.05 and annual direct fiscal costs of about $2,430.10. The small business licensees may also experience annual direct fiscal benefits of approximately $5,983.10.

D) Persons other than small businesses, businesses, 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)**:**

Affected:	No ___; Yes _X__

It is difficult to determine how many persons as defined above will be impacted by these proposed rules. An individual will only be affected by the proposed rule changes regarding applications to be named on a license as an authorized user or an authorized medical physicist if the individual is board certified and has not previously been named on a radioactive materials license. This information cannot be determined until the information is received. The NRC determined that there is about a 3 % turnover rate for licensees, but this includes individuals leaving employment at one facility and beginning practice on a different license. Assuming that each licensee has approximately 4 unique physicians named on the license and there are eight medical physicists in the State, there are about 200 individuals named on the 45 medical licenses. If a 3 % turnover is assumed, 6 of the individuals would leave employment. If those individuals are replaced by physicians that have never been named on a license, it is assumed that 30% of those individuals would be certified by one of the approved specialty boards. Therefore, it is possible that 2 individuals might benefit from the proposed changes to the requirements. This would be an indirect fiscal benefit in that the individuals will save the time necessary from collecting the written

	attestation statements that they were provided when completing their schooling and providing it to their new employer (the licensee) for the licensee to request that the individual be added to the license. It is estimated that this would give save each individual about one half hour of time spent to locate the paperwork they were previously given. Therefore, each individual may experience a direct fiscal benefit of about $64.25 or a total of about $128.50 for both individuals. Note that this is a one-time benefit unless the individual requests to expand their radioactive material authorizations to add additional radioactive materials approvals for materials that they have not used before.
8.	**Compliance costs for affected persons:**
	Small business licensees providing diagnostic services may incur one-time direct fiscal costs of $181.35 and ongoing (annual) fiscal costs of about $105.18 per licensee to implement the proposed changes. These direct fiscal costs will be offset by the potential direct fiscal benefits of about $290.16 that may be experience by each of these licensees. Small business licensees providing both diagnostic and therapeutic services may experience one-time direct fiscal costs of about $2,419.90 and ongoing (annual) direct fiscal costs of approximately $272.03 per licensee. Additionally, each of these licensees may experience direct fiscal benefits of about $647.47 per license. Large business licensees providing diagnostic services may incur one-time direct fiscal costs of $181.35 and ongoing (annual) fiscal costs of about $217.62per licensee to implement the proposed changes. These direct fiscal costs may be offset by the potential direct fiscal benefits of $435.24 that could be experience by each of these licensees. Large business licensees providing both diagnostic and therapeutic services may experience one-time direct fiscal costs of about $2,419.90 and ongoing (annual) direct fiscal costs of approximately $285.10 per licensee. Additionally, each of these licensees could experience direct fiscal benefits of about $560.97 per license to offset the costs associated with the proposed changes. Individuals who are approved by an authorized specialty board and work for a licensee who wishes to add the individual to the licensee's radioactive materials license may save approximately one half hour of their time to locate the written attestation statement that they were provided upon completion of their training. Therefore, each individual may save about $64.25.
9.	**A) Comments by the department head on the fiscal impact the rule may have on businesses:**
	The proposed requirements are being adopted to remain compatible with the US Nuclear Regulatory Commission requirements and to include specific requirements for holding radioactive waste for "decay-in-storage" (DIS) if the radioactive material has a half-life of greater than 120 days but less than 175 days. Although rough estimates of the possible costs and benefits to these entities are provided above, the numbers may not be very accurate for each separate licensee. Many of the proposed changes may or may not be implemented by a licensee depending on the types of radioactive materials used. Additionally, many of the proposed requirements could be used many times within a year. For example, if the licensee is adding multiple Authorized Users for radioactive materials listed in R313-32 [incorporating 10 CFR 35.100 by reference], the licensee may experience the possible direct fiscal benefit associated with the proposed change for each board approved individual that is being added to their license. It is also possible that the licensee will not experience a benefit from the addition of any individual to the license if the individuals are not board certified or were previously named on another radioactive materials license. Licensees may

	implement the proposed changes in a myriad of combinations or may not implement any of the proposed changes. Because of this, there is a wide range of potential costs and benefits associated with the proposed changes for each licensee. The reported costs and benefits assume that each licensee would implement the proposed changes applicable to the two main categories of services provided at least once, unless the proposed change was not applicable to the facilities within the State. For example, although the proposed changes add a requirement to test the breakthrough concentration for each eluate of a Mo-99/Tc-99m medical generator, there are no medical use licensees that possess one of these generators therefore, the costs associate with the testing of the generator were not addressed in the estimate. The possible direct fiscal benefits associated with the addition of the requirement regarding the disposal of certain radioactive waste were also not included in the estimate. The radioactive materials address by the requirement added by the DWMRC are new to the market and there is no data available for its use in Utah.
	B) Name and title of department head commenting on the fiscal impacts:
	Alan Matheson, Executive Director, Department of Environmental Quality

