UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2056 WESTINGS AVENUE, SUITE 400
NAPERVILLE, IL 60563-2657

November 25, 2024

EA-23-121
EN 56337
NMED No. 230049 (Closed)

Lee Seabrooke
Associate Vice President Research,
Integrity, and Compliance
Saint Louis University
1402 South Grand Blvd.
St. Louis, MO 63104

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03011789/2023001(DRSS) - SAINT LOUIS UNIVERSITY

Dear Lee Seabrooke:

From June 21-23, 2023, inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your locations in St. Louis, Missouri, with continued in-office review through October 28, 2024. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements, and to review the circumstances surrounding the loss of a radium-223 (Ra-223) unit dose that occurred on February 1, 2023. The purpose of the in-office review was to review information that was made available after the onsite inspection. The enclosed inspection report presents the results of the inspection. The inspector discussed the preliminary inspection findings with you and your staff at the conclusion of the on-site portion of the inspection. A final exit meeting was conducted with you and your staff on October 28, 2024.

This inspection examined activities conducted under your license as they relate to safety and compliance with the NRC's rules and regulations and with the conditions in your license. Within these areas, the inspection consisted of an examination of selected procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, five apparent violations of NRC requirements 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 concerned the licensee's failure to: (1) secure a unit dose of Radium-223 (Ra-223) from unauthorized removal or limit access to it in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1801; (2) perform an adequate survey before disposing of a unit dose of Ra-223 as normal, non-radioactive waste in accordance with 10 CFR 20.1501(a); (3) report by telephone, immediately after its occurrence became known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the

quantity specified in appendix C to 10 CFR Part 20 under such circumstances that it appeared to the licensee that an exposure could result to persons in unrestricted areas in accordance with 10 CFR 20.2201(a); (4) have written procedures that included steps for determining whether a medical event occurred for each yttrium-90 administration in accordance with 10 CFR 35.41(b)(5); and (5) prepare written directives that were dated and signed by an authorized user before administration of any therapeutic dose of radiation from byproduct material in accordance with 10 CFR 35.40(a).

The circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with you and your staff at the inspection exit meeting conducted by Elizabeth Tindle-Engelmann on October 28, 2024.

Before the NRC makes its enforcement decision, we are providing you an opportunity to (1) respond to the apparent violations addressed in this 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 will issue a press release to announce the time and date of the conference. **Please contact Rhex Edwards at (630) 829-9722 or Rhex.Edwards@nrc.gov within 10 days of the date of this letter to notify the NRC of your intended response or request.** 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 “Response to the Apparent Violations in Inspection Report No. 03011789/2023001(DRSS); EA-23-121,” and should include, for the apparent violations: (1) the reason for the apparent violations, or, if contested, the basis for disputing the apparent violations; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance was or will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. Your response should be sent to the NRC’s Document Control Desk, Washington, DC 20555-0001, with a copy mailed to the NRC Region III Office, 2056 Westings Avenue, Suite 400, Naperville, IL 60563, 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 pre-decisional enforcement conference 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 action, 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. You can find the information notice on the NRC website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html.

You may also 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 has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral party (the “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 program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. **Please contact ICR 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. In addition, if you choose ADR, please also contact Rhex Edwards at the telephone number or email address listed above.**

Since one apparent violation involves the improper disposal of approximately 146 microcuries of Ra-223, the NRC is considering proposing imposition of a civil monetary penalty. Consistent with Section 2.3.4, Civil Penalty, of the NRC Enforcement Policy, for violations where a licensee has lost regulated radioactive material, the NRC will normally exercise discretion to impose a civil penalty. The base civil penalty amount is based on approximately three times the expected average cost of authorized disposal; however, the NRC may exercise its discretion to mitigate or escalate a civil penalty amount based on the merits of a specific case. Therefore, you may provide information regarding the actual expected cost of authorized disposal for the NRC to consider in making a final enforcement decision. However, the NRC will not normally decrease the civil penalty to an amount below the lowest base civil penalty for such cases.

In addition, please be advised that the number and characterization of the 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 of our deliberations on this matter.

