UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

June 16, 2021

EN 55211
NMED No. 210171 (Closed)

Mr. Mark G. Haenchen, M.S., J.D., RSO
Saint Louis University
Office of Environmental Health and Safety
1402 South Grand Blvd.
St. Louis, MO 63104

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03011789/2021002(DNMS) – SAINT LOUIS UNIVERSITY

Dear Mr. Haenchen:

On May 12, 2021, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at your facility in St. Louis, Missouri, with continued in-office review through May 25, 2021. The purpose of the inspection was to review the circumstances surrounding the report of an underdose administration of yttrium-90 microspheres at your South Grand Boulevard location in St. Louis, Missouri, on April 23, 2021. The in-office review included a review of documents not available at the time of the inspection. Mr. Luis Nieves of my staff presented the findings of this inspection during a final exit meeting with you on May 25, 2021. The enclosed inspection report presents the results of the inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety, and security. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

No violations were identified during this inspection; therefore, you are not required to respond to this letter or the enclosed inspection report unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, please submit the information in accordance with the methods described in Title 10 of the *Code of Federal Regulations* (CFR) 30.6(a)(1) and (b)(2).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and any response you may 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, your 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 Mr. Nieves if you have any questions regarding this inspection. Mr. Nieves can be reached at (630) 829-9571.

Sincerely,

Michael A. Kunowski Digitally signed by Michael A. Kunowski
Date: 2021.06.16 05:54:26 -05'00'

Michael Kunowski, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

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

Enclosure: IR 03011789/2021002

cc w/encl: State of Missouri

Letter to Mark Haenchen from Michael Kunowski, dated June 16, 2021.

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03011789/2021002(DNMS) – SAINT LOUIS UNIVERSITY

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DATE	6/14/21		6/14/21					

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U.S. NUCLEAR REGULATORY COMMISSION
REGION III

Docket No.	030-11789
License No.	24-00196-07
Report No.	03011789/2021002(DNMS)
EN/NMED No.	55211/210171
Licensee:	Saint Louis University
Facility:	1201 South Grand Blvd., St. Louis, Missouri 63104
Inspection Date:	May 12, 2021 to May 25, 2021
Exit Meeting Date:	May 25, 2021
Inspector:	Luis Nieves, Health Physicist
Approved By:	Michael Kunowski, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Saint Louis University
NRC Reactive Inspection Report 03011789/2021002(DNMS)

On May 12, 2021, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection of Saint Louis University (licensee) to review the circumstances surrounding a medical event in which an underdose of yttrium-90 (Y-90) was administered. On April 23, 2021, the licensee administered a prescribed dose of 43.2 millicuries (mCi) of Y-90 SIR-Spheres to the liver of a patient. All steps provided by the manufacturer to prevent clogging, such as agitating the microspheres at different parts of the procedure, were followed, and a representative of the manufacturer of the microspheres was present during the administration. When the Authorized User (AU) started to inject the microspheres, he noticed resistance on the plunger and stopped the procedure. The licensee subsequently calculated that only 4.53 mCi of the prescribed 43.2 mCi were administered. The licensee's RSO then reported the underdose medical event, as required by 10 CFR 35.3045(a), to the NRC the same day of the procedure, April 23, 2021. On May 7, 2021, the licensee submitted to the NRC the 15-day report required by 10 CFR 35.3045(d). The licensee determined that the medical event occurred due to clogging of the microspheres in the catheter. The inspector reviewed the type of catheter used for the administration and concluded that its use was in accordance with the manufacturer's instructions. The licensee also concluded that the underdose would have resulted in no harm to the patient, who subsequently received another administration of Y-90 microspheres to continue the medical treatment. The NRC determined that there were no violations of NRC regulatory requirements related to this medical event. The NRC further determined that the licensee's response to and assessment of the incident were adequate.

REPORT DETAILS

1 Program Overview and Inspection History

Saint Louis University (licensee) is a medical broad-scope licensee authorized to use byproduct material with atomic numbers 1-83 and specifically listed sealed sources for medical diagnosis, therapy, and research in humans, and research and development as defined in Title 10 of the *Code of Federal Regulations* (CFR) 30.4. The licensee is also authorized for byproduct material permitted by 10 CFR 35.100, 35.200, 35.300, 35.500, and 10 CFR 31.11.

