UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

July 17, 2015

NMED No. 150125 (closed)

Mark Haenchen
Director, Office of Environmental Health
and Safety
Radiation Safety Officer
Saint Louis University
Office of Environmental Health and Safety
1402 South Grand Boulevard
St. Louis, MO 63104

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03011789/2015001(DNMS) – SAINT LOUIS UNIVERSITY

Dear Mr. Haenchen:

On February 26, 2015, two U.S. Nuclear Regulatory Commission (NRC) inspectors conducted a reactive inspection at the Saint Louis University Hospital in St. Louis, Missouri, with continued NRC in-office review through June 23, 2015. The purpose of this inspection was to review the circumstances, root and contributing causes, and proposed corrective actions for the medical event that your staff reported to the NRC on February 23, 2015. The in-office review included receipt and review of information that was unavailable during the onsite inspection, including the licensee's and the manufacturer's assessments of equipment that was used during the administration of the dosage to identify the cause of the medical event. The inspection findings were discussed during a final, telephonic exit meeting with you and Mr. Kevin Ferguson, on June 23, 2015. The enclosed report presents the results of this inspection.

The inspectors determined that Saint Louis University Hospital staff conducted licensed activities safely and followed sound radiation safety principles. Specifically, the inspectors noted that, based on demonstrations and selected staff member interviews, your staff implemented proper safety practices during use of yttrium-90 microspheres. No violations were identified during this inspection.

In accordance with Title 10 of the *Code of Federal Regulations* (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be 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.

Please contact Mr. Ed Harvey if you have any questions regarding this inspection. Mr. Harvey can be reached by telephone at (630) 829-9819.

Sincerely,

/RA Julio Lara Acting for/

Patrick L. Louden, Director
Division of Nuclear Materials Safety

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

Enclosure:
IR 03011789/2015001(DNMS)

cc w/encl: State of Missouri

Please contact Mr. Ed Harvey if you have any questions regarding this inspection. Mr. Harvey can be reached by telephone at (630) 829-9819.

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IR 03011789/2015001(DNMS)

cc w/encl: State of Missouri

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U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-11789
License No.	24-00196-07
Report No.	03011789/2015001(DNMS)
NMED No.	150125
Licensee:	Saint Louis University
Facility:	Saint Louis University Hospital 3635 Vista Avenue St. Louis, Missouri 63104
Inspection Dates:	February 26, 2015, with continued in-office review through June 23, 2015
Exit Meeting Date:	June 23, 2015
Inspectors:	Kenneth J. Lambert, Senior Health Physicist Edward F. Harvey, Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Saint Louis University
NRC Inspection Report 03011789/2015001(DNMS)

On February 26, 2015, two inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted an announced, reactive inspection, with continued NRC in-office review through June 23, 2015, to review the facts and circumstances associated with the medical event that Saint Louis University (the licensee) staff reported to the NRC on February 23, 2015. The in-office review included receipt and review of information that was unavailable during the onsite inspection, including the licensee's and the vendor's assessments of the equipment used during administration of the dosage to identify the cause of the medical event.

The licensee determined, and the inspectors confirmed, that a medical event occurred as a result of administering approximately 78 percent of the prescribed dosage of yttrium-90 (Y-90) microspheres to the patient. Because the treatment resulted in a dose that differed from the prescribed dose by more than 0.5 Sievert (Sv) (50 rem) and a total dose delivered that differed from the prescribed dose by 20 percent or more, the treatment constituted a medical event per NRC's definition in Title 10 of the *Code of Federal Regulations* (CFR) Section 35.2. The licensee determined that the medical event would not result in adverse effects to the patient.

The root cause of the medical event was an abnormally high concentration of Y-90 microspheres being administered, which resulted in an accumulation of microspheres at the three-way stopcock.

The inspectors identified that the licensee had developed, implemented, and maintained written procedures to provide high confidence that each administration is in accordance with the written directive. No violations of NRC regulatory requirements were identified.