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

Please feel free to contact Elizabeth Tindle-Engelmann of my staff if you have any questions regarding this inspection. Elizabeth can be reached at 630-829-9681 or Elizabeth.Tindle-Engelmann@nrc.gov.

Sincerely,

Feibus, Jonathan signing on behalf
of Curtis, David
on 11/25/24

David Curtis, Director
Division of Radiological Safety and Security

Docket No. 030-11789
License No. 24-00196-07

Enclosure:
Inspection Report No. 03011789/2023001(DRSS)

cc w/encl: Mark Haenchen, M.S., J.D., RSO
Dana Baum, Ph.D., RSC Chair
Kelly Baumer, Vice President Clinical Operations
State of Missouri

Letter to L. Seabrooke from D. Curtis, dated November 25, 2024.

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03011789/2023001(DRSS) - SAINT LOUIS UNIVERSITY

DISTRIBUTION w/encl:
Jack Giessner
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ADAMS Accession Number: ML24306A130

OFFICE	RIII-DRSS	RIII-DRSS	OE	OE
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DATE	11/1/24	11/5/24	11/14/24	11/15/24
OFFICE	RIII-EICS	RIII-DRSS		
NAME	DBetancourt-Roldan	JFeibus on behalf of DCurtis		
DATE	11/25/24	11/25/24		

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U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-11789
License No.	24-00196-07
Report No.	03011789/2023001(DRSS)
EA No.	EA-23-121
EN No. / NMED No.	56337 / 230049 (closed)
Licensee:	Saint Louis University
Address:	1402 South Grand Blvd. St. Louis, MO 63104
Locations Inspected:	Doisy Research Center, Doisy Hall, Schwitalla Hall, and SSM Health Saint Louis University Hospital
Inspection Dates:	Onsite June 21-23, 2023 In-office review through October 28, 2024
Exit Meeting Date:	October 28, 2024
Inspector:	Elizabeth Tindle-Engelmann, Health Physicist Carol Dye, Health Physicist
Approved By:	Rhex Edwards, Chief Materials Inspection Branch Division of Radiological Safety and Security

Enclosure

EXECUTIVE SUMMARY

Saint Louis University
NRC Inspection Report 03011789/2023001(DRSS)

This was an announced routine inspection of a multi-site broad scope medical institution with facilities located in St. Louis, Missouri. Saint Louis University (SLU) was authorized under NRC License Number 24-00196-07 to possess and use a variety of types of radioactive material for medical, research and development, instrument calibrations, and student instruction.

The scope of the inspection was to examine the activities conducted under the license and to confirm compliance with the NRC rules, regulations, and the conditions of the license. The scope of the inspection also included a review of the circumstances surrounding the loss of a radium-223 (Ra-223) unit dose that occurred on February 1, 2023.

The inspection identified five apparent violations regarding the licensee's failure to: (1) secure a unit dose of Ra-223 from unauthorized removal or limit access to it in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1801; (2) perform an adequate survey before disposing of a unit dose of Ra-223 as normal, non-radioactive waste in accordance with 10 CFR 20.1501(a); (3) report by telephone, immediately after its occurrence became known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in appendix C to 10 CFR part 20 under such circumstances that it appeared to the licensee that an exposure could result to persons in unrestricted areas in accordance with 10 CFR 20.2201(a); (4) have written procedures that included steps for determining whether a medical event occurred for each yttrium-90 administration in accordance with 10 CFR 35.41(b)(5); and (5) prepare written directives that were dated and signed by an authorized user (AU) before administration of any therapeutic dose of radiation from byproduct material in accordance with 10 CFR 35.40(a).

REPORT DETAILS

1 Program Overview and Inspection History

1.1 Inspection Scope

The inspectors reviewed the license application and supporting documents. Additional information was gathered through interviews with the licensee's staff and a review of selected records.

1.2 Observations and Findings

SLU was authorized under NRC License Number 24-00196-07 to possess and use a wide range of byproduct material in various forms for: (1) medical diagnosis, therapy, and research in humans in accordance with any applicable U.S. Food and Drug Administration requirements; (2) research and development as defined in 10 CFR 30.4, including animal studies and in-vitro studies; (3) instrument calibration; and (4) student instruction.