10. This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws.
State code or constitution citations (required) (e.g., Section 63G-3-402; Subsection 63G-3-601(3); Article IV) **:**

19-3-104	
19-6-104	

11. 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 Division of Administrative Rules; *if none, leave blank*)**:**

	First Incorporation	**Second Incorporation**
Official Title of Materials Incorporated (from title page)	10 CFR Part 35	
Publisher		
Date Issued	January 1, 2019	
Issue, or version	2019	
ISBN Number (optional)		
ISSN Number (optional)		
Cost of Incorporated Reference		
Action: Adds, updates, or removes	10 CFR Part 35 (2010)	

(If this rule incorporates more than two items by reference, please attach additional pages)

12. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted until 5:00 p.m. on	July 31, 2019

	(mm/dd/yyyy):		
	B) A public hearing (optional) will be held:		
	On (mm/dd/yyyy)**:**	**At** (hh:mm AM/PM)**:**	**At** (place)**:**
13.	**This rule change may become effective on** (mm/dd/yyyy)**:**		August 9, 2019
	NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 12(A) above, the agency must submit a Notice of Effective Date to the Division of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.		
14.	**Indexing information -- keywords** (maximum of four, in lower case, except for acronyms (e.g., "GRAMA") or proper nouns (e.g., "Medicaid"); may not include the name of the agency**:**		
	radioactive materials	radiopharmaceutical	
	brachytherapy	nuclear medicine	
15.	**Attach an RTF document containing the text of this rule change** (filename)**:**		R313-032 Fiscal Tables and Rules.rtf

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 AUTHORIZATION

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

Appendix 1: Regulatory Impact Summary Table*

Fiscal Costs	**FY 2020**	**FY 2021**	**FY 2022**
State Government	$9,443.96	$3,166.94	$3,166.94
Local Government	$0	$0	$0
Small Businesses	$20,276.22	$2,430.10	$2,430.10
Non-Small Businesses	$65,805.97	$8,515.89	$8,515.89
Other Person	$0	$0	$0
Total Fiscal Costs:	**$95,526.15**	**$14,112.93**	**$14,112.93**
Fiscal Benefits			
State Government	$5,972.45	$5,972.45	$5,972.45
Local Government	$0	$0	$0
Small Businesses	$5,983.10	$5,983.10	$5,983.10
Non-Small Businesses	$16,819.57	$16,819.57	$16,819.57
Other Persons	$128.51	$128.51	$128.51
Total Fiscal Benefits:	**$28,903.63**	**$28,903.63**	**$28,903.63**
Net Fiscal Benefits:	**-$66,623**	**$14,790.70**	**$14,790.70**

***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 for State Government, Local Government, Small Businesses and Other Persons are described in the narrative. Inestimable impacts for Non-Small Businesses are described in Appendix 2.**

Appendix 2: Regulatory Impact to Non-Small Businesses

There are 32 non-small business entities (NAICS #622110, NAICS # 622111) that hold radioactive materials licenses for use of radioactive materials under the provisions of R313-32 and that are not owned or operated by a State Agency. The implementation of these proposed requirements is dependent on the uses of radioactive materials authorized for use by each separate licensee. Those licensees that use radioactive materials only for diagnostic purposes may not implement any of the proposed changes, may implement just a few of the proposed changes or may implement all of the proposed changes that could be applicable to their operations. Licensees using radioactive materials for the therapeutic treatment of patients will be required to implement certain of the proposed changes; however, may not implement all proposed changes. Since each licensee is not required to implement all of the proposed rule changes, may avail themselves of some of the proposed requirements that benefit licensees multiple times in a year, or may choose not to implement any of the proposed changes, an estimate of the costs and benefits to licensees and State Agencies is

difficult to determine. However, as before, it was assumed that the 32 non-small business medical use licensees could simplistically be separated into businesses that provide therapeutic treatments with radioactive materials and those licensees that perform diagnostic scans using radioactive materials. Although it is quite unlikely, each licensee was assumed to implement all proposed changes that could apply to their operations one time each year. Therefore, the provided estimates are likely to overestimate the costs and benefits that may be experienced by the licensees. As an example, businesses performing only diagnostic scans would have no need to write, document, and implement procedures to verify the post-implant source positions within 60 days from the date that the sources were implanted since this is a therapeutic procedure. However, there are also numerous businesses that provide therapeutic services to patients that are not authorized to permanently implant the sources to which this requirement would apply.

