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

February 29, 2016

EN 51640
NMED No. 160018 (closed)

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

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03002043/2016001(DNMS)
HENRY FORD HOSPITAL

Dear Ms. Martin:

On January 19, 2016, two inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at your facility in Detroit, Michigan, with continued in-office review through January 27, 2016. The purpose of the inspection was to review the facts and circumstances surrounding a medical event that was reported to the NRC on January 7, 2016. The in-office review included a review of the written report provided to the NRC concerning the medical event. Mr. Geoffrey Warren of my staff conducted a final exit meeting by telephone with Mr. Alan Jackson of your staff on February 16, 2016, 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. 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 and interviews with personnel.

No violations were identified during this inspection. Therefore, you are not required to respond to this letter unless the description herein 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. Warren of my staff if you have any questions regarding this inspection. Mr. Warren can be reached at 630-829-9742.

Sincerely,

/RA/

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

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

Enclosure:
IR 03002043/2016001(DNMS)

cc w/encl: Alan Jackson, MS, CHP, Radiation
Safety Committee Chairman
Donald Peck, Ph.D., Radiation Safety Officer
State of Michigan

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State of Michigan

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DATE	3/29/2016		3/29/2016		3/29/2016			

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U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-02043
License No.	21-04109-16
Report No.	03002043/2016001(DNMS)
NMED No.	160018
Licensee:	Henry Ford Hospital
Facility:	2799 West Grand Blvd. Detroit, Michigan
Inspection Dates:	January 19, 2016, with in-office review through January 27, 2016
Exit Meeting Date:	February 16, 2016
Inspector:	Geoffrey Warren, Senior Health Physicist 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 03002043/2016001(DNMS)

This was an announced, reactive inspection, performed in response to a medical event reported to the U.S. Nuclear Regulatory Commission (NRC) on January 7, 2016. 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 Blvd. The medical event concerned a yttrium-90 (Y-90) microspheres procedure in which the calculated dosage of Y-90 microspheres was inadequate to provide the intended dose to the treatment volume, the left lobe of the liver.

After administering the dosage and imaging the patient using Bremsstrahlung radiation from the Y-90 in the liver, the licensee identified a mismatch between the volume indicated by this image and the image taken before the administration using technetium-99m (Tc-99m) sulfur colloid, though the materials were both released at points within 1 millimeter. The volume indicated in the Bremsstrahlung image was consistent with the volume in an angiography image taken while planning the procedure; these were both consistent with the treatment volume specified in the written directive, while the Tc-99m image did not cover the entire volume. The licensee has been unable to explain the discrepancy, and had never seen or heard of another case where these images did not agree.

Because the Tc-99m image showed a smaller volume than the written directive had specified and the quantity of Y-90 microspheres to be administered was calculated based on the volume shown in this image, the Y-90 dosage resulted in only 79.3 percent of the intended dose to the intended volume. The licensee identified that the incident constituted a medical event under the requirements of Title 10 of the *Code of Federal Regulations* (CFR), Section 35.3045(a)(1), and reported the event properly to the NRC. In addition, the licensee provided a timely written report containing all information required under 10 CFR 35.3045(d).

The root cause of the medical event was the discrepancy between the angiography and Tc-99m images prepared before planning the procedure. As a contributing factor, the nuclear medicine authorized user (AU) who approved the procedure and signed the written directive did not note the discrepancy because his focus was on verifying that the calculated dosage of Y-90 microspheres would give the intended dose to the volume of liver identified in the Tc-99m scan.

As corrective action for the medical event, the licensee changed their work flow for such procedures and updated the network planning and tracking system to reflect the change. The previous work flow required a nuclear medicine AU to approve the calculations and written directive, and the revised work flow adds a second review by an angiographer to verify that the volume in the Tc-99m image is correct. The network planning system was updated on January 18 to ensure that no further action can be taken toward treating the patient until both physicians have approved the plan. An email was sent to personnel involved with microspheres treatments to describe the updated system.

The inspectors identified no violations of NRC requirements concerning the medical event.

REPORT DETAILS

1 Program Overview

Henry Ford Hospital (licensee) is authorized to perform a variety of 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 Blvd. 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 6, 2016, and reported to the NRC on January 7, 2016.

2 Sequence of Events

2.1 Inspection Scope

The inspectors interviewed licensee staff and management personnel concerning the events surrounding a medical event that occurred on January 6, 2016, and reviewed documentation concerning the events leading up to and following the medical event.

2.2 Observations and Findings

In December 2015, licensee staff prepared to perform a Y-90 microspheres procedure to treat liver cancer for a patient at the licensee's main hospital at 2799 West Grand Blvd. in Detroit, Michigan. The intention was to treat the entire left lobe of the liver with a 120-gray (Gy) dose of microspheres. An angiographer (an interventional radiologist) imaged the liver in radiology using iodinated contrast solution, imaging the entire left lobe of the liver.