REPORT DETAILS

1 Program Overview and Inspection History

Saint Louis University is authorized under NRC Materials License No. 24-00196-07 to use licensed materials for medical diagnosis and therapy, including Y-90 microspheres for therapeutic treatment of cancerous liver tumors. The licensee is authorized to use licensed materials for research on humans in accordance with applicable U.S. Food and Drug Administration. The licensee is also authorized to use licensed materials for research and development, including animal studies and irradiation of blood and other materials.

The last routine inspection was conducted in April 2014 and identified two violations of a security-related nature. A followup inspection was performed in August 2014 to review the licensee's corrective actions to the violations. The followup inspection confirmed that the licensee had implemented appropriate corrective actions and no additional violations were identified.

The previous routine inspection was conducted in June 2012 and identified one violation involving the failure to secure information from unauthorized access. The licensee implemented immediate corrective actions to limit access only to authorized individuals.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspectors observed reenactments of the medical event and interviewed, in part, the physician authorized user (AU), the interventional radiologist (IR), the radiation safety officer (RSO), two nuclear medicine technologists (NMTs), an interventional radiology technician (IRT), and other licensee personnel to determine the sequence of events that resulted in the medical event. The inspectors observed the Y-90 microsphere delivery system, including the occlusion in the delivery tubing. In addition, the inspectors reviewed selected licensee records, licensee procedures, and the licensee's compliance with regulatory requirements for Y-90 microspheres treatments.

2.2 Observations and Findings

a. Medical Event Details

On February 23, 2015, the licensee planned to administer a therapeutic dosage of Y-90 microspheres to treat a patient's liver cancer. The written directive, dated February 23, 2015, called for the administration of 13.23 millicuries (mCi) of Y-90 microspheres to treat the left lobe of the patient's liver. The written directive was signed by the physician AU and IR. Prior to the delivery of the treatment, an NMT drew the dose from the stock vial and measured a dosage of 13.2 mCi in the administration vial. The dosage was verified by the physician AU per the licensee's written directive form.

The licensee assembled the dosage delivery system in accordance with licensee procedures, the manufacturer's instructions, and in the presence of the manufacturer's representative. The IR inserted a catheter into the patient's liver using medical imaging for proper placement. The catheter was then connected to the delivery system. Prior to administration of the dosage, the delivery system was flushed with saline to ensure proper operation.

During dosage administration, the IR felt no unusual resistance during the procedure and the flushing of the administration lines at the conclusion of the procedure to ensure all the Y-90 microspheres were delivered to the patient's liver. The IR believed all the prescribed dosage was administered.

After the dosage administration, a licensee staff member conducted radiation surveys of the Interventional Radiology Suite and all of the individuals that were involved with the dosage administration. The survey results were negative for radioactivity.

During the radiation survey measurements of the vial and administering delivery system, the NMT noted that the radiation levels were higher than expected. Based on these radiation measurements, the NMT determined the dosage delivered to the liver was 10.34 mCi, which represented 78.1 percent of the prescribed 13.23 mCi dosage. The licensee also determined that the treatment site received a total dose of 541 rem, which was 152 rem less than what the liver would have received if all of the prescribed dosage had been administered to the treatment site. The licensee identified that the administration met the criteria for an NRC medical event as described in 10 CFR 35.3045(a)(1) because the delivered dose differed from the dose that would have resulted from the prescribed dose by more than 50 rem to the tissue and the total dosage delivered differed from the prescribed dosage by more than 20 percent.

b. Medical Event Assessment

The licensee staff performed surveys of the equipment used during the dosage administration to locate the high radiation survey measurements identified during the post-administration survey of the delivery equipment. The licensee staff determined that the high radiation measurements were located at the three-way stopcock valve near where the delivery line from the microspheres vial entered the stopcock. The licensee did not observe any damage to the delivery line or three-way stopcock.

The licensee informed the inspectors that the microsphere delivery system was going to be held in storage approximately four weeks, so that the Y-90 microspheres can decay. The licensee indicated that after decaying, the delivery system was to be shipped to the manufacturer for evaluation. The licensee had contacted the manufacturer who had requested the delivery system be sent to them for further evaluation to determine the cause of the medical event. The manufacturer provided the results of its investigation to the licensee on May 26, 2015.

