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

February 1, 2018

EN 53040
NMED No. 170527 (closed)

Mr. Edward E. Wroblewski
Radiation Safety Officer
St. Vincent Indianapolis Hospital
2001 W. 86th Street
Indianapolis, IN 46260

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03001579/2017001(DNMS) –
ST. VINCENT HOSPITAL & HEALTH CARE CENTER

Dear Mr. Wroblewski:

On November 9, 2017, two U.S. Nuclear Regulatory Commission (NRC) inspectors conducted a reactive inspection at the St. Vincent Hospital & Health Care Center in Indianapolis, Indiana, with continued NRC in-office review through January 9, 2018. The purpose of this inspection was to review the circumstances, root and contributing causes, and proposed corrective actions for the medical event that the licensee reported to the NRC on October 28, 2017. 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 dose preparation and delivery techniques that were used during the administration of the dosage to identify the cause of the medical event. Mr. Zahid Sulaiman of my staff discussed the inspection findings with you during a final, telephonic exit meeting on January 9, 2018. The enclosed report presents the results of this inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. 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. The inspectors determined that licensee staff conducted licensed activities within the bounds of NRC requirements and the manufacturer's instructions. Based on demonstrations and interviews with select licensee staff, the inspectors determined that licensee staff implemented proper safety practices during this administration of yttrium-90 (Y-90) microspheres and that the medical event occurred for reasons outside of the licensee's control.

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 Agency wide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html.

Please contact Mr. Sulaiman if you have any questions regarding this inspection. Mr. Sulaiman can be reached by telephone at 630-829-9752.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-01579
License No. 13-00133-02

Enclosure:
IR 03001579/2017001(DNMS)

cc w/encl: State of Indiana

Letter to Edward E. Wroblewski from Aaron T. McCraw dated February 1, 2018

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03001579/2017001(DNMS) –
ST. VINCENT HOSPITAL & HEALTH CARE CENTER

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REGION III

Docket No.	030-01579
License No.	13-00133-02
Report No.	03001579/2017001(DNMS)
NMED No.	170527
Licensee:	St. Vincent Hospital & Health Care Center
Facility:	2001 W. 86th Street Indianapolis, Indiana 46260
Inspection Dates:	November 9, 2017, with continued in-office review to January 9, 2018
Exit Meeting Date:	January 9, 2018
Inspectors:	Zahid Sulaiman, Health Physicist Jason D. Draper, Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

St. Vincent Hospital & Healthcare
NRC Inspection Report 03001579/2017001(DNMS)

On November 9, 2017, two inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted an announced, reactive inspection, with continued NRC in-office review through January 9, 2018, to review the facts and circumstances associated with the medical event that St. Vincent Hospital & Health Care Center (licensee) staff reported to the NRC on October 28, 2017. 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 dose preparation and delivery techniques that was used during the administration of the dosage to identify the cause of the medical event.

On October 27, 2017, the licensee treated a patient for metastatic uveal melanoma, a liver only metastatic disease. The activity prescribed in the written directive prescribed was 60 millicuries (mCi), of Y-90 microspheres (Sir-Spheres®) to right hepatic artery. The dose was assayed at 1415 hours and the calculated assayed dose of 54.7 mCi was recorded. The authorized user (AU) placed the micro-catheter in the proper hepatic artery and identified the hepatic arterial anatomy. The dose administration kit was connected per manufacturer protocol and standards. The dose infusion was initiated and the first aliquot was infused. The flush line was then opened and flush was initiated with 50/50 contrast. At this point the AU noted the microspheres were not infusing. The AU made attempts to troubleshoot the infusion process by using smaller syringes and manipulating the connection and catheters present. The AU identified the infusion process was not going to be successful and stopped the treatment. The licensee determined, and the inspectors confirmed, that a medical event occurred as a result of administering a calculated dose of 11.5 mCi (828 rad) which is 80.83 percent less than the prescribed dose as noted on the written directive. 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 the NRC's definition in Title 10 of the *Code of Federal Regulations* (CFR) 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 the combination of two factors that resulted in the clogging of the microcatheter: 1) the delay of patient treatment by a day due to patient medical condition instability on the day of the original day of procedure, October 26, 2017, caused the Y-90 to decay by approximately 25 percent, and this required approximately 25 percent increase in number of Y-90 microspheres, and 2) the abnormally high concentration of Y-90 microspheres being administered, resulted in an accumulation of microspheres in the microcatheter.

