UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

September 12, 2021

EA-21-034

James Adamson, Chief Executive Officer
Mountain View Hospital
2325 Coronado Street
Idaho Falls, ID 83404

SUBJECT: NRC INSPECTION REPORT 030-38701/2020-001

Dear Mr. Adamson:

This letter and the enclosed inspection report refer to the routine inspection that commenced as a remote inspection on November 9, 2020. An onsite inspection was performed at your facilities in Idaho Falls, Idaho, between November 16 and 19, 2020. The inspection continued with in-office review through September 2, 2021. The inspection was performed to examine activities conducted under your license as they relate to public health and safety and to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC's) rules and regulations and the conditions of your license. Within these areas, the inspection consisted of an examination of selected procedures and representative records, observation of licensed activities and facilities, independent radiation measurements, and interviews with personnel. The enclosed inspection report presents the results of this inspection. The inspector discussed the preliminary inspection findings with Amy Larsen, Director, Ancillary Services; Lisa Anderson, Manager, Oncology Services; and David Theel, Radiation Safety Officer, on November 19, 2020, at the conclusion of the onsite portion of the inspection. A final exit briefing was conducted via videoconference with Mr. Ned Hillyard, Chief Compliance Officer, Ms. Larsen, Ms. Anderson, Mr. Theel, and other members of your staff on September 2, 2021.

Based on the results of this inspection, six apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violations involve failures related to the implementation of your program for the therapeutic administration of lutetium-177 dotate Lutathera® (Lu-177) under Title 10 of the *Code of Federal Regulations* (10 CFR) Section 35.300, "Unsealed Byproduct Material-Written Directive Required." Specifically, the apparent violations involve the: (1) failure to develop, implement, and maintain written procedures to provide high confidence that each administration of Lu-177 is in accordance with the written directive; (2) release of individuals who had been administered Lu-177 and had radiation dose rates that exceeded your release criteria; (3) failure to document the instructions or training provided to individuals caring for patients administered Lu-177; (4) failure to document radiation surveys to demonstrate that rooms used for Lu-177 patients could be released for unrestricted use; (5) discharge to the sanitary sewer of Lu-177 contaminated

materials that were not readily soluble in water or biological materials; and (6) failure to label a Lu-177 radioactive waste storage container and its contents to indicate that they contained radioactive material.

The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with Ms. Larsen, Ms. Anderson, Mr. Theel, and other members of your staff during the videoconference exit meeting on September 2, 2021.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond in writing to the apparent violations addressed in the inspection report within 30 days of the date of this letter; (2) request a pre-decisional enforcement conference (PEC); or (3) request alternative dispute resolution (ADR). If a PEC is held, it will be open for public observation and the NRC may issue a press release to announce the time and date of the conference. Please contact Dr. Lizette Roldán-Otero, Chief, Materials Inspection Branch, at 817-200-1455 or Lizette.Roldan-Otero@nrc.gov within 10 days of the date of this letter to notify the NRC of your intended response to either provide a written response, participate in a PEC, or pursue ADR. A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violations in NRC Inspection Report 030-38701/2020-001; EA-21-034" and should include for each apparent violation: (1) the reason for the apparent violation or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence if the correspondence adequately addresses the required response. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction. Your written response, should you chose to provide one, should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with identical copies mailed to Ms. Mary Muessle, Director, Division of Nuclear Materials Safety, Region IV, 1600 East Lamar Boulevard, Arlington, TX 76011, and emailed to R4Enforcement@nrc.gov within 30 days of the date of this letter. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing your response (Agencywide Documents Access and Management System (ADAMS) Accession No. ML061240509).

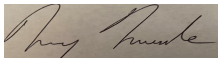
In lieu of a PEC, you may request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC employs is mediation. Mediation is a voluntary, informal process in which a trained neutral mediator works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's ADR program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact the Institute on Conflict Resolution at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

Please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results on our deliberations in this matter.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, and its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's ADAMS, accessible from the NRC Web website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction.

If you have any questions concerning this matter, please contact Dr. Lizette Roldán-Otero of my staff at 817-200-1455.

Sincerely,



Signed by Muessle, Mary
on 09/12/21

Mary C. Muessle, Director
Division of Nuclear Materials Safety

License No. 11-35120-01
Docket No. 030-38701

Enclosure:
NRC Inspection Report 030-38701/2020-001

cc w/Enclosure:
Mark Dietrich
Radiation Control Program Director
Idaho Department of Environmental Quality
1410 North Hilton Drive
Boise, ID 83706

SUBJECT: NRC INSPECTION REPORT 030-38701/2020-001 DATED SEPTEMBER 12, 2021

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ADAMS ACCESSION NUMBER – **ML21250A165**

X SUNSI Review by: **JFK**	ADAMS **X** Yes ☐ No	**X** Publicly Available ☐ Non-Publicly Available	**X** Non-Sensitive ☐ Sensitive	Keyword:

OFFICE	RIV:MIB	BC MIB	ACES:TL	RIV: RC	OE	NMSS	D: DNMS
NAME	JFKatanic	LRoldanOtero	DDodson	DCylkowski	LSreenivas	RSun	MCMuessle
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U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket No.:	030-38701
License No.:	11-35120-01
Inspection Report No.:	030-38701/2020-001
EA No.:	EA-21-034
Licensee:	Mountain View Hospital
Locations Inspected:	Mountain View Hospital 2325 Coronado Street Idaho Falls, Idaho Teton Cancer Institute 1550 Hoopes Avenue Idaho Falls, Idaho
Inspection Dates:	Remote inspection commenced on November 9, 2020; onsite inspection occurred during November 16-19, 2020; continued in-office review conducted through September 2, 2021
Exit Meeting Date:	September 2, 2021
Inspector:	Janine F. Katanic, PhD, CHP Senior Health Physicist Materials Inspection Branch Division of Nuclear Materials Safety, Region IV
Approved by:	Lizette Roldán-Otero, PhD Chief, Materials Inspection Branch Division of Nuclear Materials Safety, Region IV
Attachment:	Supplemental Inspection Information

Enclosure

EXECUTIVE SUMMARY

Mountain View Hospital (MVH)
NRC Inspection Report 030-38701/2020-001

On November 9, 2020, the NRC began a remote routine inspection of MVH. Onsite inspection activities were performed during November 16-19, 2020, at the licensee's facilities in Idaho Falls, Idaho. The inspector continued in-office review through September 2, 2021. The scope of the inspection was to examine the activities conducted under the license and to confirm compliance with the NRC's rules and regulations and the conditions of the license.