Only nine of the 32 licensees qualifying as large businesses restrict their services to diagnostic services while the remaining 23 licensees provide both diagnostic and therapeutic services using radioactive materials. There are no fees associated with the proposed changes and no fees charged for amendments to the radioactive materials licenses. The costs and benefits for each group of licensees are direct fiscal impacts for the licensee and are based on estimated savings and costs due to personnel time that will be used or saved and the average wage for the personnel performing the task or duty delineated by the proposed change. Those licensees providing only diagnostic services may experience an initial one-time direct fiscal impact of about $1,632.15 and ongoing direct fiscal impacts (annual) of about $1,958.59. These licensees may also experience a direct fiscal benefit of about $3,917.16 annually.

The remaining 23 licensees of the 32 large business licensees provide both diagnostic and therapeutic services using radioactive materials. These licensees may experience an initial one-time direct fiscal impact of approximately $55,657.93 and on-going (annual) direct fiscal impacts of about $6,557.30. Additionally, these licensees may experience direct fiscal benefits of about $12,902.41 annually. These licensees will also be impacted by the requirement proposed for the disposal of certain materials.

The impact of the requirement proposed by the DWMRC that is not contained in 10 CFR Part 35 was not included in this analysis. This requirement will result in a direct benefit to the licensees; however, the benefit cannot be analyzed at this time. The radioactive material in question is from a new medical treatment for certain cancers and it is unknown how many facilities will provide this treatment to patients or how much waste will be created from its use. Therefore, this direct fiscal benefit cannot be estimated.

In total, the non-small business licensees may experience one-time direct fiscal implementation costs of about $57,290.08 and annual direct fiscal costs of about $8,515.89. These licensees may also experience annual direct fiscal benefits of approximately $16,819.57.

The Director of the Department of Environmental Quality, Alan Matheson, has reviewed and approved this fiscal analysis.

****"Non-small business" means a business employing 50 or more persons; "small business" means a business employing fewer than 50 persons.**

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

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

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

R313-32-2. Clarifications or Exceptions.

For the purposes of Rule R313-32, 10 CFR 35.2 through 35.7; 35.10(d) through 35.10(f); 35.11(a) through 35.11(b); 35.12; and 35.13(b) through [~~35.3067~~]35.3204 ([~~2010~~]2019) are incorporated by reference with the following clarifications or exceptions:

(1) The exclusion of the following:

(a) In 10 CFR 35.2, exclude definitions for "Address of Use," "Agreement State," "Area of Use," "Dentist," "Pharmacist," "Physician," "Podiatrist," and "Sealed Source";[~~ and~~]

(b) In 10 CFR 35.19, exclude "or the common defense and security ";

[~~(b)~~](c) In 10 CFR 35.3067, exclude ", with a copy to the Director, Office of Nuclear Material Safety and Safeguards[~~.~~]";

(d) In 10 CFR 35.3045(d), 10 CFR 3047(d), 10 CFR 35.3067, and 10 CFR 35.3204(b), exclude "By an appropriate method listed in Sec. 30.6(a) of this chapter, ."

(2) The substitution of the following date references:

(a) "May 13, 2005" for "October 24, 2002"; and

(b) [~~"May 10, 2006" for "April 29, 2005."~~]"December 31, 2019" for "January 14, 2019."