The licensee had an active Radiation Safety Committee (RSC) that was responsible for oversight of licensed activities. The licensee's Radiation Safety Office reported to the RSC. The licensee had a full-time Radiation Safety Officer (RSO) that was supported by an assistant RSO and one health physicist. The RSO's staff was onsite daily to provide oversight of licensed activities.

The licensee maintained active Nuclear Medicine, PET, and Interventional Radiology departments at SSM Health SLU Hospital. The licensee's Nuclear Medicine and PET departments performed administrations of unsealed byproduct material not requiring a written directive on a daily basis. The licensee's Nuclear Medicine and Interventional Radiology departments performed administrations of unsealed byproduct material requiring a written directive on a weekly basis. Radionuclides handled at SSM Health SLU University included: copper-64, fluorine-18, gallium-68, iodine-123, iodine-131, lead-203, lead-212, lutetium-177, Ra-223, technetium-99m, and yttrium-90 (Y-90).

The licensee had active research laboratories on its north and south campuses. At the time of the inspection, there were fifteen laboratories. Two of the laboratories were storing material and seven of the laboratories were actively using byproduct material. Radionuclides handled in research laboratories included: carbon-14, hydrogen-3, and iodine-125.

A routine inspection of the licensee was conducted in August of 2018; no violations were identified. A routine inspection of the licensee was conducted remotely in March and August of 2021; no violations were identified. A limited scope, reactive inspection was conducted in May of 2021 to review the circumstances of a medical event involving Y-90; no violations were identified.

2 Radiation Safety Oversight

2.1 Inspection Scope

The inspectors examined the activities conducted under the license to confirm compliance with NRC rules, NRC regulations, and the conditions of the license. The inspectors conducted interviews with the licensee's staff, reviewed selected records, reviewed selected procedures, and toured the licensee's facilities. Selected records

included: ALARA reviews, area monitoring, audits, bioassays, decommissioning surveys, dose estimates, dosimetry, effluent evaluations, human research protocols, laboratory permits, incident reports, informed consents, Institutional Review Board approvals, patient release evaluations, RSC meeting minutes, sealed source leak tests, sealed source inventories, surveys, training, waste disposal, and written directives. Selected procedures included: area surveys, calibration of survey instruments, package receipt, safe handling of radioactive material, and waste handling.

2.2 Observations and Findings

The inspectors determined that the RSC had active participation from all required committee members. In general, the RSC established quorum and met on a quarterly basis to discuss radiation safety topics related to events, facility changes, incidents, program audits, program changes, and new authorizations. Protocols for human studies were reviewed by the licensee's Institutional Review Board and results were discussed at the RSC meetings. The RSC approved AUs in accordance with applicable requirements. The RSC approved new laboratories and permit authorizations in accordance with the conditions of the license. The inspectors reviewed RSC meeting minutes since the last inspection. During a review of the 2023 RSC minutes, the inspectors noted discussion related to a nuclear medicine daily area survey that had not been performed. Based on the complexity of the issue, the NRC opened a second inspection to document the review of that issue. The NRC is still reviewing the circumstances of the matter and will document the results in NRC Inspection Report 03011789/2023003(DRSS).

The licensee implemented a personnel monitoring program for monitoring external and internal occupational dose as required by 10 CFR 20.1502. The licensee provided whole body and/or extremity monitoring devices, as appropriate, to those individuals who routinely handled specified quantities of beta/gamma-emitting material in nuclear medicine, PET, interventional radiology, radiation safety, and research. The licensee implemented a bioassay program to monitor potential intake of radioactive material, such as routine thyroid monitoring which was conducted on workers who handled radioiodine above specified thresholds. The licensee performed area monitoring and effluent calculations to ensure compliance with limitations in 10 CFR Part 20.

The inspectors toured research labs and other medical use facilities and observed the licensee's staff handling radioactive materials and the safety protocols they used while handling radioactive materials. The inspectors observed the use of byproduct material, including the administration of radiopharmaceuticals. Demonstrations of research protocols and complex radiopharmaceutical administrations were also observed.

2.3 Conclusions

The inspectors reviewed the applicable focus elements and risk modules. The inspectors determined that the licensee had adequate oversight of its radiation safety program. No violations were identified.