Program Overview

Mountain View Hospital is authorized under NRC Materials License 11-35120-01 to possess and use byproduct material for diagnostic and therapeutic medical use under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35 at its facilities in Idaho. At its Teton Cancer Center outpatient facility in Idaho Falls, Idaho, the licensee performed therapeutic administrations requiring written directives for lutetium-177 dotate (Lu-177) (Lutathera®).

Lutetium-177 Administration Program

The inspector identified six apparent violations associated with the licensee's Lu-177 administration program and the licensee's: (1) failure to develop, implement, and maintain written procedures to provide high confidence that each administration of Lu-177 is in accordance with the written directive; (2) release of individuals who had been administered Lu-177 and had radiation dose rates that exceeded the licensee's release criteria; (3) failure to document the instructions or training provided to individuals caring for patients administered Lu-177; (4) failure to document radiation surveys to demonstrate that rooms used for Lu-177 patients could be released for unrestricted use; (5) discharge to the sanitary sewer of Lu-177 contaminated materials that were not readily soluble in water or biological materials; and (6) failure to label a Lu-177 radioactive waste storage container and its contents to indicate that they contained radioactive material.

At the conclusion of the onsite portion of the inspection, the licensee voluntarily suspended its Lu-177 administration program. The licensee later committed to rebuild its Lu-177 administration program from the ground up prior to resuming patient administrations of Lu-177.

REPORT DETAILS

1 Program Overview (Inspection Procedures (IPs) 87131, 87132)

1.1 Program Scope

Mountain View Hospital (MVH or licensee) is authorized under NRC Materials License 11-35120-01 to possess and use byproduct material for diagnostic and therapeutic medical use under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35 at its facilities in Idaho.

1.2 Observations and Findings

On November 9, 2020, the NRC began a remote routine inspection of MVH. Onsite inspection activities were performed during November 16-19, 2020. Mountain View Hospital is the name of the licensee but also the name of one of its facilities listed on the license. Inspection activities were performed at the licensee's two authorized locations: MVH and Teton Cancer Institute (TCI), which are separated by approximately 1 mile. The inspector continued in-office review through September 2, 2021. The purpose of the inspection was to examine the activities conducted under the NRC license and to confirm compliance with the NRC's rules and regulations and with the conditions of the license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of licensed activities, independent radiation measurements, and interviews with personnel. The inspector also obtained and reviewed additional documents provided by the licensee following the onsite inspection.

At the MVH facility, the licensee was authorized to perform activities in accordance with 10 CFR 35.400, which consisted of permanent implant brachytherapy.

At the TCI facility, the licensee was authorized to use unsealed materials for: (1) uptake, dilution, and excretion studies in accordance with 10 CFR 35.100, (2) imaging and localization studies in accordance with 10 CFR 35.200; and (3) administrations requiring a written directive in accordance with 10 CFR 35.300. Under the provisions of 10 CFR 35.300, the licensee performed administrations requiring written directives for lutetium-177 dotate (Lutathera®). For ease of discussion, lutetium-177 dotate Lutathera® will hereafter be referred to in this inspection report as Lu-177.

2 Lutetium-177 Administration Program (IP 87131)

2.1 Inspection Scope

On November 9, 2020, the NRC began a remote routine inspection of the licensee. Onsite inspection activities were performed during November 16-19, 2020. Inspection activities were performed at the licensee's two authorized locations in Idaho Falls, Idaho. The inspection consisted of a selected examination of procedures and representative records, observations of licensed activities, independent radiation measurements, and interviews with personnel. The inspector also obtained and reviewed additional documents provided by the licensee following the onsite inspection.

2.2 Background

The licensee was authorized to perform licensed activities under the provisions of 10 CFR 35.300 at the TCI facility in Idaho Falls, Idaho. These licensed activities included the performance of administrations requiring written directives for Lu-177, which is used to treat certain types of neuroendocrine tumors that have somatostatin receptor-expressing cells.

Typically, a full therapeutic regimen for a patient consists of four administrations of 200 millicuries of Lu-177, with each 200 millicurie administration typically occurring at 8-week intervals. Each administration of Lu-177 typically begins with the administration of a non-radioactive antiemetic to help the patient avoid nausea and vomiting, which are frequently experienced by patients receiving this therapeutic regimen. Vomit from patients who have been administered Lu-177 is a known radioactive contamination consideration.

A patient is also administered certain non-radioactive amino acids that help provide protection and reduce radiation dose to the kidneys, since Lu-177 distributes to, and is cleared by, the renal system. As a result, urine is also a known radioactive contamination consideration.

Then, 200 millicuries of Lu-177 is administered to a patient as an intravenous infusion. The actual infusion of Lu-177 takes approximately 30-40 minutes. The infusion of Lu-177 involves careful regulation of the flow of the Lu-177 solution into the patient, either through a gravity infusion technique or aided by an infusion pump. With either infusion method there are certain complexities involving inserting long and short needles at specified heights into the Lu-177 vial, as well as using other equipment and techniques, including the use of valves and stopcocks. Proper implementation of the infusion method is necessary to keep the pressure within the Lu-177 administration system steady while varying the infusion rate of Lu-177 over time in accordance with the vendor's recommendations. The stability and penetration angles of the long and short needles into the Lu-177 vial septum must be carefully controlled so that the puncture holes in the septum are not stretched or enlarged, which could create an air gap. Similarly, there is an added risk that if the pressure in the Lu-177 administration system is not maintained, Lu-177 can leak from the punctured holes or air gap in the septum, causing a radioactive contamination concern. Additionally, if the pressure is not maintained in the infusion system or if there is leakage of Lu-177 solution, there is risk that the full prescribed quantity of 200 millicuries of Lu-177 will not be infused into the patient, which could result in a reportable medical event.

Patients are administered a long-acting non-radioactive octreotide between 4 and 24 hours following the Lu-177 infusion. Altogether, it typically takes 4 to 5 hours from the start of the administration of the antiemetic, to the infusion of the Lu-177, to the end of the administration of the long-acting octreotide. The long-acting octreotide is normally continued every 4 weeks following the last Lu-177 administration for up to 18 months following Lu-177 treatment initiation.

