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

November 1, 2016

EA-16-214
EN 51888
NMED No. 160158 (Closed)

Mr. Larry Genzink
Director, Radiology Services
Spectrum Health Hospitals
100 Michigan Street NE
Grand Rapids, MI 49503

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03001989/2016001(DNMS)
SPECTRUM HEALTH HOSPITALS

Dear Mr. Genzink:

On May 3, 2016, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at your facility in Grand Rapids, Michigan, with continued in-office review through August 25, 2016. The purpose of the inspection was to review the circumstances, root and contributing causes, and corrective actions for a medical event that you reported to the NRC on April 27, 2016. The in-office review included an evaluation of your written report and the receipt and review of a report by an expert medical consultant, who conducted an independent assessment of the probable deterministic effects of radiation exposure to the patient as a result of this medical event. 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, observations of activities, and interviews with personnel.

Based on the results of this inspection, one apparent violation of NRC requirements was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violation concerned the failure to implement written procedures which provided high confidence that an administration of yttrium-90 microspheres was in accordance with the written directive, as required by Title 10 of the *Code of Federal Regulations* (CFR) Section 35.41(a)(2).

Because the NRC has not made a final determination in this matter, the NRC is not issuing a Notice of Violation for this inspection finding at this time. Mr. Ryan Craffey of my staff discussed the circumstances surrounding this apparent violation, the significance of the issue, and the need for lasting and effective corrective action with your Chief Medical Physicist and Radiation Safety Officer, Dr. Evan Boote, by telephone during a final exit meeting on October 18, 2016.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond in writing to the apparent violation addressed in the enclosed inspection report within 30 days of the date of this letter, or (2) request a Predecisional Enforcement Conference (PEC). **Please contact Mr. Aaron T. McCraw, Chief of the Materials Inspection Branch, at 630-829-9650 or Aaron.McCraw@nrc.gov within ten days of the date of this letter to notify the NRC of your intended response.**

If you choose to provide a written response, it should be clearly marked as "Response to the Apparent Violation in Inspection Report No. 03001989/2016001(DNMS); EA-16-214," and should include, for the apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance was or will be achieved. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the information notice on the NRC's website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, it will afford you the opportunity to provide your perspective on the apparent violation and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the PEC may include the following: information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. If a PEC is held, it will be open for public observation; the NRC will issue a press release to announce the time and date of the conference.

Because your facility has not been the subject of escalated enforcement action within the last two years or two inspections, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. In addition, based upon NRC's understanding of the facts and your corrective actions, it may not be necessary to conduct a PEC in order to enable the NRC to make a final enforcement decision. Our final decision will be based on your confirming on the license docket that the corrective actions previously described to the staff and documented in the enclosed inspection report have been or are being taken.

Please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

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, any 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. Craffey if you have any questions regarding this inspection. Mr. Craffey can be reached at 630-829-9655.

Sincerely,

/RA/

John B. Giessner, Director
Division of Nuclear Materials Safety

Docket No. 030-01989
License No. 21-26543-01

Enclosure:
IR 03001989/2016001(DNMS)

cc: Evan J. Boote, Ph.D.,
Radiation Safety Officer
State of Michigan

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Sincerely,

/RA/

John B. Giessner, Director
Division of Nuclear Materials Safety

Docket No. 030-01989
License No. 21-26543-01

Enclosure:
IR 03001989/2016001(DNMS)

cc: Evan J. Boote, Ph.D.,
Radiation Safety Officer
State of Michigan

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Letter to Larry Genzink from John Giessner dated November 1, 2016

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03001989/2016001(DNMS) – SPECTRUM HEALTH HOSPITALS

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U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-01989
License No.	21-26543-01
Report No.	03001989/2016001(DNMS)
EA No.	EA-16-214
Licensee:	Spectrum Health Hospitals
Facilities Inspected:	Spectrum Health Butterworth Hospital 100 Michigan Street NE Grand Rapids, Michigan
Inspection Date:	May 3, 2016, with continued in-office review through August 25, 2016
Exit Meeting Date:	October 18, 2016
Inspector:	Ryan Craffey, Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Spectrum Health Hospitals
NRC Inspection Report 03001989/2016001(DNMS)

This was an announced reactive inspection of the circumstances surrounding a medical event that Spectrum Health Hospitals (the licensee) reported to the U.S. Nuclear Regulatory Commission (NRC) on April 27, 2016.

