UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

May 28, 2015

Docket No. 03001245 License No. 06-00843-03

Dale Danowski
Senior Vice President, RN, MBA
St. Vincent's Medical Center
2800 Main Street
Bridgeport, CT 06606

SUBJECT: NRC INSPECTION REPORT NO. 03001245/2015001, ST. VINCENT'S MEDICAL CENTER, BRIDGEPORT, CONNECTICUT SITE

Dear Ms. Danowski:

On February 3, 2015, Penny Lanzisera of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was limited to a review of a medical event reported to the NRC Operations Center on January 15, 2015. Additional information provided in your correspondence dated January 21, March 10 and April 13, 2015, and during the telephone conversation on April 16, 2015 with you and other members of your staff were also examined as part of the inspection. The findings of the inspection were discussed with you at the conclusion of the inspection. The enclosed report presents the results of this inspection.

Within the scope of this inspection, no violations were identified.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Regulations, Guidance and Communications.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents;** then **Enforcement Policy (Under 'Related Information').** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

No reply to this letter is required. Please contact Penny Lanzisera at 610-337-5169 if you have any questions regarding this matter.

Sincerely,

/RA/

James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Inspection Report No. 03001245/2015001

cc:
Sean M. Mathews, Radiation Safety Officer
State of Connecticut

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cc:
Sean M. Mathews, Radiation Safety Officer
State of Connecticut

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SUNSI Review Complete: PLanzisera

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NAME	PLanzisera/pl		JDwyer/jpd					
DATE	05/08/15		05/28/15					

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03001245/2015001
Docket No.	03001245
License No.	06-00843-03
NMED Item No.	150039
Licensee:	St. Vincent's Medical Center
Location:	2800 Main Street Bridgeport, Connecticut 06606
Inspection Dates:	February 3, 2015 April 16, 2015 (telephonic exit)
Date Follow-up Information Received:	March 10 and April 13, 2015

Inspector: ***/RA/*** _____ ***05/08/15*** _____

Penny Lanzisera
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

date

Approved By: ***/RA/*** _____ ***05/28/15*** _____

James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

date

EXECUTIVE SUMMARY

St. Vincent's Medical Center
NRC Inspection Report No. 03001245/2015001

An announced, special inspection was conducted on February 3, 2015, at St Vincent's Medical Center (SVMC) in Bridgeport, Connecticut, to review the circumstances surrounding a medical event reported on January 15, 2015 (NMED Item Number 150039) involving delivery of yttrium-90 microspheres to a patient on January 14, 2015, where the entire dosage could not be administered. Additional information provided by SVMC on March 10 and April 13, 2015, was also reviewed. The inspection consisted of a review of licensed activities associated with the use of microspheres at SVMC. The inspector coordinated with headquarters and determined that a medical consultant was not necessary in this case since SVMC was scheduled to complete the patient's treatment and since the licensee had requested that both the microsphere manufacturer and the delivery catheter manufacturer review their respective devices. In-office evaluation of the medical event, the microsphere and catheter manufacturers' assessments of their respective devices, and SVMC's corrective actions continued through April 16, 2015. The microsphere manufacturer determined on March 10, 2015, that since the vial was successfully used after the catheter was replaced; the delivery device operated as intended. The catheter manufacturer reported on April 3, 2015, that "blood may have been present in the inner lumen of the catheter prior to the embolic infusion" and that "it is likely that the embolic beads became impacted in the clotted blood within the catheter lumen which caused the catheter to clog." The manufacturer suggested that the mixing of blood in the catheter may be "an indication that the catheter was not sufficiently flushed prior" to infusion. The licensee reviewed this information with the Authorized Users from April 7-13, 2015, and concluded that a continuous flushing system as described in their letter dated January 21, 2015, should prevent recurrence. The licensee forwarded the information to the NRC on April 13, 2015.

Based on the results of this inspection, no violations were identified.

REPORT DETAILS

I. Event Description

a. Inspection Scope

An announced, special inspection was conducted on February 3, 2015, at SVMC in Bridgeport, Connecticut to review the circumstances surrounding a medical event reported on January 15, 2015 (NMED Item Number 50736). The inspection was conducted in accordance with Inspection Procedure 87103 and Management Directive 8.10. An in-office review to evaluate the event, the microsphere manufacturer's and delivery catheter manufacturer's evaluation of their respective devices, and SVMC's corrective actions continued through April 16, 2015. The medical event was identified by SVMC during a routine patient treatment on January 14, 2015. The inspector conducted interviews with licensee personnel, toured the facility, and reviewed records applicable to the event. The inspector also reviewed SVMC's procedures related to microsphere use and documentation regarding the design and use of the delivery catheter and vial.

b. Observations and Findings

Microsphere Program

License No. 06-00843-03 authorizes SVMC to provide microsphere treatments using the SIR-Sphere delivery system at its facility in Bridgeport, Connecticut. The licensee began its microsphere program in March 2013 and currently has four authorized users (AUs) approved for performing these treatments. In administering these treatments the licensee uses various delivery catheters made by multiple manufacturers. One of the catheter types used is manufactured by Surefire Medical Inc. (Surefire).