The licensee began performing Lu-177 administrations in 2018. Since the commencement of the licensee's Lu-177 administration program the licensee has treated 11 patients and administered 34 Lu-177 infusions. Seven of these patients obtained all four scheduled Lu-177 infusions; three only obtained one Lu-177 infusion

but their treatment regimen was discontinued based on a physician's medical judgment; and one patient had completed three Lu-177 infusions as of the date of the onsite inspection.

2.3 Observations and Findings

The inspector identified six apparent violations associated with the licensee's Lu-177 administration program and the licensee's: (1) failure to develop, implement, and maintain written procedures to provide high confidence that each administration of Lu-177 is in accordance with the written directive; (2) release of individuals who had been administered Lu-177 and had radiation dose rates that exceeded the licensee's release criteria; (3) failure to document the instructions or training provided to individuals caring for patients administered Lu-177; (4) failure to document radiation surveys to demonstrate that rooms used for Lu-177 patients could be released for unrestricted use; (5) discharge to the sanitary sewer of Lu-177 contaminated materials that were not readily soluble in water or biological materials; and (6) failure to label a Lu-177 radioactive waste storage container and its contents to indicate that they contained radioactive material.

2.3.1 Procedures to Provide High Confidence

Title 10 CFR 35.41(a)(2) requires, in part, that for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

The inspector found that the licensee had a bulletized list for performing Lu-177 administrations, but the list was focused on the nursing care aspect of the administration of Lu-177. The list focused on scheduling the patient, preparing the patient, gathering necessary medical supplies, and checking the patient's vital signs. The bulletized list failed to describe the requirement for a properly prepared, dated, and signed written directive prior to Lu-177 administration.

As described in Section 2.2 of this report, the infusion of Lu-177 warrants careful attention to detail to avoid situations where there could be radioactive contamination concerns or where improper infusion techniques could lead to a reportable medical event. Accordingly, written procedures must be developed, implemented, and maintained by the licensee to provide high confidence that each administration is performed in accordance with the written directive. The licensee's bulletized list did not contain radiation safety information or guidance on properly setting up the Lu-177 infusion system. The specific bullet that referenced Lu-177 infusion simply stated to set up the infusion set. It did not specify, for example, the necessary placement of the long and short needles within the Lu-177 vial or other instructions necessary to provide assurance that the administration would be in accordance with the written directive.

Based on discussions with the Radiation Safety Officer (RSO), an Authorized User (AU), and a TCI radiation oncology technologist, it was revealed that an incident occurred where the AU was having difficulty infusing the Lu-177 into the patient. The bulletized list for Lu-177 administration that was being used by the licensee contained no troubleshooting guidance to address Lu-177 administration problems. When the infusion difficulty was encountered, the AU removed and reinserted the needles into the Lu-177

vial septum several times, puncturing numerous holes in the Lu-177 vial septum. As a result, the licensee was unable to maintain the appropriate pressure necessary to properly infuse the Lu-177 into the patient. The infusion of Lu-177 into the patient, which should have taken 30-40 minutes, took several hours to complete. The licensee reported that the prescribed dose was eventually able to be administered to the patient and that a medical event did not occur.

During the onsite inspection, the RSO provided the inspector with a different, more detailed Lu-177 administration procedure. A TCI radiation oncology technologist, who had participated in nearly all of the licensee's 34 Lu-177 administrations stated that they had never seen the procedure prior to that moment. The TCI radiation oncology technologist reviewed the procedure and noted that it described equipment and methodologies that were not utilized by the licensee for Lu-177 administrations, and the procedure was not consistent with their processes for performing Lu-177 administrations.

Apparent violation of 10 CFR 35.41(a)(2)

Title 10 CFR 35.41(a)(2) requires, in part, that for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

Contrary to the above, from September 4, 2018, to November 16, 2020, for administrations requiring a written directive, the licensee failed to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Specifically, the licensee failed to develop, implement, and maintain written procedures for the administration of Lu-177 that would provide high confidence that each administration is in accordance with the written directive.

The licensee's failure to develop, implement, and maintain written procedures for administrations requiring written directives was identified as an apparent violation of 10 CFR 35.41(a)(2). (030-38701/2020-001-01)

2.3.2 Patient Release after Lu-177 Administration

Title 10 CFR 35.75(a) requires, in part, that a licensee may authorize the release from its control of any individual who has been administered byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 500 mrem.

The NRC provides guidance regarding patient release in Regulatory Guide 8.39, Revision 1, "Release of Patients Administered Radioactive Material," issued April 2020. The guidance does not contain specific patient release criteria for Lu-177. When specific patient release criteria are not provided, the licensee may use the calculations in Regulatory Guide 8.39 to develop its own release criteria consistent with 10 CFR 35.75, under which licensees may release individuals from their control if the total effective dose equivalent to any other individual from the exposure to the released individual is not likely to exceed 500 mrem. At the time of the inspection, the Lu-177 vendor did not provide specific guidance to licensees regarding patient release criteria, other than that

licensees should refer to NRC guidance. As a result, the licensee developed its own patient release criteria for Lu-177 administrations.

The licensee performed Lu-177 administrations at its TCI facility, which is an outpatient only facility. The licensee's other facility, MVH, is a 41-bed inpatient hospital. Licensee management determined that no patients receiving licensed radioactive material at TCI, such as Lu-177, could be admitted as inpatients at MVH because "none of the beds were contracted for radiation oncology use."

At the start of its Lu-177 administration program, the licensee based its Lu-177 patient release criteria on a post-Lu-177 infusion radiation survey measurement at 1 meter from the patient. The licensee determined that if the radiation survey measurement at 1 meter from the patient was 2.5 mrem/h or less, the patient could be released from the licensee's control. When the licensee had patients whose radiation levels at 1 meter exceeded 2.5 mrem/h, the licensee's release criteria for Lu-177, they nonetheless released the patients from their control and sent them to other local medical facilities for inpatient observation.