Based on the manufacturer's investigation results, the inspectors determined that the root cause of the medical event was an abnormally high concentration of Y-90 microspheres being administered, which resulted in an accumulation of micro spheres at the three-way stopcock.

2.3 Conclusions

The licensee implemented its procedures for Y-90 microspheres administration without error. The inspectors determined that the licensee's response to and assessment of the medical event were adequate. No violations of NRC regulatory requirements were identified.

3 Licensee Assessment of Patient Effects

3.1 Inspection Scope

The inspectors interviewed the physician AU and IR, and reviewed the licensee's aforementioned written report of the medical event to obtain information about potential adverse effects to the patient as a result of the medical event.

3.2 Observations and Findings

The physician AU determined that there were no adverse consequences to the patient as a result of the medical event. The patient's liver received 541 rem of the intended 693 rem; therefore, the physician AU determined that the treatment site received enough radiation dose to achieve the palliative effect of the treatment.

3.3 Conclusions

The physician AU determined that there were no adverse effects to the patient as a result of the medical event.

4 Review of Recent Microspheres Administrations

4.1 Inspection Scope

The inspectors reviewed records for the 21 Y-90 microspheres treatments administered since the last inspection in May 2014.

4.2 Observations and Findings

The selected records reviewed indicated that the licensee implemented its Y-90 microspheres procedures without error. None of the administrations involved the spillage of Y-90 microspheres or the occlusion of material in the delivery system based on the licensee's adequate pre- and post-dosage administration radiation measurements. The administered dosages did not result in NRC medical events.

4.3 Conclusions

The inspectors determined that the most recent Y-90 microspheres administrations conducted prior to the medical event and after the last inspection did not result in any NRC medical events.

5 Notifications and Reports

5.1 Inspection Scope

The inspectors reviewed selected records and interviewed selected staff to understand the licensee's response to its discovery of the medical event. The inspectors also reviewed the licensee's notification of the medical event to the NRC Operations Center, dated February 23, 2015. In addition, the inspectors reviewed the licensee's associated written report of the medical event, dated March 8, 2015, to assess compliance with reporting requirements.

5.2 Observations and Findings

On February 23, 2015, the physician AU attempted to reach the referring physician, but was unable to do so. Because the referring physician was not available, the physician AU notified the patient on February 24, 2015. On February 23, 2015, the licensee notified the NRC Operations Center about the medical event, as required by regulatory requirement. The licensee provided its written report of the medical event in a letter, dated March 8, 2015. The inspectors determined that the written report was submitted within 15 days of discovery of the event and included the information required by 10 CFR 35.3045(d), except for actions to prevent recurrence. Instead of addressing actions to prevent recurrence, the report appropriately stated that corrective actions to prevent recurrence were pending the outcome of the manufacturer's investigation of the tubing and three-way stopcock valve. The licensee committed to forward the manufacturer's report to the NRC, and take appropriate corrective actions, if any, in response to the report.

5.3 Conclusions

The inspectors determined that the licensee provided the notifications and written report as required by 10 CFR 35.3045.

6 Exit Meeting Summary

At the completion of the on-site inspection, the inspectors discussed the preliminary inspection findings with licensee management during an exit meeting. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature. A final telephonic exit meeting was conducted on June 23, 2015.

Partial List Of Personnel Contacted

#* Kevin Ferguson, Associate Radiation Safety Officer
#* Mark Haenchen, Director, Office of Environmental Health and Safety; Radiation Safety Officer
Elyse Koester, Quality Coordinator Nuclear Medicine/PET; Nuclear Medicine Technologist
Razi Muzaffar, D.O., Authorized User
Hugh Robichaux, Nuclear Medicine Manager
Kirubahara Vaheesan, M.D., Interventional Radiologist
Rebekka Smith, Nuclear Medicine Technologist
Cory Prindivelle, Interventional Radiology Technician

Attended the on-site exit meeting on February 26, 2015
* Participated in the telephone exit meeting on June 23, 2015