On April 27, 2016, the licensee administered a treatment for hepatocellular carcinoma to a patient using yttrium-90 (Y-90) microspheres. The physician authorized user (AU) prescribed a dose of 120 gray (Gy) to segments 5-8 of the patient's liver. The licensee noted nothing unusual during the treatment itself. However, during a review of post-infusion imaging of the patient's liver, the AU discovered that the dose had gone to segments 4a and 4b of the patient's liver, instead of segments 5-8 as intended.

The licensee determined, and the NRC agreed, that the root cause of the medical event was human error by the AU, who did not verify the position of the catheter used to administer the microspheres as required by written procedures, and therefore did not notice that the tip of the catheter had moved slightly between the time he placed it and the time he administered the dose of microspheres.

The movement of the catheter resulted in essentially no dose delivered to the intended treatment site. The licensee estimated, based on the relative size of the segments, that 4a and 4b (which were not intended to receive any significant dose from the prescribed treatment) received approximately 400 Gy instead. The licensee observed no deleterious effects to the individual beyond the nausea and fatigue normally experienced after a microspheres treatment. The license expected that there would be gradual atrophy of segments 4a and 4b, but not enough to affect overall liver function. The licensee concluded that the most significant impact on the patient would be a delay in the treatment of segments 5-8.

The NRC retained the services of a medical consultant to conduct an independent assessment of the probable deterministic effects of radiation exposure to the patient as a result of this medical event. The consultant corroborated the licensee's dose estimates, and determined that no significant consequences to the patient were expected as a result of this medical event.

As a result of the reactive inspection, the inspector identified an apparent violation of Title 10 of the *Code of Federal Regulations* (10 CFR) 35.41(a)(2) for the licensee's failure to implement written procedures which provided high confidence that an administration of yttrium-90 microspheres was in accordance with the written directive. Specifically, the AU did not properly implement the licensee's written procedure with regard to verification of catheter position prior to administration.

As corrective action, the licensee revised its in-room checklist for microsphere treatments to more explicitly describe how the existing verification of catheter position should be done. The licensee implemented this revised checklist beginning on April 28, 2016.

REPORT DETAILS

1 Program Overview and Inspection History

Spectrum Health Hospitals (the licensee) was authorized to use radioactive material for medical purposes at several facilities on its campus in downtown Grand Rapids, Michigan, and at various satellite facilities in southwestern Michigan. The licensee performed diagnostic and therapeutic administrations of unsealed byproduct and accelerator-produced material, temporary and permanent implant manual brachytheraphy, high dose-rate remote afterloader (HDR) brachytherapy, and implantation of iodine-125 sees for localization of non-palpable lesions.

The licensee had also performed over 300 Y-90 microsphere administrations since first receiving authorization from the NRC to do so in 2009, including 50 treatments in fiscal year 2015, and over 90 in fiscal year 2016 through May 3. The licensee had three physician AUs on staff to perform both SIR-Sphere® and TheraSphere® administrations.

The NRC last conducted an inspection of Spectrum Health Hospitals on May 18-21, 2015. During that routine inspection, one violation of 10 CFR 36.643(a) and (d)(6) was identified regarding the conduct of HDR spot checks. Corrective actions for the violation were outside of the scope of this reactive inspection, and therefore were not reviewed. The correct actions will be reviewed at the next routine inspection. No other violations were open at the time of this inspection.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspector interviewed a number of involved staff and reviewed a selection of procedures, checklists and other documents to obtain the licensee's understanding of the circumstances surrounding the medical event.

2.2 Observations and Findings

On April 27, 2016, the licensee performed a TheraSphere® treatment for a hepatocellular carcinoma. The AU had prescribed a dose of 120 Gy to segments 5-8 of the patient's liver via the right hepatic artery (RHA), using 3.29 gigabequerels (GBq) of Y-90. The license received a vial of approximately 7.50 GBq from the manufacturer for this administration, and had drawn 3.32 GBq from the vial for use.