(3) The substitution of the following rule references:

(a) "Rules R313-32 and R313-15" for reference to "this part and 10 CFR Part 20" in 10 CFR 35.61(a);

(b) "Rule R313-15[~~or~~] for reference to "Part 20 of this chapter" in 10 CFR 35.70(a) and 10 CFR 35.80(a)(4);

[~~(b)~~](c) "Rules R313-19 and R313-22" for reference to "Part 30 of this chapter" in 10 CFR 35.18(a)(4);

(d) "Rules R313-19 and R313-22 or equivalent Nuclear Regulatory Commission or Agreement State requirements for reference to "10 CFR Part 30 or the equivalent requirements of an Agreement State" in ;[~~ except for the reference to "Part 30 of this chapter" found in 10 CFR 35.65(d)~~];

[~~(c)~~](e) "10 CFR Part 30" for reference to "Part 30 of this chapter" as found in 10 CFR 35.65[~~(d)~~](a)(4);

[~~(d)~~](f) "Rules R313-15[~~ and~~], R313-19, and R313-22" for reference to "parts 20 and 30 of this chapter" as found in 10 CFR 35.63(e)(1);

[~~(e)~~](g) "Section R313-12-110" for reference to "Sec. 30.6 of this chapter" as found in 10 CFR 35.14(c).[~~or for reference to "Sec. 30.6(a)" or for reference to "Sec. 30.6(a) of this chapter"~~];

[~~(f)~~](h) "Section R313-15-101" for reference to "Sec. 20.1101 of this chapter" as found in 10 CFR 35.24(a);

[~~(g)~~](i) "Subsection R313-15-301(1)(a)" for reference to "Sec. 20.1301(a)(1) of this chapter" as found in 10 CFR 35.310(a)(2)(i) and 10 CFR 35.410(a)(4)(i);

[~~(h)~~](j) "Subsection R313-15-301(1)(c)" for reference to "Sec. 20.1301(c) of this chapter" as found in 10 CFR 35.310(a)(2)(ii) and 10 CFR 35.410(a)(4)(ii);

[~~(i)~~](k) "Section R313-15-501" for reference to "Sec. 20.1501 of this chapter" as found in 10 CFR 35.652(a);

[~~(j)~~](l) "Section R313-18-12" for reference to "Sec. 19.12 of this chapter" as found in 10 CFR 35.27(a)(1), 10 CFR 35.27(b)(1), 10 CFR 35.310, and 10 CFR 35.410;

[~~(k)~~](m) "Rules R313-19, R313-22 and Subsection R313-22-75(10) or equivalent U.S. Nuclear Regulatory Commission or Agreement State [~~regulations~~]requirements" for reference to "10

CFR Part 30 and Sec. 32.74 of this chapter or equivalent requirements of an Agreement State[~~,~~]" as found in 10 CFR 35.[~~65(b)~~]49(a);

[~~(l)~~](n) "Subsection R313-22-75(10) or equivalent Nuclear Regulatory Commission or Agreement State requirements" [~~for reference to "10 CFR 32.74 of this chapter," or for reference to "Sec. 32.74 of this chapter" except~~]for [~~the~~]references to "Sec. 32.74 of this chapter or equivalent Agreement State regulations" found in 10 CFR 35.65[~~(b)~~](a)(1) and 10 CFR 35.65(a)(2);

[~~(m)~~](o) "Rule R313-70" for reference to "Part 170 of this chapter";

[~~(n)~~](p) "Subsection R313-19-34(2)" for reference to "Sec. 30.34(b) of this chapter" as found in 10 CFR 35.14(b)(4);

[~~(o)~~](q) "[~~Rule~~]Section 313-22-50" for reference to "Part 33 of this chapter" in 10 CFR 35.15;

[~~(p)~~](r) "Subsection R313-22-50(2)" for reference to "Sec. 33.13 of this chapter" in 10 CFR 35.12(e);

[~~(q)~~](s) "Subsection R313-22-75(9)(b)(iv)" for reference to "Sec. 32.72(b)(4)" in the definition of Authorized Nuclear Pharmacist in 10 CFR 35.2;

[~~(r)~~](t) "Subsection R313-22-75(9) or equivalent Nuclear Regulatory Commission or Agreement State requirements[~~, 10 CFR 32.72, ~~]" for references to "Sec. 32.72 of this chapter or equivalent Agreement State requirements" as found in 10 CFR 35.63(b)(2)(i), 10 CFR 35.63(c)(3)(i), 10 CFR 35.100(a)(1), 10 CFR 35.200(a)(1), and 10 CFR 35.300(a)(1);[

~~(s) "Subsection R313-22-75(9)(b)(v)" for reference to "Sec. 32.72(b)(5)"~~

~~(t) "(c)(1) or (c)(2)" for reference to "(c)(1)" in 10 CFR 35.50(d);~~

~~(u) "35.600 or 35.1000" for reference to "35.600" in 10 CFR 35.41(b)(1);~~] and

[~~(v)~~](u) "Subsection R313-22-32(9)[~~, 10 CFR 30.32(j),~~]or equivalent Nuclear Regulatory Commission or Agreement State requirements" for reference to "Sec. 30.32(j)of this chapter or equivalent Agreement State requirements" as found in 10 CFR 35.63(b)(2)(iii), 10 CFR 35.63(c)(3)(ii), 10 CFR 35.100(a)(2), 10 CFR 35.200(a)(2), or 10 CFR 35.300(a)(2).