3 Loss of Radioactive Material

3.1 Inspection Scope

The inspectors reviewed the circumstances related to the loss of a Ra-223 unit dose. Within the scope of the inspection, the inspectors examined the activities conducted under the license to confirm compliance with NRC rules, NRC regulations, and the

conditions of the license. The inspectors conducted interviews with the licensee's staff, reviewed selected records, reviewed selected procedures, and toured the licensee's facilities. Selected records and procedures are described in Section 2.1.

3.2 Observations and Findings

On February 1, 2023, at approximately 11:30 AM the licensee's nuclear medicine department received a package containing one dosage containing approximately 146 microcuries of Ra-223. The licensee received the package in accordance with its package receipt procedure and placed the package on the counter in the hot lab. The package was labeled as Hazard Class 7 Radioactive Material with a Yellow II label affixed. At the time of receipt, there were measurable exposure rates on contact and at 1 meter. Specifically, the exposure rate on the surface of the box was 1 milliroentgen/hour. The dosage was to be administered to a patient the next day, on February 2, 2023, at 1:00 PM.

On February 1, 2023, from approximately 1:00 PM to 1:30 PM, the nuclear medicine staff was cleaning the hot lab and disposing of waste that was no longer radioactive. During this time frame, the staff inadvertently disposed of the box containing the Ra-223 unit dose in the regular trash. The trash was then placed in the hallway outside of the hot lab where it was picked up by housekeeping for disposal. The housekeeping staff placed the trash into a large rolling trash can on the afternoon of February 1, 2023. The trash can was then emptied into a roll-off dumpster at approximately 7:00 PM on February 1, 2023. The dumpster was then taken to a landfill at approximately 3:00 AM on February 2, 2024. The dosage remained in its shielded pig within the original shipping container. The dosage was not detected during the end of day survey of the nonradioactive waste container. The hospital's central waste facility was not equipped with any survey instruments.

On February 2, 2023, at the time the administration was supposed to occur, the licensee's staff could not locate the dosage within the hot lab. On February 2, 2023, the licensee's investigation of the missing dosage concluded that the nuclear medicine staff inadvertently disposed of the unit dose in the nonradioactive waste on February 1, 2023.

The licensee reported the loss of the Ra-223 to the NRC on February 3, 2023 (Event Notification (EN) 56337). On March 3, 2023, the licensee submitted a written report (ML23066A205) on the lost material. The licensee made all the notifications and reports for the lost dose as required by 10 CFR 20.2201(a)(1) and 10 CFR 20.2201(b) on February 3, 2023, and March 3, 2023, respectively. The licensee's report included the information required by 10 CFR 20.2201(b).

The licensee concluded that attempting to retrieve the source from the landfill would pose significant and completely unnecessary safety risks due to the physical hazards associated with searching a landfill. The licensee implemented immediate corrective actions including designating an area for incoming therapy treatment shipments, formalizing a procedure for disposal of shipping containers, and installing cameras in the hot lab and the nuclear medicine hallway.

Apparent Violation of 10 CFR 20.1801

Title 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. Contrary to the above, between February 1, 2023, and February 2, 2023, the licensee failed to secure from unauthorized removal or limit access to a unit dose containing approximately 146 microcuries of Ra-223 that was stored in a controlled area.

Specifically, the failure to secure the unit dose resulted in the dosage being disposed of in the normal hospital trash and then disposed of in a municipal waste landfill. This is an apparent violation of 10 CFR 20.1801 and is being considered for escalated enforcement in accordance with section 2.3.4 and 6.7.c.10(a) of the NRC's Enforcement Policy.

Apparent Violation of 10 CFR 20.1501

Title 10 CFR 20.1501(a) requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in 10 CFR Part 20 and are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels, concentrations or quantities of residual radioactivity, and the potential radiological hazards of the radiation levels and residual radioactivity detected. 10 CFR 20.2001(a) requires a licensee dispose of licensed material by transfer to an authorized recipient as provided in § 20.2006 or in the regulations in parts 30, 40, 60, 61, 63, 70, and 72 of this chapter. Contrary to the above, between February 1, 2023, and February 2, 2023, the licensee did not make surveys to assure compliance with 10 CFR 20.2001(a) to dispose of licensed material by transfer to an authorized recipient. Specifically, the licensee did not perform an adequate survey of the shipping package and the hot lab nonradioactive waste container before disposing of a unit dose, containing 146 microcuries of radium-223, as normal, non-radioactive waste. This is an apparent violation of 10 CFR 20.1501(a) and is being considered for escalated enforcement in accordance with section 6.3 of the NRC's Enforcement Policy.