The licensee noted nothing unusual during the treatment itself. Post-operation surveys of residual activity in the injection apparatus and other waste determined that approximately 1.3 percent of the dose had not been injected, resulting in an estimated administered dose of 3.28 GBq. However, during a comparative review of SPECT bremsstrahlung images fused with CT scans of the patient's liver immediately following the treatment, the AU discovered that this dose had actually gone to segments 4a and 4b of the patient's liver, instead of segments 5-8. The radiation safety officer (RSO) and AU, after reviewing the administration, collectively determined that the dose had gone to the wrong lobes because the tip of the catheter used to infuse the dose had moved out of the RHA and into the medial RHA (MRHA), which fed segments 4a and 4b.

The AU had originally advanced the tip of the catheter along the RHA, using intermittent "puffs" (2-3 milliliters (mL)) of contrast agent under fluoroscopy as a guide, to just 1 centimeter beyond the junction between the RHA and MRHA. The AU placed it there in order to more effectively diffuse the dose across segments 5-8, which were all fed by the RHA. After completing the placement, the AU conducted an automated "power injection" of 20-30 mL of contrast agent under fluoroscopy to fully map the vasculature of segments 5-8, then completed preparation of the injection apparatus. Approximately 10 minutes later, and just before connecting the catheter to the apparatus, the attending interventional radiology (IR) technologist asked the AU to verify the catheter's position, as required by a line item in the licensee's in-room checklist for microsphere administrations. According to published American College of Radiology guidelines, this confirmation should have been completed by means of one last puff of contrast under fluoroscopy as a final check before injection. The AU acknowledged, however, that he did not perform the verification in this manner, and instead signaled his confirmation to the IR technologist based solely on an assumption that the catheter was still where he had initially placed it. The AU speculated that, because of the short distance from the tip of the catheter to the junction of the RHA and MRHA, any one of a number of factors, including movement of the patient, the patient's breathing, or the automated power injection itself, could have caused the catheter tip to move into the MRHA.

The licensee determined that it expected limited consequences to the patient as a result of this medical event. The licensee noted that the patient had not suffered any immediate adverse consequences beyond those normally expected from a microspheres administration, such as nausea and fatigue. The licensee estimated that segments 4a and 4b received approximately 400 Gy from the administration, and were therefore expected to atrophy gradually, and effectively cease to exist within 12 months of dosing. However, the licensee expected the remaining segments of the liver to compensate for the loss of segments 4a and 4b over the next 12 months, and did not expect the overall function of this patient's liver to be adversely affected. Moreover, the AU had previously treated segments 4a and 4b with 0.84 GBq of Y-90 on January 27, 2016, giving a dose of approximately 120 Gy as intended, and until this event had been planning on treating these segments again in the future, as they were still approximately 50 percent tumor by volume. The licensee concluded therefore that the most significant impact on the patient would be a delay in the treatment of the tumors still present in segments 5-8.

The licensee rescheduled the patient for the treatment of segments 5-8, as originally planned. On May 31, 2016, the licensee successfully treated these segments with a new dose of Y-90 microspheres.

The licensee confirmed that, among the 300 or so microsphere administrations performed since first receiving authorization to perform them in 2009, this was the only administration in which dose was given to an unintended segment of the liver.

2.3 Conclusions

The inspector found the licensee's response to and assessment of the medical event to be adequate.

3 Notifications and Reporting

3.1 Inspection Scope

The inspector discussed the relevant reporting requirements with the licensee's RSO and reviewed the initial notification and 15-day written report for this medical event to evaluate compliance with reporting requirements.

3.2 Observations and Findings

The medical event occurred at approximately 2:00 pm eastern time on April 27, 2016. After reviewing the post-operation images, the AU who performed the treatment notified the licensee's RSO of a potential medical event, who notified the NRC's Headquarters Operations Center at approximately 5:00 pm the same day. The notification resulted in Event Number 51888, and was recorded in the Nuclear Materials Events Database (NMED) under No. 160158. The AU also notified the patient and his family shortly thereafter on April 27. The RSO notified the referring physician through his nurse on the following day.