Event Chronology, Reporting, On-Site Inspection, and Corrective/Preventative Actions

January 14, 2015 – A patient scheduled to receive 22 millicuries of yttrium-90 SIR-Spheres instead received 11.5 millicuries. A written directive was prepared, as required. The injection of the microspheres through the delivery system met with significant resistance and the AU determined that the delivery catheter was clogged. The clogged catheter was removed and during removal a few drops of microspheres dropped onto the table. The AU decided to deliver the remainder of the dosage to the left liver lobe and to formulate a plan to deliver any additional dosage needed to complete the treatment when the patient returned for treatment of the right liver lobe in approximately four weeks. A new catheter was inserted and 11.5 millcuries of the remaining dosage was delivered without incident. SVMC contacted the microsphere manufacturer and the catheter manufacturer and held the delivery system and delivery catheter for decay to accommodate the manufacturers' analysis.

January 15, 2015 - SVMC reported the medical event to the NRC Operations Center and Region I contacted the licensee to arrange an inspection date to review the event.

January 21, 2015 – SVMC submitted its 15-day report in accordance with 10 CFR 35.3045. In the report, SVMC described the event, the suspected cause of the event, the patient notification of the event, and the actions taken to prevent recurrence. Corrective and preventative actions included a revised procedure to include: (i) a constant flush of the delivery catheter prior to microsphere administration; and (ii) minimal delivery of microspheres during the initial infusion to minimize the chance of catheter clogging. All AUs were trained on the new procedure.

February 3, 2015 – NRC Region I conducted an on-site inspection to review the circumstances surrounding the reported medical event. The inspector conducted interviews with licensee personnel, toured the facility, and reviewed records applicable to the event. The inspector also reviewed SVMC's procedures related to microsphere use and the manufacturers' documentation regarding the design and use of the delivery catheter and the SIR-Sphere vial.

February 6, 2015 – Region I coordinated with the NRC's Headquarters Office to determine whether a medical consultant or scientific consultant was necessary to review the event as outlined in Management Directive 8.10. It was determined that a medical consultant was not necessary since the event resulted in an under-dose and SVMC planned the completion of the patient's treatment in a few weeks. It was determined that a scientific consultant was not necessary to review the equipment since SVMC had requested that Sirtex review the SIR-Sphere vial and Surefire review the delivery catheter.

March 10, 2015 – Sirtex examined the SIR-Sphere vial and did not identify any concerns. Additionally, the Sirtex representative concluded that the vial was used successfully to continue the treatment on January 14, 2015, and therefore, performed as designed. Surefire received the catheter for examination and indicated that the examination would take at least two weeks.

April 7-13, 2015 – Surefire provided its assessment of the delivery catheter in a letter dated April 3, 2015. Surefire concluded that "blood may have been present in the inner lumen of the catheter prior to the embolic infusion" and that "it is likely that the embolic beads became impacted in the clotted blood within the catheter lumen which caused the catheter to clog." The manufacturer suggested that the mixing of blood in the catheter may be "an indication that the catheter was not sufficiently flushed prior" to infusion. SVMC reviewed this information with the AUs from April 7-13, 2015, and concluded that a continuous flushing system as described in their letter dated January 21, 2015, should prevent recurrence.

April 13, 2015 - SVMC provided a copy of Surefire's report to the NRC.

April 16, 2015 – a final exit meeting was conducted via telephone with SVMC's Vice President, Radiation Safety Officer, AU, and two Radiology Managers. During the exit, the inspector summarized the event, the event reporting, the manufacturers' reviews, and SVMC's corrective and preventative actions. SVMC confirmed that the corrective and preventative actions stated in their January 21, 2015, letter had been implemented and that the delivery catheter is connected to a constant flush prior to treatment and

disconnected from the flush at the time of dose delivery. SVMC also confirmed that the patient had returned for a treatment to the right lobe and during this treatment, the additional dosage to the left lobe was administered to complete the treatment.

c. Conclusions

SVMC reported the medical event as required by 10 CFR 35.3045 and took appropriate corrective and preventative actions. SVMC also notified the involved patient of the event and completed the patient's treatment to the left lobe when the patient returned for treatment of the right lobe. Based on the inspector's observations, no violations of NRC requirements were identified.

II. Exit Meeting

A preliminary exit meeting was conducted on February 3, 2015, to discuss the scope of the inspection and the inspector's initial observations. On April 16, 2015 an exit meeting was held by telephone with Dale Danowski, Senior Vice President, and other members of SVMC's staff, to discuss the results of this inspection.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

*+ Dale Danowski - Senior Vice President
*+ Sean Mathews – Radiation Safety Officer
+ Kenneth Zinn, M.D. – Authorized User
*+ Kelly Hannan - Radiology Manager, Interventional Radiology
*+ Latishia Greene – Radiology Manager, Nuclear Medicine

Various nuclear medicine and interventional radiology staff involved in the microsphere program.

* Present at preliminary exit meeting on February 3, 2015
+ Participated in telephonic exit meeting conducted on April 16, 2015