Apparent Violation of 10 CFR 20.2201

Title 10 CFR 20.2201(a) requires, in part, that each licensee shall report by telephone, immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in appendix C to part 20 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas. Contrary to the above, on February 2, 2023, the licensee failed to report by telephone, immediately after its occurrence became known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in appendix C to part 20 under such circumstances that it appeared to the licensee that an exposure could result to persons in unrestricted areas. Specifically, the licensee determined that 146 microcuries of radium-223 was lost and that an exposure could result to persons in unrestricted areas but failed to report the loss until February 3, 2023. This is an apparent violation of 10 CFR 20.2201(a) and is being considered for escalated enforcement in accordance with section 6.9 of the NRC's Enforcement Policy.

3.3 Conclusions

The inspectors reviewed the applicable focus elements and risk modules. Three apparent violations were identified and are being considered for enforcement. The apparent violations involve the licensee's failure to: (1) secure a unit dose of Ra-223 from unauthorized removal or limit access to it in accordance with 10 CFR 20.1801; (2) perform an adequate survey before disposing of a unit dose of Ra-223 as normal, non-radioactive waste in accordance with 10 CFR 20.1501(a); and (3) report by telephone, immediately after its occurrence became known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in appendix C to 10 CFR part 20 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas in accordance with 10 CFR 20.2201(a).

4 Y-90 Microsphere Program

4.1 Inspection Scope

The inspectors reviewed the licensee's Y-90 microsphere program. Within the scope of the inspection, the inspectors examined the activities conducted under the license to confirm compliance with NRC rules, NRC regulations, and the conditions of the license. The inspectors conducted interviews with the licensee's staff, reviewed selected records, reviewed selected procedures, and toured the licensee's facilities. In addition to the selected records and procedures described in Section 2.1, the inspector's reviewed the licensee's procedures titled: "SIR-Spheres Therapy Protocol," dated September 29, 2022, and "Nuclear Medicine TheraSpheres Therapy Y-90," dated September 27, 2022.

4.2 Observations and Findings

The inspectors observed licensee staff demonstrate the preparation and administration of Y-90 microspheres. Additionally, the inspectors sampled the records associated with Y-90 microsphere administrations that had been completed since the last inspection.

While reviewing a sample of written directives, the inspectors observed on two occasions that the licensee's written directive for SIR-Sphere administrations failed to identify the treatment site. Through review of procedures and discussion with the licensee's staff, it was determined that roles and responsibilities for completing the written directive and procedural steps for determining whether a medical event had occurred were insufficient. Specifically, the inspectors identified that the licensee's written procedures titled: "SIR-Spheres Therapy Protocol," and "Nuclear Medicine TheraSpheres Therapy Y-90," did not include steps for determining whether a medical event had occurred. In the two cases that the written directive did not include the treatment site, the licensee had not reviewed the cases to determine whether the administrations were done in accordance with the treatment plan which denoted the treatment site, nor had it determined whether a medical event had occurred. During the inspection, the NRC requested that an AU review the treatment plan to determine whether the administration had been completed in accordance with the treatment plan and whether a medical event had occurred. In both cases, the AU confirmed that the administration had been completed in accordance with the treatment plan and the correct treatment site received the correct dose. Thus, no medical events had occurred in either case.

While reviewing the licensee's quarterly audits, the inspectors observed that the licensee identified a written directive prescribing yttrium-90 microspheres to deliver a therapeutic dose of radiation that was not dated and signed by an AU. As a corrective action the licensee changed their process to require the nuclear medicine coordinator verify that the written directive was signed by the AU prior to administration of Y-90 microspheres.

