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

June 24, 2025

EN 56601
NMED No. 230281 (Closed)

Lee Seabrooke
Associate Vice President of
Research, Integrity, and Compliance
Saint Louis University
1201 South Grand Blvd.
St. Louis, MO 63104

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03011789/2023002(DRSS) AND NOTICE OF VIOLATION – SAINT LOUIS UNIVERSITY

Dear Lee Seabrooke:

This letter refers to the inspection conducted on July 13, 2023, at your St. Louis, Missouri, facility with continued in-office review through June 2, 2025. The purpose of the inspection was to review the circumstances surrounding a medical event involving a yttrium-90 microsphere therapy that was reported to the NRC on June 30, 2023. The inspection consisted of selected examination of procedures and representative records, observation of activities, and interviews with personnel. An onsite inspection briefing was held with your staff on July 13, 2023, and a virtual exit meeting was held with you and your staff on June 2, 2025. The purpose of the in-office review was to evaluate information not available at the time of the on-site inspection. The enclosed inspection report presents the results of the Inspection.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred.

The violation was evaluated 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 violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection record. The violation is being cited in the enclosed Notice because the inspectors identified it.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket in this letter and in additional correspondence. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

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 any response you provide 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,

Signed by Edwards, Rhex
on 06/24/25

Rhex Edwards, Chief
Materials Inspection Branch
Division of Radiological Safety and Security

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

Enclosures:
(1) Notice of Violation
(2) Inspection Report No. 03011789/2023002(DRSS)

cc (w/encl): K. Ferguson, RSO
State of Missouri

Letter to L. Seabrooke from R. Edwards, dated June 24, 2025.

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03011789/2023002(DRSS) AND NOTICE OF VIOLATION – SAINT LOUIS UNIVERSITY

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OFFICE	RIII-DRSS		RIII-DRSS					
NAME	ETindleEngelmann:mh		REdwards					
DATE	6/18/2025		6/24/2025					

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Saint Louis University
St. Louis, MO

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

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on July 13, 2023, with continued in-office review through June 2, 2025, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

A. Title 10 of the Code of Federal Regulations (10 CFR) Part 35.67(a) requires, in part, that a licensee in possession of any brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.

   The manufacturer supplied the licensee with Instructions for Use for TheraSphere™ Yttrium-90 Glass Microspheres. Section 11, titled Operational Instructions for TheraSphere administration, states, in part, do not use extension tubing between the TheraSphere Administration Set and the microcatheter.

   Contrary to the above, on June 29, 2023, the licensee was in possession of a brachytherapy source and failed to follow the radiation safety and handling instructions supplied by the manufacturer. Specifically, the licensee failed to follow Section 11 of the TheraSphere™ Yttrium-90 Glass Microspheres Instructions for Use during a TheraSphere brachytherapy procedure, when they utilized a piece of extension tubing between the TheraSphere Administration Set and the microcatheter.

This is a Severity Level IV violation (Section 6.3.d.3).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in this letter and in additional correspondence. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, IR 03011789/2023002(DRSS)" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice.

Any response you provide will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible at http://www.nrc.gov/reading-rm/adams.html. Therefore, to the extent possible, your response should not include any personal privacy, proprietary, or security-related information so that it can be made available to the Public without redaction.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 24th day of June 2025.

U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-11789
License No.	24-00196-07
Report No.	03011789/2023002(DRSS)
EN No./NMED No.	EN 56601 / 230281 (Closed)
Licensee:	Saint Louis University
Facility:	1201 South Grand Blvd. St. Louis, MO
Inspection Dates:	Onsite July 13, 2023; In-office review through June 2, 2025
Exit Meeting Date:	June 2, 2025
Inspector:	Elizabeth Tindle-Engelmann, Health Physicist Laura Dresen, Health Physicist
Approved By:	Rhex Edwards, Chief Materials Inspection Branch Division of Radiological Safety and Security

EXECUTIVE SUMMARY

Saint Louis University
NRC Inspection Report 03011789/2023002(DRSS)

This was an announced reactive inspection at Saint Louis University's (SLU's) SSM Health SLU Hospital. The licensee was a multi-site broad scope medical institution with facilities located in St. Louis, Missouri. 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 licensee was permitted to possess and use yttrium-90 (Y-90) microspheres.

