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

June 5, 2017

EN 52524
NMED No. 170083 (Closed)

Ms. Cheryl Martin
Vice President, Radiology Services
Henry Ford Hospital
2799 West Grand Boulevard
Detroit, MI 48202

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03002043/2017002(DNMS)
HENRY FORD HOSPITAL

Dear Ms. Martin:

On February 8, 2017, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at your facility in Detroit, Michigan, with continued in-office review through May 15, 2017. The purpose of the inspection was to review the facts and circumstances surrounding a medical event that was reported to the NRC on February 1, 2017. The in-office review included a review of the written report provided to the NRC concerning the medical event in addition to the written report from a medical consultant contracted by the NRC to independently review the circumstances of the medical event. Mr. Edward Harvey of my staff conducted a final exit meeting by telephone with Mr. Alan Jackson of your staff on May 18, 2017, to discuss the inspection findings. 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) Section 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 your response if you choose to provide one, 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. Harvey if you have any questions regarding this inspection. Mr. Harvey can be reached at 630-829-9819.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch

Docket No. 030-02043
License No. 21-04109-16

Enclosure:
IR 03002043/2017002(DNMS)

cc w/encl: Alan Jackson, Radiation
Safety Officer
State of Michigan

Letter to Cheryl Martin from Aaron McCraw dated June 5, 2017

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03002043/2017002(DNMS)
HENRY FORD HOSPITAL

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DATE	6/2/2017		6/5/2017					

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U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-02043
License No.	21-04109-16
Report No.	03002043/2017002(DNMS)
NMED No.	170083
Licensee:	Henry Ford Hospital
Facility:	2799 West Grand Boulevard Detroit, MI 48202
Inspection Dates:	February 8, 2017, with in-office review through May 17, 2017
Exit Meeting Date:	May 18, 2017
Inspector:	Edward Harvey, Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Henry Ford Hospital
NRC Inspection Report 03002043/2017002(DNMS)

This was an announced, reactive inspection, performed in response to a medical event reported to the U.S. Nuclear Regulatory Commission (NRC) on February 1, 2017. Henry Ford Hospital (licensee) operates several medical facilities in the Detroit, Michigan area; this event occurred at the main hospital, located at 2799 West Grand Boulevard. The medical event, which occurred on January 31, 2017, concerned an yttrium-90 (Y-90) microspheres treatment in which a fraction of the microspheres were delivered to an unintended lobe of the liver. Specifically, a portion of the intended 45-millicurie (mCi) Y-90 microspheres treatment to the left lobe of the patient's liver went to the right lobe of the liver.

The root cause of the medical event is unclear; however, the licensee believes it to be either a potential movement of the catheter caused by an unnoticed patient movement or angiographically undetected reflux caused by the difference in flow dynamics between Theraspheres® and both the contrast agent and Tc-99m macro-aggregated albumin (MAA) used for treatment planning. The licensee stated that the only corrective action to prevent recurrence of a similar event that they could identify would be to exclude patients with challenging vascular anatomy. However, given the rarity of this type of incident and the potential benefits to the treatment, the licensee believes that this action is not viable.

A third party medical consultant, contracted by the NRC, reviewed the circumstances of this medical event and agreed with the licensee's evaluation of: (1) why the event occurred; (2) the effects on the individual who received the unintended dose; (3) the licensee's immediate actions on discovery; and (4) improvements needed to prevent recurrence. The consultant added that patient movements as subtle as breathing may have affected the position of the catheter enough to influence the path of the microspheres within the liver once injected.

The inspector identified no violations of NRC requirement concerning the medical event.

REPORT DETAILS

1 Program Overview

Henry Ford Hospital (licensee) is authorized to use byproduct material for diagnostic and therapeutic medical procedures under NRC Materials License No. 21-04109-16. Among these procedures are microspheres therapy procedures using Y-90 microspheres, which are performed only at the main hospital at 2799 West Grand Boulevard, in Detroit, Michigan. The purpose of this announced inspection was to review the events surrounding a medical event that occurred during a microspheres procedure on January 31, 2017, and reported to the NRC on February 1, 2017.

2 Sequence of Events

2.1 Inspection Scope

The inspector interviewed licensee staff and management personnel concerning the events surrounding a medical event that occurred on January 31, 2017, and reviewed documentation concerning the events leading up to and following the medical event.

2.2 Observations and Findings

On January 31, 2017, licensee staff administered a Y-90 microspheres treatment with the intention of delivering 60 Gray (Gy) to the left lobe of the patient's liver. Approximately two weeks prior to the procedure, an interventional radiologist began the treatment planning process by using an iodinated contrast solution to image the entire left lobe of the liver. During this process, the interventional radiologist determined the appropriate injection point such that the distribution of the contrast would be isolated to the left lobe of the liver.

Later, the nuclear medicine department administered a dosage of Tc-99m MAA solution to image the volume of left lobe. A nuclear medicine physicist reviewed the Tc-99m MAA image and calculated the dosage of Y-90 microspheres to administer to achieve the intended dose of 60 Gy based of the volume of this image. The calculated activity for the procedure was 45 mCi.