Figure 1 provides the record of the licensee's release of a patient that exceeded the licensee's Lu-177 patient release criteria on October 24, 2019. The record includes the licensee's release criteria of 2.5 mrem/h at 1 meter for Lu-177. The documented exposure rate from the patient that was administered Lu-177 was 13.0 mrem/h at 1 meter at the time of release from the licensee's control. The measurement of 13 mrem/h at 1 meter from the patient considerably exceeded the licensee's patient release criteria, but the licensee released the patient from its control. The patient was sent to another local medical facility to be admitted as an inpatient. This other local medical facility will hereafter be referred to in this inspection report as "Facility B."

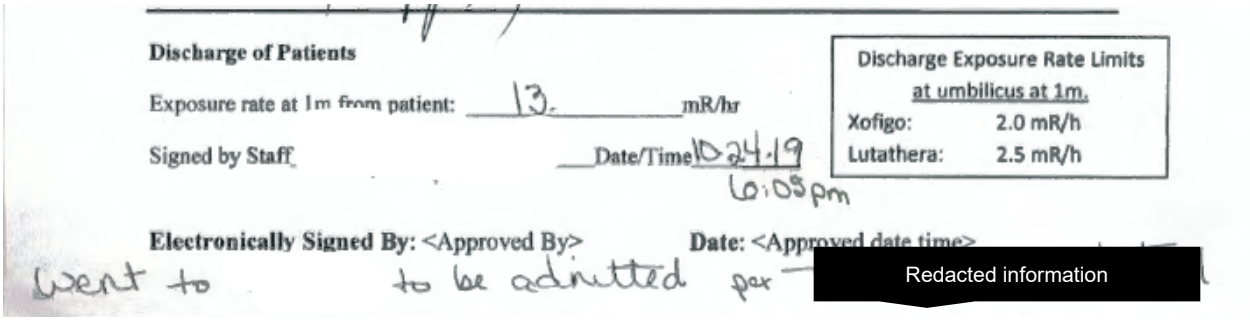


Figure 1. Patient release record for October 24, 2019

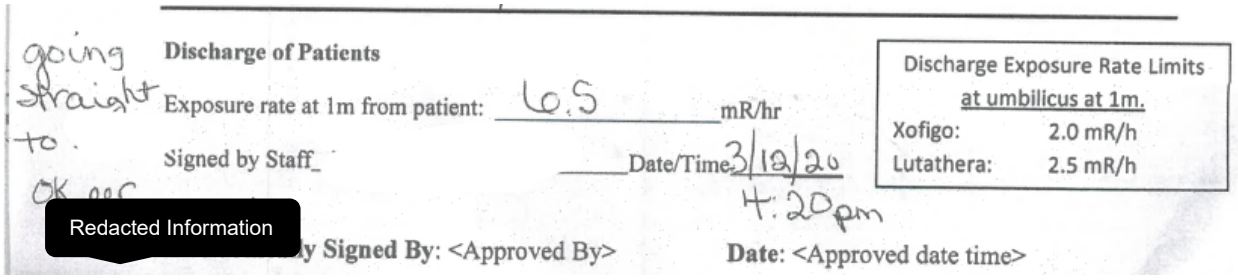
Facility B is an NRC licensee located in Idaho Falls, Idaho, that is authorized to perform various licensed activities, including administrations under 10 CFR 35.300. However, Facility B did not perform Lu-177 administrations. The Facility B radiation safety staff had no familiarity with any specific radiation safety concerns for patients administered Lu-177. The RSO did not perform any coordination with the Facility B radiation safety staff prior to releasing the patient from its control.

When the patient arrived at Facility B for admission, a nurse that was admitting the patient called the Facility B nuclear medicine technologist after hours, seeking radiation safety advice regarding Lu-177. The Facility B nuclear medicine technologist had not

previously heard of or used Lu-177 or cared for any patients administered Lu-177. Earlier in their career, the Facility B nuclear medicine technologist had worked with patients administered iodine-131 that were hospitalized as inpatients at a facility in another state. The Facility B nuclear medicine technologist called upon their past knowledge and experience with handling such patients that had been administered therapeutic quantities of radioactive material.

The Facility B nuclear medicine technologist arrived at Facility B after hours and prepared the Facility B inpatient room. The Facility B nuclear medicine technologist covered room surfaces with disposable materials, as if the patient had received iodine-131. The Facility B nuclear medicine technologist provided and documented radiation safety training to the Facility B nursing personnel. The training consisted of basic radiation precautions, contamination concerns, and information regarding keeping radiation doses as low as reasonably achievable by limiting time with the patient. During the time the patient was an inpatient at Facility B, the Facility B nuclear medicine technologist performed radiation surveys and collected radioactively contaminated materials from the patient room. After the patient was discharged, the Facility B nuclear medicine technologist did not release the patient room for unrestricted use for several weeks due to significant and extensive radioactive contamination from Lu-177.

A review of licensee records indicated that there were two other occasions when patients who were administered Lu-177 exceeded the licensee's release criteria for Lu-177 but were released from the licensee's control. Figure 2 provides the licensee's patient release record for a Lu-177 administration that occurred on March 12, 2020, which resulted in a radiation reading of 6.5 mrem/h at 1 meter from the patient. Figure 3 provides the licensee's patient release record for a Lu-177 administration that occurred on May 14, 2020, which resulted in a radiation reading of 6.5 mrem/h at 1 meter. The patient released by the licensee on March 12, 2020, is the same patient that was released on May 14, 2020. The March 12, 2020, administration was the patient's first Lu-177 administration, and the later administration on May 14, 2020, was their second Lu-177 administration.


going straight to.

Discharge of Patients

Exposure rate at 1m from patient: 6.5 mR/hr

Signed by Staff_____ Date/Time 3/12/20 4:20pm

Discharge Exposure Rate Limits at umbilicus at 1m.