The scope of the inspection was limited to the review of the circumstances surrounding a medical event that was reported to the NRC on June 30, 2023, and the licensed activities associated with the use of Y-90 at SSM Health SLU Hospital. The medical event involved a deviation of more than 20 percent from the prescribed activity and prescribed dose from a Y-90 microsphere administration on June 29, 2023. The licensee made a telephone notification to the NRC on June 30, 2023, and submitted a written report to the NRC on July 14, 2023.

Based on the results of this inspection, one violation was identified regarding the licensee's failure to follow the radiation safety and handling instructions supplied by the manufacturer, as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 35.67(a). Specifically, the manufacturer supplied the licensee with Instructions for Use for TheraSphere™ Yttrium-90 Glass Microspheres, which required, in part, not to use extension tubing between the TheraSphere Administration Set and the microcatheter. However, on June 29, 2023, the licensee failed to follow radiation safety and handling instructions supplied by the manufacturer when approximately 20 centimeters of extension tubing was used between the TheraSphere Administration Set and the microcatheter.

The licensee implemented immediate corrective actions including: adjusting stock levels of longer microcatheters to prevent the need for extension tubing, providing remedial training to the Authorized Users (AUs) on the manufacturer's instructions, conducting remedial training with the manufacturer for Nuclear Medicine Staff and AUs, providing a case study overview to all AUs, and requiring each AU to read and certify receipt of the manufacturer's instructions.

REPORT DETAILS

1 Program Overview and Inspection History

1.1 Inspection Scope

The scope of this inspection was limited to the use of Y-90 microspheres BWXT Medical Ltd. brachytherapy afterloader delivery systems, and the circumstances surrounding a medical event that occurred at SSM Health SLU Hospital on June 23, 2023.

The inspectors reviewed the license application and supporting documents within the scope of the inspection. Additional information was gathered through interviews with the licensee's staff.

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 and Interventional Radiology departments at SSM Health SLU Hospital. The licensee's Nuclear Medicine and Interventional Radiology departments performed administrations of Y-90 microspheres on a weekly basis.

The licensee's inspection history is summarized below:

- 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.
- A routine inspection of the licensee was conducted in June of 2023 which resulted in escalated enforcement for the loss of a radium-223 source and deliberate misconduct of a Nuclear Medicine Technologist.
- A limited scope inspection was conducted remotely in December of 2024; no violations were identified.

2 Medical Event and Y-90 Program

2.1 Inspection Scope

From July 13, 2023, through June 2, 2025, the inspectors reviewed the circumstances surrounding a medical event involving the under administration of a Y-90 microsphere dose to an individual that occurred on June 29, 2023, and the licensed activities associated with the licensee's use of Y-90. The inspectors toured the facility, observed demonstrations of licensed activities, conducted interviews, and reviewed selected records. Selected records included: dose calibrator calibrations, dose estimates, event chronology, notifications, patient release determinations, policies and procedures, SPECT images, treatment plans, training, and written directives.

2.2 Observations and Findings

Prior to June 29, 2023, an individual was counselled and screened by a physician, and it was determined that the individual was a candidate for Y-90 TheraSphere™ intravascular brachytherapy. A written directive was prepared. The prescribed activity was 0.54 gigabecquerels (14.58 millicuries). The microspheres were ordered and received by the licensee. On June 29, 2023, the licensee prepared a written directive form and prepared the dose for administration.

The licensee's nuclear medicine staff took the dosage to the interventional radiology suite for the administration. During the patient catheterization, the physician utilized a 120 centimeter Trinav microcatheter that had an anti-reflux basket to prevent reflux. The AU determined that the catheter was not of sufficient length so the AU added a piece of extension tubing that was 20 centimeters long. The extension tubing had a wider diameter than the microcatheter. The extension tubing was placed between the TheraSphere Administration Set and the microcatheter. The administration of the Y-90 began. The AU did not observe any issues during the administration.

The licensee performed post-implant imaging and calculated the administered activity. During the post implant imaging, the Nuclear Medicine Technologist observed that there were no Y-90 microspheres detected in the patient's liver. The licensee began an investigation to locate the microspheres. Through surveys, they determined that the majority of the dose remained in the waste container and more specifically within the administration tubing kit. The TheraSphere™ manufacturer stated that the larger internal diameter of the extension tubing reduced saline velocity and caused the microspheres to fall out of suspension which caused retention of the microspheres in the extension tubing. The licensee reassessed the amount of material that was administered to the patient on June 29, 2023, and determined that 36.7 megabecquerels (0.993 millicuries) were administered which was approximately 7% of the intended activity.