(4) The substitution of the following terms:

(a) "radioactive material" for reference to "byproduct material";

(b) [~~"original" for "original and one copy";~~]"a Director, a Nuclear Regulatory Commission, or Agreement State" for reference to "an NRC or Agreement State" in 10 CFR 35.63(b)(2)(ii), 10 CFR 35.100(c), 10 CFR 35.200(c), or 10 CFR 35.300(c);

(c) "Director is (801) 536-0200 or after hours, (801) 536-4123" for "NRC Operations Center is (301) 816-5100[~~951-0550~~]" as found in the footnote included for 10 CFR 35.3045(c);

(d) "Form DWMRC-01, 'Application for Radioactive Material License[~~ Application~~]'" for reference to "NRC Form 313, 'Application for Material License'" as found in 10 CFR 35.12(b)(1), 10 CFR 35.12(c)(1)(i) and 10 CFR 35.18(a)(1);

(e) "Form DWMRC-01" for reference to "NRC Form 313" as found in 10 CFR 35.12(c)(1)(ii);

[~~(e)~~](f) "[~~State of Utah radioactive materials~~]medical use license issued by the Director" for reference to "NRC medical use license" in 10 CFR 35.6(c);

[~~(f)~~][~~(g)~~] "[~~the~~]Director, the U.S. Nuclear Regulatory Commission, or an Agreement State" for reference to "[~~the~~]Commission or Agreement State" in 10 CFR 35.2 in the definitions for Authorized Medical Physicist (2)(i), Authorized Nuclear Pharmacist (2)(iii), Radiation Safety Officer (2)(i), 10 CFR 35.57(b)(1) (first instance), 10 CFR 35.57(b)(2) (first instance), 10 CFR 35.433(a)(2)(i); or for references to "[~~the~~]Commission or an Agreement State" in 10 CFR 35.2 in the definitions for Associate Radiation Safety Officer (2)(i), Ophthalmic Physicist (2)(i), 10 CFR 35.11(a), 10 CFR 35.50(a), 10 CFR 35.50(a)(2)(ii)(A), 10 CFR 35.50(c)(1), 10 CFR 35.51(a), 10 CFR 35.51(a)(2)(i), 10 CFR 35.55(a), 10 CFR 35.190(a), 10 CFR 35.290(a), 10 CFR 35.390(a), 10 CFR 35.392(a), 10 CFR 35.394(a), 10 CFR 35.396(a)(3), 10 CFR 35.433(a)(2)(i), 10 CFR 35.490(a), 10 CFR 35.590(a), 10 CFR 35.605(a), 110 CFR 35.605(b), 10 CFR 35.605(c), 10 CFR 35.655(b) and 10 CFR 35.690(a);

[~~(g)~~](h) "[~~an~~]Director, [~~the~~] U.S. Nuclear Regulatory Commission, or an Agreement State" for references to "[~~a~~]Commission or Agreement State" in 10 CFR 35.2 in the definitions for Authorized Medical Physicist (2)(iii), Authorized Nuclear Pharmacist (2)(i), Authorized User (2)(i), Authorized User (2)(iii), Ophthalmic Physicist (2)(ii), 10 CFR 13(b)(4)(ii), 10 CFR 35.14(a)(2)(second instance), 10 CFR 35.57(a)(1)(second instance), 10 CFR 35.57(b)(1)(second

instance), 10 CFR 35.57(b)(2)(second instance), 10 CFR 35.433(a)(2)(ii)(second instance); or for references to "Commission or an Agreement State" in 10 CFR 35.50(c)(2)(second instance);