Xofigo:	2.0 mR/h
Lutathera:	2.5 mR/h

Redacted Information

y Signed By: <Approved By> **Date**: <Approved date time>

Figure 2. Patient release record for March 12, 2020

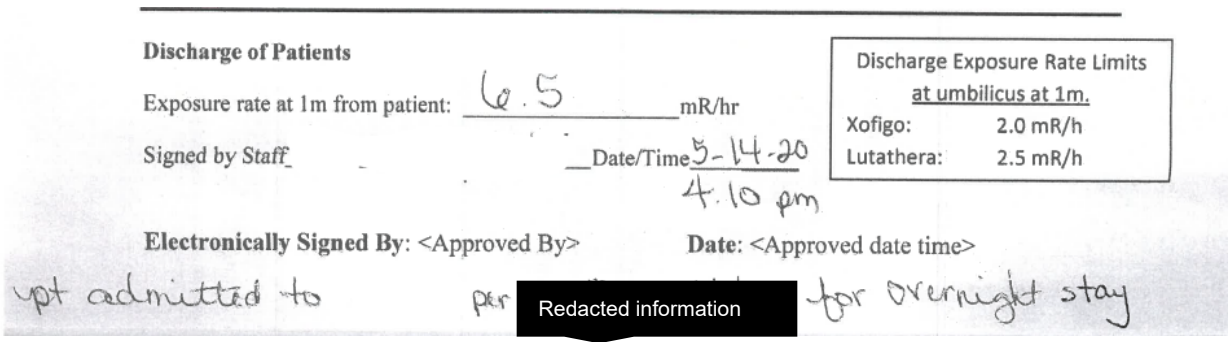


Figure 3. Patient release record for May 14, 2020

In these two instances, the documented exposure rate from the patient exceeded the licensee's patient release criteria, but the licensee released the patient from its control. The licensee sent the patient to a different local medical facility to be admitted as an inpatient. This other local medical facility will hereafter be referred to in this inspection report as "Facility C." Facility C is also an NRC licensee located in Idaho Falls, Idaho. Facility C was not authorized by NRC to perform Lu-177 administrations under 10 CFR 35.300. Facility C was only authorized by the NRC to perform uptake, imaging, and localization studies for diagnostic purposes.

Facility C was a newly-built hospital that opened in December 2019 and had 88 inpatient beds. Facility C is physically attached to MVH as a contiguous building, and its NRC license has the same RSO as the MVH NRC licensee.

The licensee's RSO, also being the RSO for Facility C, didn't inform the Facility C nuclear medicine technologist about the Lu-177 patients being sent to Facility C for inpatient admission. The RSO did not solicit any radiation safety support from the Facility C nuclear medicine technologist. Although the Facility C nuclear medicine technologist was not familiar with Lu-177, they were experienced in radiation safety considerations for individuals administered therapeutic amounts of licensed radioactive material.

When the patient was admitted to Facility C, the RSO sent the TCI radiation oncology technologist to prepare the patient room at Facility C. The TCI radiation oncology technologist had limited experience with handling radioactive contamination and relied on the RSO for guidance. The RSO, a medical physicist, also had limited experience with such matters. This led to deficiencies in conducting radiation surveys, performing radioactive decontamination, and the handling of radioactive Lu-177 waste.

After the second occurrence of sending a patient to Facility C in May 2020, the licensee encountered additional patients that exceeded its 2.5 mrem/h at 1 meter patient release criteria for Lu-177. In response, the licensee revised its patient release criteria for Lu-177 to be 8.0 mrem/h at 1 meter from the patient, as indicated by Figure 4. Figure 4 provides the licensee's patient release criteria for Lu-177, which was crossed off by the RSO and revised to be 8.0 mrem/h at 1 meter from the patient, rather than the prior criteria of 2.5 mrem/h at 1 meter from the patient.

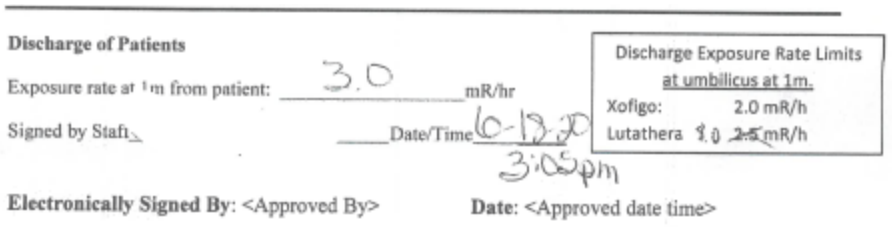


Figure 4. Revised patient release criteria for Lu-177, circa June 2020

Later, the licensee again changed the release criteria, adding an "alert" at greater than 4.0 mrem/h at 1 meter from the patient. The RSO was unable to explain to the inspector what was meant by "alert," or what actions needed to be taken at the "alert" level other than for the TCI radiation oncology technologist to notify the RSO. The licensee's revised patient release criteria for Lu-177 is provided in Figure 5.

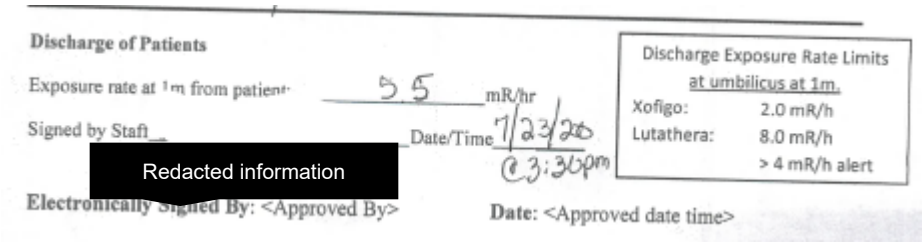


Figure 5. Revised patient release criteria for Lu-177, circa July 2020

In November 2020, just prior to the inspector's onsite inspection, the licensee again revised its patient release criteria for Lu-177. As provided in Figure 6, the licensee set a value of greater than 4 mrem/h at 1 meter from the patient as a "discharge exposure alert limit" to "alert/consider Lasix." Lasix is a diuretic that could help clear Lu-177 from the body.

At that time the licensee also set a "discharge exposure alert limit" at greater than 8 mrem/h at 1 meter from the patient as conditions to "refer for observation." The RSO stated that "refer for observation" meant to refer the patient to a medical facility for admission as an inpatient.

The licensee also set a "discharge requirement" based on the administration of 200 millicuries of Lu-177.