Apparent Violation of 10 CFR 35.41

Title 10 CFR 35.41(a) states, in part, that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Title 10 CFR 35.41(b)(5) states, in part, that the written procedures required by 10 CFR 35.41(a) must address determining if a medical event, as defined in 10 CFR 35.3045, has occurred. Contrary to the above, prior to June 20, 2023, the licensee failed to have written procedures that provided high confidence that each yttrium-90 administration did not result in a medical event, as defined in

10 CFR 35.3045. Specifically, the licensee's written procedures titled “SIR-Spheres Therapy Protocol,” dated September 29, 2022, and “Nuclear Medicine TheraSpheres Therapy Y-90,” dated September 27, 2022, failed to include steps for determining whether a medical event occurred. This is an apparent violation of 10 CFR 35.41(a) and is being considered for escalated enforcement in accordance with section 6.3.c.2(a) of the NRC’s Enforcement Policy.

Apparent Violation of 10 CFR 35.40

Title 10 CFR 35.40(a) requires, in part, that a written directive must be dated and signed by an AU before the administration of any therapeutic dose of radiation from byproduct material. Contrary to the above, on October 24, 2022, the licensee failed to prepare written directives that were dated and signed by an AU before administration of any therapeutic dose of radiation from byproduct material. Specifically, one written directive prescribed yttrium-90 microspheres to deliver a therapeutic dose of radiation that was not dated and signed by an AU. This is an apparent violation of 10 CFR 35.40(a) and is being considered for enforcement in accordance with section 6.3.d.1 of the NRC’s Enforcement Policy.

4.3 Conclusions

The inspectors reviewed the applicable focus elements and risk modules. Two apparent violations were identified and are being considered for enforcement. The apparent violations involved the licensee’s failure to: (1) have written procedures that included steps for determining whether a medical event occurred for each yttrium-90 administration in accordance with 10 CFR 35.41(b)(5); and (2) prepare written directives that were dated and signed by an AU before administration of any therapeutic dose of radiation from byproduct material in accordance with 10 CFR 35.40(a).

5 Independent Radiation Measurements

Independent radiation surveys were conducted at the inspected facilities. The survey results were consistent with the licensee’s postings, the licensee’s survey results, and applicable regulatory limits.

Instrumentation:	Model: RadEye G Serial Number: 30653 Calibration Expiration: May 9, 2024
Instrumentation:	Model: RadEye G Serial Number: 30716 Calibration Expiration: 05/9/2024

6 Exit Meeting Summary

The NRC inspectors presented the preliminary inspection findings during an onsite inspection briefing following the onsite inspection on June 23, 2023. Upon completion of in-office review, a virtual exit meeting was held on October 28, 2024, in which five apparent violations were described to the licensee. On both occasions, the licensee acknowledged the findings that were presented by the NRC. The licensee did not identify any documents or processes reviewed by the inspectors as proprietary.

LIST OF PERSONNEL CONTACTED

^*# Dana Baum, Ph.D., RSC Chair
^*# Kelly Baumer, Vice President Clinical Operations
^*# Jeff Brown, M.D., Radiology
^*# Kevin Ferguson, Assistant RSO
^*# Mark Haenchen, M.S., J.D., RSO
Kirubahara Vaheesan. MD
* Razi Muzaffar, D.O., Nuclear Medicine
^* Medhat Osman, M.D., Nuclear Medicine
Keith Pereira, M.D., Radiology
^* Jerry Robichaux, Nuclear Medicine
*# Lee Seabrooke, Ph.D., Associate Vice President
John Tavis, Ph.D., Molecular Virology

^ Attended entrance meeting on June 21, 2023.
* Attended inspection briefing on June 23, 2023.
# Attended exit meeting on October 28, 2024.

INSPECTION PROCEDURES (IPs) USED

IP 87103, “Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing”
IP 87126, “Broad Scope Academic and Research & Development Programs”
IP 87134, “Medical Broad Scope Programs”

LIST OF ACRONYMS AND ABBREVIATIONS USED

AU: authorized user
EN: event notification
IP: inspection procedure
Ra-223: radium-223
RSC: radiation safety committee
RSO: Radiation Safety Officer
SLU: Saint Louis University
Y-90: yttrium-90
10 CFR: Title 10 of the *Code of Federal Regulations*