The inspectors independently reviewed the licensee's calculations. The licensee stated that no impact to the patient was expected. The AU performed an assessment of the patient and observed no indications of negative impact to the patient. The patient underwent a subsequent treatment two week later. No complications were observed, and the patient received the intended dose during the subsequent administration.

The inspectors determined that the licensee had never utilized extension tubing for a Y-90 administration in the past. However, extension tubing was routinely utilized in other

types of procedures in the interventional radiology department. The inspectors determined the medical event was an isolated occurrence.

The AU was the referring physician. The licensee notified the patient of the medical event within 24 hours after its discovery. The RSO notified the NRC by telephone on June 30, 2023, that a medical event occurred. EN Number 56601 and NMED number 230281 were assigned. The licensee submitted a written report on July 14, 2023. The inspectors determined that the licensee's notifications and the written report met the content and timeliness requirements of 10 CFR 35.3045.

Violation of 10 CFR 35.67

Title 10 CFR 35.67(a) states, in part that a licensee in possession of any brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer. On June 29, 2023, the licensee was in possession of a brachytherapy source and failed to follow the radiation safety and handling instructions supplied by the manufacturer.

Specifically, the licensee failed to follow the manufacturer's instructions for use when they utilized a piece of extension tubing between the TheraSphere Administration Set and the microcatheter. The manufacturer supplied the licensee with Instructions for Use for TheraSphere™ Yttrium-90 Glass Microspheres. Section 11, titled Operational Instructions for TheraSphere administration, states, in part, do not use extension tubing between the TheraSphere Administration Set and the microcatheter. When the licensee added the extension tubing, approximately 93% of the intended activity became stuck in the tubing. This resulted in 36.7 megabecquerels (0.993 millicuries) of the prescribed 0.54 gigabecquerels (14.58 millicuries) being administered to the patient resulting an under administration. This is a Severity Level IV violation in accordance with NRC Enforcement Policy Section 6.3.d.3.

Corrective Actions and Preventative Measures

The licensee reviewed their Y-90 program and implemented corrective actions and preventative measures to reduce the risk of recurrence of medical events. The licensee implemented immediate corrective actions including: (1) increasing stock levels of 150 millimeter microcatheters to prevent the need for extension tubing; (2) providing remedial training to the AUs on the manufacturer's instructions; (3) conducting remedial training with the manufacturer for Nuclear Medicine Staff and AUs; (4) providing a case study overview to all AUs; and (5) requiring each AU to read the manufacturer's Instructions for Use and provide certification to the RSO.

2.3 Conclusions

The inspectors reviewed the applicable risk modules and focus elements. The inspectors identified one violation of NRC requirements with regard to the licensee's failure to follow the radiation safety and handling instructions supplied by the manufacturer, as required by 10 CFR 35.67(a), when approximately 20 centimeters of extension tubing was used between the TheraSphere Administration Set and the microcatheter leading to the microspheres falling out of suspension in the extension tubing and causing an under administration of Y-90 microspheres on June 29, 2023.

3 Independent Radiation Measurements

Independent radiation surveys were conducted at the inspected facility. 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

4 Exit Meeting Summary

The NRC inspectors presented preliminary inspection findings following the onsite inspection on July 13, 2023, and during a virtual meeting with the RSO on May 22, 2025. Upon completion of in-office review, a virtual exit meeting was held on June 2, 2025, with the licensee. The licensee acknowledged the finding and stated corrective actions have been implemented.

LIST OF PERSONNEL CONTACTED

^*# Dana Baum, Ph.D., RSC Chair
^*# Kelly Baumer, Vice President Clinical Operations
Renee Knoll, EHS Director
^*# Kevin Ferguson, RSO
^* Mark Haenchen, M.S., J.D., RSO
# Lee Seabrooke, Ph.D., Associate Vice President

^ Attended entrance meeting on July 13, 2023
* Attended inspection debrief on July 13, 2023
# Attended virtual exit meeting on June 2, 2025

INSPECTION PROCEDURES USED

IP 87103 – Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing
IP 87130 – Nuclear Medicine Programs