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

REPORT DETAILS

1.0 Program Overview and Inspection History

St. Vincent Hospital & Health Care Center is authorized under NRC Materials License No. 13-00133-02 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 medical use permitted by 10 CFR 35.1000

The last routine inspection was conducted from February 29 through March 3, 2016, and identified one non-cited violation. The violation was licensee-identified involving the failure to secure licensed material, as required by 10 CFR 20.1801. The corrective actions included training the staff on the importance of securing licensed material and discussing the audit finding during the March 1, 2016, radiation safety committee meeting.

The previous routine inspection was conducted from September 12 through 19, 2013, with continued in-office review through October 8, 2013, and identified one non-cited violation. The violation was a licensee-identified violation of NRC requirements involving use of licensed material by a qualified but unauthorized physician who was not listed on the license as an authorized user in License Condition 12.B.

2.0 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspectors observed reenactments of the medical event and interviewed, in part, the interventional radiologist (IR)/authorized user (AU), the radiation safety officer (RSO), the junior physicist, and the assistant physicist/nuclear medicine technologist (NMT) to determine the sequence of events that resulted in the medical event. In addition, the inspectors reviewed selected licensee records, licensee procedures, and the manufacturer's training manuals to assess the licensee's compliance with regulatory requirements for Y-90 microspheres treatments.

2.2 Observations and Findings

a. Medical Event Details

On October 27, 2017, at around 1415 hours a 61-year-old male was being treated for metastatic uveal melanoma, a liver only metastatic disease. The licensee planned to administer a therapeutic dose of Y-90 microspheres to treat a patient's liver cancer. The patient was initially scheduled to have the procedure done on October 26, 2017. The patient treatment was delayed by one day due to the medical instability of the patient. The written directive, dated October 27, 2017, called for the administration of 60 mCi of Y-90 microspheres to treat the right lobe of the patient's liver. The written directive was signed by the physician AU. Prior to the delivery of the treatment, an NMT drew the dosage from the stock vial and measured a dosage of 54.7 mCi in the administration vial (v-vial). During dosage preparation, the NMT observed that the v-vial was completely full with no air bubble gap, as required by the manufacturer's instructions. The NMT contacted the AU and got the authorization to remove 0.8 milliliters (mL) of fluid from the v-vial. The NMT measured the 0.8 mL fluid for any residual activity and found no activity. The dosage was verified by the AU per the licensee's written directive form.

The licensee assembled the dose delivery system in accordance with the manufacturer's instructions. The AU inserted a catheter into the patient's hepatic artery, and the hepatic arterial anatomy was identified. 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.

The licensee then initiated the dose infusion. The dosage had a very large number of microspheres because of the prolonged decay and large prescribed dosage ordered. The licensee opened the flush line and flushed the line with 50/50 contrast. At this point, the AU noted the microspheres were not infusing as expected. The AU made attempts to troubleshoot the infusion process by using smaller syringes and manipulating the connections and catheters present. The AU noticed the v-vial had lost its seal and was in danger of overflowing. Once the AU identified the infusion process was not going to be successful, the AU stopped the procedure and contained the material in a closable plastic container with the help of the NMT. The failed dose administration appeared to be result of the microcatheter clogging.

After the procedure was stopped, the NMT conducted radiation surveys of the Interventional Radiology Suite and all of the individuals that were involved with the dose administration. The survey results were negative for radioactivity.

The NMT conducted the radiation survey measurements of the vial and the dosage delivery system. Based on these radiation measurements, the NMT determined the calculated patient dosage delivered to the liver at 1528 hours was 11.5 mCi, which represented 19.17 percent of the prescribed 60-mCi dosage. The licensee also determined that the treatment site received a total dose of 828 rem, which was 3,492 rem less than what the liver would have received if all of the prescribed dose 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 dose delivered differed from the prescribed dose by more than 20 percent.

b. Medical Event Assessment

The licensee staff believed the clogging of the microcatheter occurred as a result of the combination of two factors: 1) the patient's treatment was delayed by one day (roughly 26 hours) due to the medical instability of the patient on the day of the initial scheduled procedure, October 26, 2017. This delay caused the activity to decay by approximately 25 percent, and therefore required a 25 percent increase in the number of microspheres to meet the prescribed dosage; and 2) the prescribed dosage of 60 mCi is at the high end of the range for this treatment. The high prescribed dosage resulted in an increase in the concentration of microspheres in the v-vial.