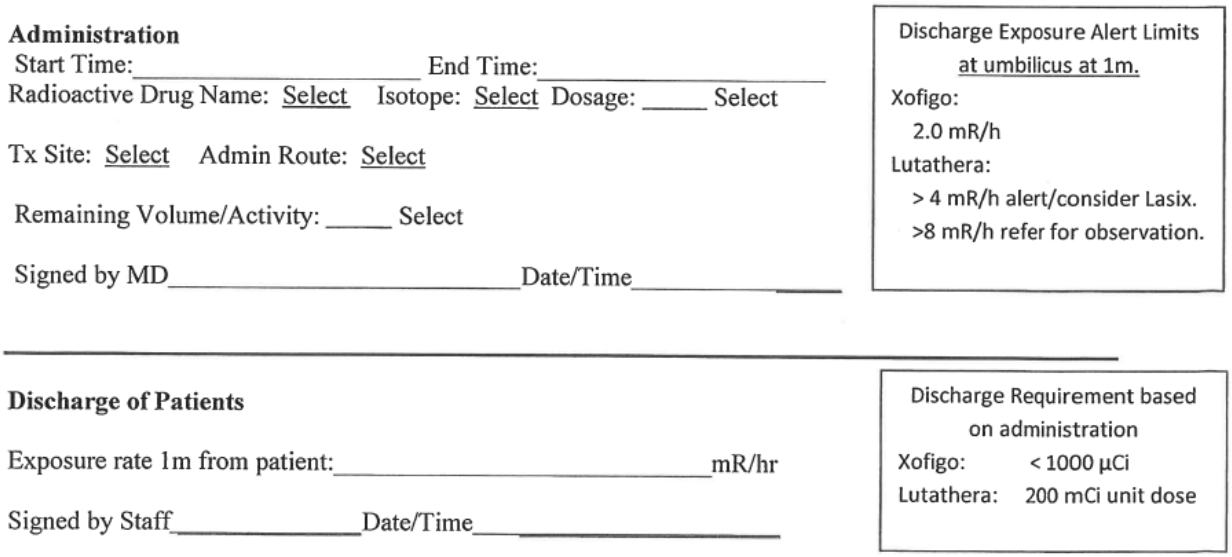


Figure 6. Revised patient release criteria for Lu-177, circa November 2020

The inspector observed that the licensee revised its patient release criteria for Lu-177 administration over time, with little to no technical basis, radiation safety basis, or documentation of the revisions. The revisions appear to have been made by the licensee to avoid additional situations where patients administered Lu-177 could not be released from the licensee's control. The licensee was motivated to release the patients that were administered Lu-177 because the TCI facility was an outpatient only facility and the MVH facility would not accept these radiation oncology patients for admission.

On three occasions the licensee released patients who had been administered Lu-177 but exceeded the licensee's patient release criteria. The licensee's patient release practices for Lu-177 administrations made it more likely that radiation doses to individuals could exceed 500 mrem from exposure to the released individuals. However, the NRC is not aware of any exposures to any individuals that exceeded 500 mrem.

Apparent violation of 10 CFR 35.75(a)

Title 10 CFR 35.75(a) requires, in part, that a licensee may authorize the release from its control of any individual who has been administered byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 500 mrem.

Contrary to the above, on October 24, 2019; March 12, 2020; and May 14, 2020, the licensee authorized the release from its control individuals who had been administered byproduct material where the total effective dose equivalent to any other individual from exposure to the released individual was likely to exceed 500 mrem. Specifically, the licensee's criteria for the release of patients administered Lu-177 was that if the radiation dose rate at 1 meter from the patient was less than or equal to 2.5 mrem/h, then the total effective dose equivalent to any other individual was not likely to exceed 500 mrem. However, on October 24, 2019; March 12, 2020; and May 14, 2020, the licensee authorized the release from its control individuals who had been administered byproduct material with resultant radiation dose rates at 1 meter that were 13.0 mrem/h, 6.5 mrem/h, and 6.5 mrem/h, respectively, exceeding the licensee's patient release criteria for Lu-177 administration.

The licensee's release of individuals who had been administered Lu-177 and had radiation dose rates that exceeded the licensee's release criteria was identified as an apparent violation of 10 CFR 35.75(a). (030-38701/2020-001-02)

2.3.3 Safety Instructions for Personnel

Title 10 CFR 35.310(a) requires, in part, that the licensee shall provide radiation safety instruction, initially and annually, to personnel caring for patients or human research subjects who cannot be released under 10 CFR 35.75.

The staff at Facility C had not previously cared for an inpatient at Facility C that had been administered any therapeutic quantity of radioactive material. Therefore, they were not familiar with radiation safety protocols for safely providing patient care. The RSO stated that both times when the patient was admitted to Facility C, he provided training to the nursing staff at Facility C. However, the RSO did not document who the training was provided to and whether it included all appropriate staff at Facility C caring for the patient. The RSO also did not have records regarding the content of the training provided.

During the onsite portion of the inspection, the inspector attempted to speak with members of the Facility C nursing staff that had cared for the patient. Due to COVID-19 restrictions, the inspector was only able to interview one nurse that was involved in caring for the Lu-177 patient at Facility C. The nurse had sufficient knowledge to describe to the inspector that that access to the patient room for the patient admitted Lu-177 was controlled and that close contact with the patient was limited.

Apparent violation of 10 CFR 35.310(b)

Title 10 CFR 35.310(b) requires, in part, that the licensee shall retain a record of individuals receiving instruction in accordance with 10 CFR 35.2310.

Title 10 CFR 35.2310 requires, in part, that the licensee shall maintain a record of safety instructions required by 10 CFR 35.310 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

Contrary to the above, from September 4, 2018, to November 16, 2020, the licensee failed to retain a record of individuals receiving instruction in accordance with 10 CFR 35.2310. Specifically, the licensee failed to retain a record of safety instructions that were provided as required by 10 CFR 35.310, including failing to maintain a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

The licensee's failure to retain a record of individuals receiving instruction was identified as an apparent violation of 10 CFR 35.310(b). (030-38701/2020-001-03)

2.3.4 Records of Surveys

As described above, on March 12, 2020, and May 14, 2020, the licensee administered Lu-177 to a patient and released that patient from its control although the radiation dose rates exceeded the licensee's release criteria. For these two instances, the RSO

facilitated the admission of the individual to Facility C, where he was also serving as the RSO on the NRC license. The RSO stated that on both occasions, the patient room was surveyed and released for unrestricted use after the patient was discharged from Facility C. There is no evidence to support that that the patient room was released improperly. The TCI radiation oncology technologist described spending hours at Facility C, scrubbing surfaces to remove Lu-177 contamination, before the RSO released the rooms for unrestricted use. However, the licensee does not have documented surveys to support that on either occasion the patient room was adequately decontaminated such that it was suitable for unrestricted release.