On the day of the procedure, the interventional radiologist, using a contrast agent, verified that the treatment catheter was accurately placed such that the Y-90 microsphere administration would be isolated to the left lobe of the patient's liver. This assessment was done at both high and low pressures in an effort to replicate the Therasphere® delivery conditions. Following this verification, the catheter was connected to the Y-90 treatment apparatus. Then, once again, the catheter position was checked under fluoroscopy to verify the correct position immediately prior to administering the microspheres.

The administration went forward with no apparent complications. Following the procedure, licensee staff imaged the patient's liver using the Bremsstrahlung radiation from the Y-90 microspheres. From this image, licensee staff noted that a portion of the microspheres had went to the right lobe of the liver.

At this time, the licensee began an investigation of the situation. Using spectral analysis of the Bremsstrahlung image, the licensee determined that the left lobe of the patient's liver received 48.6 Gy, or 81 percent of the intended dose of 60 Gy. The analysis also revealed that the right lobe of the liver received an unintended dose of 36.5 Gy. This

unintended dose to the right lobe constitutes a medical event under Title 10 of the *Code of Federal Regulations* (CFR) Section 35.3045(a)(3) because the dose to organ tissue outside the intended treatment site exceeded 50 rem (0.5 Sv). The patient had received a previous Y-90 microspheres treatment on December 7, 2016, with an intended dose of 141.6 Gy to the right lobe. The unintended dose received by the right lobe during the treatment intended for the left lobe on January 31, 2017, brings the cumulative dose to the right lobe to 178.2 Gy. The licensee does not expect any acute effects as a result of this additional dose.

The licensee determined that the root cause of the medical event to be either a potential movement of the catheter caused by an unnoticed patient movement or angiographically undetected reflux caused by the difference in flow dynamics between Theraspheres® and both the contrast agent and Tc-99m MAA used for treatment planning. Licensee staff stated that this type of incident has never occurred in any previous Y-90 microspheres administration at Henry Ford Hospital. A review of additional microspheres treatments showed a high level of consistency with the pre-treatment Tc-99m MAA images and the post-treatment Bremsstrahlung images, indicating that the procedures went as expected.

The licensee stated that the only corrective action to prevent recurrence of a similar event that they could identify would be to exclude patients with challenging vascular anatomy. However, given the rarity of this type of incident and the potential benefits to the treatment, the licensee believes this action is not viable. The inspector verified that the licensee followed all of the required procedures during for the administration of the Y-90 microspheres.

A third party medical consultant, contracted by the NRC, reviewed the circumstances of this medical event and agreed with the licensee's evaluation of: (1) why the event occurred; (2) the effects on the individual who received the unintended dose; (3) the licensee's immediate actions on discovery; and (4) improvements needed to prevent recurrence. The consultant added that patient movements as subtle as breathing may have affected the position of the catheter enough to influence the path of the microspheres within the liver once injected.

2.3 Conclusions

The inspector identified no violations concerning the events surrounding the medical event at Henry Ford Hospital on January 31, 2017.

3 Licensee Notifications

3.1 Inspection Scope

The inspector interviewed licensee staff and management personnel concerning the initial notification to the NRC about the medical event and the written report. In addition, the inspector reviewed the documentation of the notifications for required information.

3.2 Observations and Findings

On January 31, 2017, the licensee identified that the administration of the Y-90 microspheres dose might have resulted in a medical event. Licensee staff notified the NRC's Headquarters Operations Center about the potential medical event by telephone on February 1, meeting the requirement in 10 CFR 35.3045(c) to notify the NRC no later than the next calendar day. Licensee staff followed up during the reactive

inspection on February 8, providing additional details and stating that they had determined that the event did constitute a medical event.

In addition, the licensee notified the referring physician about the medical event on January 31, 2017, and the referring physician notified the patient the following day; updates were provided as appropriate. This met the requirement in 10 CFR 35.3045(e).

On February 13, 2017, the NRC received the licensee's written report. This was within the 15 days required by 10 CFR 35.3045(d) to provide the report to the NRC. The written report contained all required information.

3.3 Conclusions

The inspector identified no violations concerning the licensee's reporting of the medical event to the NRC.

4 Exit Meeting Summary

The NRC inspector presented preliminary inspection findings following the onsite inspection on February 8, 2017. The licensee did not identify any documents or processes reviewed by the inspector as proprietary. The licensee acknowledged the findings presented.

LIST OF PERSONNEL CONTACTED

\# Nick Beums, PhD, Division Head, Imaging Physics
\# Ishani Dalal, MD, Senior Staff Radiologist
\# Beth Harkness, Nuclear Medicine Physicist
\# Kastytis Karvelis, MD, Division Head, Nuclear Medicine
\# Alan Jackson, CHP, Radiation Safety Officer
\# Sonal Joshi, PhD, Imaging Physics Resident
\# Cheryl Martin, Vice President, Radiology Services
\# Scott Schwartz, MD, Interventional Radiologist
\# Patricia Svolos, PhD, Imaging Physics Resident
\# Rene Tsang, Pharmacist
\# Matt Vanderhoek, PhD, Imaging Physicist

\# Attended preliminary exit meeting on February 8, 2017.