[(h)](i) ["Equivalent U.S. Nuclear Regulatory Commission or Agreement State"]"license issued by the Director, the Nuclear Regulatory Commission, or the Agreement State" for reference to ["equivalent Agreement State"]"Commission or Agreement State license" [as found]in 10 CFR 35.14(a)(2)(first instance)[63(b)(2)(i), 10 CFR 35.63(c)(3), 10 CFR 35.65(a), 10 CFR 35.100(a), 10 CFR 35.200(a), and 10 CFR 35.300(a)];

[(i)](j) "Director" for reference to "NRC Operations Center" in 10 CFR 35.3045(c),[and] 10 CFR 35.3047(c), and 10 CFR 35.3204(a);

(k) "license issued by the Director, the Nuclear Regulatory Commission or an Agreement State" for reference to "Commission or Agreement State license" in 10 CFR 35.13(b)(4)(i), 10 CFR 35.14(a)(2)(first instance), 10 CFR 35.50(b)(1)(ii) or for reference to "Commission or an Agreement State license" in 10 CFR 35.50(b)(1)(ii), 10 CFR 35.50(c)(2), and 10 CFR 35.57(a)(2);

[(j) "Utah Division of Waste Management and Radiation Control" for reference to "NRC Operations Center";

] [(k)](l) "Director at the address specified in Section R313-12-110" for reference to "appropriate NRC Regional Office listed in Sec. 30.6 of this chapter" in 10 CFR 35.3045(d), 10 CFR 35.3047(d), 10 CFR 35.3067, and 10 CFR 35.3204(b);

[(l)](m) "[Utah Waste Management and Radiation Control]Board" for reference to "Commission" in 10 CFR 35.18(a)(3)(second instance) and 10 CFR 35.19;

[(m)](n) "Director" for references to "Commission" in [10 CFR 35.10(b),]10 CFR 35.[12(d)(2)]12(d)(4), 10 CFR 35.14(a)[(first instance)], 10 CFR 35.14(b), 10 CFR 35.18(a), 10 CFR 35.18(a)(3)(first instance), 10 CFR 35.18(b), 10 CFR 35.24(a)(1), 10 CFR 35.24(c), 10 CFR 35.26(a), and 10 CFR 35.1000(b);

[(n)](o) "[the]Director" for reference to "NRC" in [10 CFR 35.13(b)(4)(i),]10 CFR 35.3045(g)(1), [and]10 CFR 35.3047(f)(1), and 10 CFR 35.3204(a)(second instance);

[(o)](p) ["the U.S. Nuclear Regulatory Commission or an Agreement State" for reference to "an Agreement State" in 10 CFR 35.49(a) and 10 CFR 35.49(c)]"Nuclear Regulatory Commission" for reference to "Commission" in 10 CFR 35.67(b)(2);

[(p)](q) ["A Director, a U.S. Nuclear Regulatory Commission, or Agreement State"]"Director" for reference to ["An NRC or Agreement State"]"NRC" in 10 CFR 35.[63(b)(2)(ii)]3045(g)(1), 10 CFR 35.[100(c)]3047(f)(1), [10 CFR 5.200(c),]and 10 CFR 35.[300(c)]35.3204(a)(second instance); and

[(q)](r) [In 10 CFR 35.75(a) "Footnote 1", substitute "The current version of NUREG-1556, Vol. 9" for "NUREG-1556 Vol. 9,"]"the Director" for reference to "NRC" in 10 CFR 35.13(b)(4)(i);

(s) "licenses issued by the Director" for reference to "NRC licenses" in 10 CFR 35.57(c);

(t) "Director, the Nuclear Regulatory Commission, or an Agreement State" for reference to "NRC" in 10 CFR 35.13(b)(5), 10 CFR 35.14(a)(2), 10 CFR 35.57(b)(3), and 10 CFR 35.57(a)(4);

(u) "(c)" for reference to "(b)" in 10 CFR 35.92.

(5) The addition of the following to 10 CFR 35.92:

" (b) The Director may approve a radioactive material with a physical half-life of greater than 120 days but less than 175 days for decay-in-storage before disposal without regard to its radioactivity on a case by case basis if the licensee:

(1) Requests an amendment to the licensee's radioactive materials license for the approval;

(2) Can demonstrate that the radioactive waste will be safely stored, and accounted for during the decay-in-storage period and that the additional radioactive waste will not exceed the licensee's radioactive waste storage capacity; and

(3) Commits to monitor the waste before disposal as stated in paragraphs (a)(1) and (a)(2) of this section before the waste is disposed."

KEY: radioactive materials, radiopharmaceutical, brachytherapy, nuclear medicine
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