2 Sequence of Events

2.1 Inspection Scope

On May 12, 2021, the inspector conducted a reactive inspection to review the facts and circumstances surrounding the licensee's report (EN 55211) of an underdose medical event that occurred on April 23, 2021. The reactive inspection consisted of interviews of licensee staff, a review of the sequence of events, and a review of the actions taken to investigate the incident.

2.2 Observations and Findings

On April 23, 2021, the licensee prepared a prescribed dose of 43.2 millicuries (mCi) of Y-90 SIR-Spheres (microspheres) for treatment of the liver of a patient. All steps provided by the manufacturer to prevent clogging, such as agitating the microspheres at different parts of the procedure, were followed and a representative of the microsphere manufacturer was present during the administration. In addition, the licensee went through a step-by-step checklist before administering the Y-90. The microspheres were agitated one last time before the Authorized User (AU) injected them into the patient, per manufacturer instructions. However, the AU noticed some resistance on the plunger when he began the injection and stopped the procedure, with the intent to administer any remaining dose during a second injection. When the AU disconnected the pressurize line with the microspheres, he forgot to release the pressure in the line, causing the backpressure to expel some of the microspheres onto the administration table and the floor covering. The licensee's staff surveyed the area and cleaned up the resulting spill of microspheres, some of which fell onto one of the pants legs of the surgical gown worn by the AU. All of the spilled microspheres and the pant leg of the AU were collected as radwaste. The AU visually verified the catheter line for kinks and did not notice any abnormality when removing it from the patient. Soon after the cleanup, the AU notified the patient and referring physician of the problem with the treatment and that the patient would have to come back for another dose. The AU also notified the licensee's radiation safety officer (RSO) who subsequently calculated that the dose administered to the patient was only 4.53 mCi, compared to the prescribed 43.2 mCi dose, making it a medical event. The licensee determined that the medical event occurred due to clogging of the microspheres in the catheter. The inspector verified that the licensee used the correct catheter per the manufacturer's instructions. The licensee concluded that the underdose caused no harm to the patient, who received a

second injection to continue his treatment. The NRC determined that there were no violations of NRC regulatory requirements during this medical event. The NRC further determined that the licensee's response to and assessment of the incident were adequate.

2.3 Conclusions

The inspector did not identify any violations as a result of this reactive inspection, since the licensee followed appropriate procedures and instructions for administering the Y-90 microspheres and used the correct equipment. The licensee was very cautious during the initial administration and terminated the procedure when the clogging first occurred, and no harm came to the patient as a result of this medical event. A minor spill of microspheres occurred as the authorized backed out of the terminated treatment, but the spill was cleaned up and resulted no appreciable exposure to individuals.

3 Reporting the Event

3.1 Inspection Scope

The inspector reviewed the reporting of the event for the medical event by interviewing the licensee's staff and evaluating the required telephonic notification and 15-day written report documenting the incident.

3.2 Observations and Findings

The medical event occurred April 23, 2021, at approximately 12:00 pm. The RSO determined that it was reportable to the NRC under 10 CFR 35.3045(a)(1)(i). He reported the event by telephone to the NRC Headquarters Operations Center as required by 10 CFR 35.3045(c) at approximately 6:32 pm the same day of the incident.

The licensee provided the required written report to the NRC Region III office as required by 10 CFR 35.3045(d) on May 7, 2021, within 15 days after discovery of the medical event. This report contained all required information.

The licensee notified the patient and referring physician, as required by 10 CFR 35.3045(e), immediately after the procedure on May 23, 2021, of the problem with the treatment and that the patient would have to come back for another dose.

3.3 Conclusions

The licensee made all of the proper notifications and reports within the established timeframes, in accordance with 10 CFR 35.3045(c), (d), and (e). The licensee's written reports included all necessary information.

4 Exit Meeting Summary

The NRC inspector conducted a preliminary exit meeting on May 12, 2021, at the conclusion of the onsite inspection. The licensee did not identify any documents or processes reviewed

by the inspector as proprietary. The licensee acknowledged the results presented. The final exit meeting was conducted on May 25, 2021.

LIST OF PERSONNEL CONTACTED

#! Mark Haenchen, RSO
Kirubahara Vahessan, M.D.
Hailey Broska, Nuclear Medicine Technologist

Participated in preliminary exit meeting on May 12, 2021
! Participated in final exit meeting on May 25, 2021

INSPECTION PROCEDURES USED

87103: Materials Licensees Involved in an Incident or Bankruptcy Filing
87131: Nuclear Medicine Programs-Written Directive Required