The licensee informed the inspectors that the microsphere delivery system was going to be held for decay in storage. The licensee had contacted the manufacturer to determine the cause of the medical event. The inspector independently contacted a manufacturer representative about the manufacturer's guidelines regarding the microsphere concentration in the v-vial and aliquot size in the delivery line. The manufacturer provided the results of its assessment to the inspector on December 13, 2017.

Based on the licensee staff's assessment and the manufacturer's review, the inspectors concluded that the licensee's administration of Y-90 microspheres had complied with all NRC requirements and the manufacturer's instructions, despite resulting in a medical event. The inspectors agreed with the licensee staff's assessment and the manufacturer's review that the root cause of the medical event was an abnormally high concentration of Y-90 microspheres and a large aliquot size being administered, which resulted in clogging of microspheres in the microcatheter.

2.3 Conclusions

The licensee implemented its procedures and the manufacturer's instructions for this 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.

3.0 Licensee Assessment of Patient Effects

3.1 Inspection Scope

The inspectors interviewed the AU, 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 AU determined that there were no adverse consequences to the patient as a result of the medical event. The patient's liver received an underdose of 828 rem of the intended 4,320 rem. The AU scheduled the patient for re-treatment. The licensee re-treated the patient with a prescribed dose of 61 mCi of Y-90 microspheres on November 7, 2017.

3.3 Conclusions

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

4.0 Notifications and Reports

4.1 Inspection Scope

The inspectors reviewed the licensee's notification of the medical event to the NRC Operations Center, dated October 28, 2017, the referring physicians, and the patient. In addition, the inspectors reviewed the licensee's associated written report of the medical event, dated November 8, 2017, to assess compliance with reporting requirements.

4.2 Observations and Findings

On October 28, 2017, the licensee notified the NRC Operations Center about the medical event (Event Number 53040) by the next day after discovery of the medical event, as required by 10 CFR 35.3045(c). The licensee notified the patient and the patient's referring physician on October 27, 2017. The licensee provided its written report of the medical event in a letter, dated November 8, 2017. 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).

4.3 Conclusions

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

5.0 Licensee Corrective Actions

The inspectors reviewed the licensee's corrective actions to prevent similar events. The review included the licensee's written report dated November 8, 2017, regarding the medical event. The licensee believed the medical event occurred as a result of combination of two factors that lead to the clogging of the microcatheter: 1) the patient's treatment being delayed by one day caused the activity to decay by approximately 25 percent, requiring a 25-percent increase in the number of microspheres in v-vial, and 2) the relatively high activity (60 mCi) of the prescribed dosage, which is at the high end of the range for this treatment. The high prescribed dosage resulted in an increase in the concentration of microspheres in the v-vial. Following the medical event, and to prevent future recurrence, the licensee will adjust the infusion technique by using smaller aliquots of material in the delivery line and/or a slower infusion rate and allow for a less concentrated material to be infused.

The inspectors determined that the licensee implemented adequate corrective actions to address the medical event and to prevent future recurrence.

6.0 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. The final exit meeting was conducted via telephonic on January 9, 2018, to discuss the inspection findings.

LIST OF PERSONNEL CONTACTED

#* Edward E. Wroblewski, Radiation Safety Officer
Becky Hoberty, Junior Physicist
Ryan Couevas, Physicist Assistant, Nuclear Medicine Technologist
Brandon Martinez, M.D., Interventional Radiologist/Authorized User
Diana Thompson, Radiation Safety Officer/Licensing Consultant, Sirtex Medical Inc.

Attended the on-site exit meeting on November 11, 2017
* Participated in the telephone exit meeting on January 9, 2018

INSPECTION PROCEDURES (IP) USED

IP 87103, “Inspection of a Materials Licensee Involved in an Incident or Bankruptcy”
IP 87131, “Nuclear Medicine Programs, Written Directive Required”