Apparent violation of 10 CFR 20.2103(a)

Title 10 CFR 20.2103(a) requires, in part, that each licensee shall maintain records showing the results of surveys required by 10 CFR 20.1501. The licensee shall retain these records for 3 years after the record is made.

Contrary to the above, on March 12, 2020, and May 14, 2020, the license failed to maintain records showing the results of surveys required by 10 CFR 20.1501. Specifically, for the patient admitted on March 12, 2020, and May 14, 2020, the licensee performed surveys required to release rooms for unrestricted use after the rooms were used to house the patient that had been administered licensed material, Lu-177, and the licensee failed to maintain records showing the results of the surveys.

The licensee's failure to maintain records showing the results of surveys required by 10 CFR 20.1501 was identified as an apparent violation of 10 CFR 20.2103(a). (030-38701/2020-001-04)

2.3.5 Discharge of Licensed Material to the Sanitary Sewerage

A patient who was administered Lu-177 was admitted to Facility C on March 12, 2020, and subsequently discharged. Based on discussions with the TCI radiation oncology technologist, the patient room required extensive radioactive decontamination. After the patient was discharged, the RSO directed that the room be decontaminated by the TCI radiation oncology technologist using so-called "flushable wipes." The TCI radiation oncology technologist identified areas of radioactive Lu-177 contamination, cleaned them with the flushable wipes, and then flushed the wipes down the toilet, to be discharged into the sanitary sewerage. These flushable wipes were used by the licensee, in part, to avoid creating radioactive waste containing Lu-177. The RSO recognized that Facility C was not authorized to possess or use Lu-177 and that the RSO would not be able to store any Lu-177 waste at Facility C. Another option was for the RSO to transport the Lu-177 radioactive waste from Facility C back to the TCI facility, located about a mile away. The RSO determined that neither option was viable, so he decided to utilize the flushable wipes to avoid the need to store or transport radioactive waste containing Lu-177.

The inspector learned that the "flushable wipes" that were utilized by the TCI radiation oncology technologist to decontaminate Lu-177 radioactive contamination from the patient room at Facility C were not readily soluble in water. When Facility C's sanitary sewer collector system became blocked, a member of the licensee's staff was curious about the solubility of the flushable wipes. The licensee staff member placed one of the

flushable wipes in a water-filled container and left it overnight for a few days. No discernable change occurred to the flushable wipe, demonstrating that it was not readily soluble in water.

Eventually, Facility C posted signs in its rooms prohibiting the flushing of so-called flushable wipes. When the patient was admitted to Facility C on the second occasion, on May 14, 2020, flushable wipes were prohibited to be flushed. The RSO was still reluctant to store radioactive waste containing Lu-177 at Facility C or transport it to the TCI facility. Accordingly, when the patient was discharged from Facility C, the RSO directed that the patient room be decontaminated by the TCI radiation oncology technologist using toilet paper, so that it could be flushed into the sanitary sewer, where it was readily soluble in water.

During the inspection, it was also revealed that the practice of using "flushable wipes" to decontaminate Lu-177 radioactive contamination was not limited to the licensee's use at Facility C. The licensee also used flushable wipes to decontaminate the TCI facility. During administrations of Lu-177, radioactive contamination regularly occurred in the patient administration area at the TCI facility. So-called flushable wipes were used to decontaminate these areas at TCI, and the radioactively contaminated wipes were flushed down the toilet for discharge to the sanitary sewer. The use of not readily soluble flushable wipes to decontaminate Lu-177 continued as a practice at TCI until the onsite NRC inspection.

The licensee was unable to quantify the amount of solid (non-soluble) radioactive waste containing Lu-177 that was released to the sanitary sewerage. However, the quantity discharged was unlikely to exceed the NRC's regulatory limits in 10 CFR 20.2003.

Apparent violation of 10 CFR 20.2003(a)(1)

Title 10 CFR 20.2003(a)(1) requires, in part, that a licensee may discharge licensed material into sanitary sewerage if the material is readily soluble (or is readily dispersible biological material) in water.

Contrary to the above, from September 4, 2018, to November 16, 2020, the licensee discharged licensed material into sanitary sewerage that was not readily soluble (or readily dispersible biological material) in water. Specifically, the licensee discharged wipes into the sanitary sewerage that had been used to decontaminate surfaces that were radioactively contaminated with Lu-177, a licensed material, and the wipes were not readily soluble in water and were not readily dispersible biological material.

The licensee's discharge of licensed material into sanitary sewerage that was not readily soluble (or readily dispersible biological material) in water was identified as an apparent violation of 10 CFR 20.2003(a)(1). (030-38701/2020-001-05)

2.3.6 Labeling of Radioactive Material

At the TCI facility, the licensee had a container for the storage of items that were radioactively contaminated with Lu-177 and could not be flushed into the sanitary sewer, such as the Lu-177 vial and the Lu-177 administration tubing. The inspector observed that neither the storage container nor the individual Lu-177 waste packages within it were properly labeled as containing radioactive material.

Apparent violation of 10 CFR 20.1904(a)

Title 10 CFR 20.1904(a) requires, in part, that the licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL."

Contrary to the above, from August 2019 to November 16, 2020, the licensee failed to ensure that each container of licensed material bore a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." Specifically, neither the licensee's Lu-177 radioactive waste storage container nor the individual radioactive waste containers inside of it bore a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL."

The licensee's failure to ensure that each container of licensed material bore a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" was identified as an apparent violation of 10 CFR 20.1904(a). (030-38701/2020-001-06)

2.4 Causal Evaluation

A formal root cause analysis was not performed as it was beyond the scope of the inspection. The inspector determined that when the licensee decided to provide Lu-177 administrations under its 10 CFR 35.300 authorization, licensee management and the RSO failed to adequately prepare for, oversee, and manage the risks associated with the Lu-177 administration program. As a result, the licensee lacked appropriate procedures for nearly all aspects of the Lu-177 administration program, including procedures for administering Lu-177, addressing potential radioactive contamination from Lu-177, and contingency planning for patients that exceeded the licensee's release criteria.