Later, at the nuclear medicine department, a technologist administered a dosage of Tc-99m sulfur colloid to image the same volume; the angiographer set the release point for the Tc-99m solution. While the Tc-99m solution was administered within 1 millimeter of the administration point for the iodinated contrast solution, the imaged volume did not match the angiography image. The Tc-99m image showed a major portion of the left lobe of the liver, but a small portion was not shown. This discrepancy was not noted at the time. A nuclear medicine physicist reviewed the Tc-99m image and calculated the dosage of Y-90 microspheres to administer in order to give the intended 120-Gy dose based on the volume of this image, calculating this activity as 62.2 millicuries (mCi).

In accordance with the licensee's written procedure, an AU reviewed these calculations and the image and confirmed that, in his judgement, the calculated activity of microspheres would provide the intended dose. The licensee's expectation was that this AU would catch any issues with the proposed procedure. The AU then signed the written directive on December 18, 2015.

On January 6, 2016, the patient returned to the hospital for the Y-90 microspheres procedure. Nuclear medicine staff determined that the activity of the Y-90 dosage was 66.1 mCi, within ten percent of the prescribed dosage. The procedure went forward

without incident and the licensee administered 64 mCi of the dosage. Following the procedure, licensee staff brought the patient to the nuclear medicine department to image the liver using the Bremsstrahlung radiation from the Y-90 microspheres. Licensee staff noted that the Bremsstrahlung image did not match the Tc-99m image, instead including some liver tissue not included in the Tc-99m image.

At this time, licensee staff began an investigation into the situation. They determined that the Bremsstrahlung image was consistent with the angiography image previously taken. They calculated that because of the increased volume, the left lobe of the liver received a reduced dose of 94 Gy instead of the prescribed 120 Gy, or 78.3 percent of the prescribed dose. This constituted a medical event under 10 CFR 35.3045(a)(1) because the dose difference exceeded 20 percent of the prescribed dose. No portion of the liver received a higher dose than intended; the written directive stated that the treatment volume was the entire left lobe of the liver. The licensee determined that the 94-Gy dose was within the therapeutic treatment range of 80-150 Gy for microspheres procedures, and stated that because of this no further treatment would be required.

The root cause of the medical event was the discrepancy between the angiography and nuclear medicine images prepared before planning the procedure. Licensee staff stated that they had never seen or heard of such a discrepancy before. A review of additional Y-90 microspheres procedures showed that the angiography, Tc-99m, and Bremsstrahlung images were consistent as to the liver volume shown. The licensee cannot explain the discrepancy, though they speculate that it was because of the different pressures at which different materials were administered. As a contributing factor, the AU did not note the discrepancy because his focus was on verifying that the calculated dosage of Y-90 microspheres would give the intended dose to the volume of liver identified in the Tc-99m scan. The angiographer in this case stated that he would have noted that the Tc-99m image did not include the entire left lobe of the liver if he had reviewed the image prior to the procedure.

As corrective action for the medical event, the licensee changed their work flow for such procedures and updated the network planning and tracking system to reflect the change. The previous work flow required a nuclear medicine AU to approve the calculations and written directive, and the revised work flow adds a second review by an angiographer to verify that the volume in the Tc-99m image is correct. The network planning system was updated on January 18 to ensure that no further action can be taken toward treating the patient until both physicians have approved the plan. An email was sent to personnel involved with microspheres treatments to describe the updated system. While one Y-90 microspheres treatment was performed after the medical event but prior to this planning system update, the angiographer reviewed the case prior to the procedure and documented his approval by email.

2.3 Conclusions

The inspectors identified no violations concerning the events surrounding the medical event at Henry Ford Hospital on January 6, 2016.

3 Licensee Notifications to the NRC

3.1 Inspection Scope

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

3.2 Observations and Findings

On January 6, 2016, 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 Office about the potential medical event by telephone on January 7, meeting the requirement in 10 CFR 35.3045(c) to notify the NRC no later than the next calendar day. Licensee staff followed up by email on January 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 potential medical event and the referring physician notified the patient on January 6, 2016; updates were provided as appropriate. This met the requirement in 10 CFR 35.3045(e).

On January 21, 2016, the NRC received the licensee's written report by mail. 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 inspectors 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 January 19, 2016. The licensee did not identify any documents or processes reviewed by the inspectors as proprietary. The licensee acknowledged the findings presented.

LIST OF PERSONNEL CONTACTED

Nick Beums, Physicist
John Fallucca, M.D., Interventional Radiology
Beth Harkness, M.S., Nuclear Medicine Physicist
Kastytis Karvelis, M.D., Division Head, Nuclear Medicine
Alan Jackson, Radiation Safety Committee Chairman
Sonal Joshi, Physics Resident
Cheryl Martin, Vice President, Radiology Services

Dan Myers, M.D., Nuclear Radiologist
Donald Peck, Ph.D., Radiation Safety Officer
Vivek Singh, Physics Resident
Matt Vanderhoek, Physicist

Attended preliminary exit meeting on January 19, 2016.