Following the onsite inspection, on November 23, 2020, the licensee provided a letter to the NRC, describing its causal analysis, in which the licensee acknowledged that its Lu-177 administration program was "ill-conceived in its development from the beginning." (ADAMS Accession No. ML21042B978) In its letter, the licensee stated that "staff training and education was inappropriate or completely missing," and that the "patient treatment process was not thoroughly thought through, and appropriate management of patient care was never fully discussed, documented, and implemented." The licensee further stated that "Contingencies for poor patient clearance or emergent medical needs were developed outside of the appropriate hospital mechanisms, and did not include the Radiation Safety Committee, the hospital's comprehensive expertise of professionals in various departments, nor the appropriate documentation of the decision points that were implemented."

2.5 Corrective Actions

At the conclusion of the onsite portion of the inspection, the licensee voluntarily suspended its Lu-177 administration program. When the program was suspended, there were no new Lu-177 patients scheduled, and there was one patient that had received

three of their Lu-177 administrations and was scheduled for their fourth Lu-177 administration. Based on the preliminary inspection findings, the licensee stated that it did not believe that they could safely proceed with the fourth and final administration for the patient. The RSO stated that they were going to attempt to send the patient to another Lu-177 provider for the fourth and final administration or possibly conclude the patient's treatment regimen with three administrations based on a medical analysis of the patient's condition and response to the Lu-177 therapy.

Following the onsite inspection, on November 23, 2020, the licensee provided a letter to the NRC, documenting its decision to suspend the Lu-177 administration program indefinitely (ADAMS Accession No. ML21042B978). The licensee committed to recreate its Lu-177 administration program from the ground up by developing procedures, providing specific training, engaging the licensee's Radiation Safety Committee, and seeking additional expertise.

On December 28, 2020, the licensee provided the NRC with a preliminary Lu-177 administration procedure (ADAMS Accession No. ML21042B982). The preliminary procedure was reviewed by the inspector and found to contain some inconsistencies and to lack detail in some areas. For example, it was still unclear whether the licensee intended to continue to perform Lu-177 administrations at the TCI outpatient facility or if they would perform the administrations at MVH, the inpatient hospital, which would require an amendment to the NRC license. It was also unclear whether any rooms at MVH would be made available for radiation oncology use, should a patient administered Lu-177 not meet the licensee's patient release criteria. Additionally, there were discrepancies in the document regarding the licensee's again revised patient release criteria for Lu-177 administrations. The procedure also lacked a description of the training that would be provided to individuals involved with Lu-177 administrations and how Lu-177 waste would be handled.

2.6 Conclusions

Six apparent violations were identified regarding the licensee's: (1) failure to develop, implement, and maintain written procedures to provide high confidence that each administration of Lu-177 is in accordance with the written directive; (2) release of individuals who had been administered Lu-177 and had radiation dose rates that exceeded the licensee's release criteria; (3) failure to document the instructions or training provided to individuals caring for patients administered Lu-177; (4) failure to document radiation surveys that rooms used for Lu-177 patients could be released for unrestricted use; (5) discharge to the sanitary sewer of Lu-177 contaminated materials that were not readily soluble in water or biological materials; and (6) failure to label a Lu-177 waste storage container and its contents to indicate that it contained radioactive material.

At the conclusion of the onsite portion of the inspection, the licensee voluntarily suspended its Lu-177 administration program. The licensee later committed to rebuild its Lu-177 administration program from the ground up prior to resuming patient administrations.

3 Exit Meeting Summary

On September 2, 2021, a final videoconference exit meeting was conducted with Ned Hillyard, Chief Compliance Officer; Amy Larsen, Director, Ancillary Services; Lisa Anderson, Manager, Oncology Services; David Theel, Radiation Safety Officer, and other members of the licensee's staff to discuss the inspection findings. The NRC representatives discussed the content of the inspection report, described the NRC's enforcement process, and described the options for the licensee to: (1) respond in writing to the apparent violations described in the inspection report; (2) request a predecisional enforcement conference, or (3) request alternative dispute resolution. The licensee did not identify any proprietary information.

Supplemental Inspection Information

PARTIAL LIST OF PERSONS CONTACTED

Ned Hillyard, Chief Compliance Officer
Amy Larsen, Director, Ancillary Services, Mountain View Hospital
Lisa Anderson, Manager, Oncology Services, Teton Cancer Institute
Deb Fuelling, Supervisor, Radiation Oncology, Teton Cancer Institute
David Theel, Radiation Safety Officer
Steven J. Todd, MD, Authorized User
Drew Whittier, Dosimetrist
CJ Marler, Assistant Radiation Physicist
Gail Kurpinski, Radiation Oncology Technologist
Eric Malcolm, Radiation Oncology Technologist

INSPECTION PROCEDURES USED

87131	Nuclear Medicine Programs, Written Directive Required
87132	Brachytherapy Programs

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-38701/2020-001-01	AV	Failure to develop, implement, and maintain written procedures for administrations requiring written directives. (10 CFR 35.41(a)(2))
030-38701/2020-001-02	AV	Release of individuals who had been administered Lu-177 and had radiation dose rates that exceeded the licensee's release criteria. (10 CFR 35.75(a))
030-38701/2020-001-03	AV	Failure to retain a record of individuals receiving instruction. (10 CFR 35.310(b))
030-38701/2020-001-04	AV	Failure to maintain records showing the results of surveys required by 10 CFR 20.1501. (10 CFR 20.2103(a))
030-38701/2020-001-05	AV	Discharge of licensed material into sanitary sewerage that was not readily soluble (or readily dispersible biological material) in water. (10 CFR 20.2003(a)(1))
030-38701/2020-001-06	AV	Failure to ensure that each container of licensed material bore required labels. (10 CFR 20.1904(a))

Closed

None

Discussed

None

LIST OF ACRONYMS AND ABBREVIATIONS USED

10 CFR	Title 10 *Code of Federal Regulations*
ADAMS	Agencywide Documents Access and Management System
ADR	Alternative Dispute Resolution
AV	Apparent Violation
AU	Authorized User
IP	Inspection Procedure
Lu-177	Lutetium-177 dotate Lutathera®
MVH	Mountain View Hospital
NRC	Nuclear Regulatory Commission
PEC	Pre-decisional Enforcement Conference
RSO	Radiation Safety Officer
TCI	Teton Cancer Institute