The licensee submitted its 15-day written report to the NRC on May 10, 2016. The report included the licensee's name; the name of the prescribing physician; a brief description of the event; why the event occurred; the effect, if any on the patient; actions taken to prevent recurrence; and certification that the licensee notified the individual.

3.3 Conclusions

The inspector determined that the licensee made all required notifications and reports within the required time periods, and that the licensee's written report included all required information.

4 Independent Assessment of Deterministic Effects

4.1 Inspection Scope

The NRC contracted the services of an expert medical consultant to assess the probable deterministic effects of the radiation exposure to the patient as a result of the medical event. The inspector reviewed the medical consultant's report dated August 15, 2016, with supplemental information dated August 25, 2016.

4.2 Observations and Findings

The medical consultant performed an independent dose calculation of the administration on April 27, 2016, which resulted in a medical event, and determined that segments 4a and 4b of the patient's liver received 437 Gy, within 10 percent of the licensee's estimate.

The consultant agreed that the root cause of the event was a failure to adequately verify position of the catheter. The consultant concluded that while some radionecrosis of segments 4a and 4b was evident from followup evaluation of the patient's liver via CT scans and enzyme testing, no significant consequences to the patient (such as the

loss of liver function or the need for supplemental treatment) were to be expected as a result of the medical event.

4.3 Conclusions

The NRC's medical consultant agreed with the licensee's assessment of the medical event, and determined that while a small amount of radionecrosis had occurred, no significant consequences to the patient were expected.

5 NRC Assessment of the Event

5.1 Inspection Scope

The inspector interviewed a number of involved staff; reviewed a selection of procedures, checklists, and other documentation; observed licensed activities involving Y-90 microspheres; and reviewed the medical consultant's independent assessment of the event during the period of in-office review to assess the circumstances and implications of the medical event.

5.2 Observations and Findings

The inspector agreed with the licensee's determination that this administration led to a medical event, as it met the criteria in 10 CFR 35.3045(a)(1)(i) on the basis of dose to the intended treatment site of segments 5-8 of the patient's liver, and also as it met the criteria in 10 CFR 30.3045(a)(3) on the basis of dose to segments 4a and 4b, which were outside the intended treatment site. The inspector also agreed with the licensee's determination of the root cause of the medical event.

The inspector concluded, based on corroborating assessments by the licensee (section 2 of this report) and an expert medical consultant (section 4), that this event would not result in significant consequences to the patient. However, because of the localized radionecrosis and the need to reschedule the patient for the originally intended treatment, the inspector concluded that the medical event was of more than limited consequences.

As a result of the inspection and the additional in-office review, the inspector determined that the licensee apparently failed to implement its written procedures which provided high confidence that an administration of yttrium-90 microspheres was in accordance with the written directive. Title 10 CFR 35.41(a)(2) requires that, for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The AU's apparent failure to implement the licensee's written procedures for microsphere administrations – specifically, the step related to verification of catheter position – represents an apparent violation of 10 CFR 35.41(a)(2).

The inspector, in agreement with the licensee and the medical consultant, concluded that the root cause of the apparent violation was that of the medical event itself – human error.

As corrective action to prevent recurrence of a medical event and to address the underlying apparent violation, the licensee revised its in-room checklist for microsphere

treatments to now explicitly describe how the verification of catheter position should be accomplished. Instead of simply asking the IR to verify catheter position, the checklist now requires verification that the radiologist confirmed "proper catheter position with 2-3 mLs of contrast and perform fluoroscopy to confirm catheter position and flow to the intended treatment site" as the last check before connecting the catheter to the injection apparatus for administration. The licensee implemented this revised checklist on April 28, 2016. The licensee also committed to discuss the checklist revisions with staff, and to solicit suggestions for other revisions.

5.3 Conclusions

The inspector determined that a medical event had occurred, and that the licensee had adequately identified the root cause of the medical event. The inspector identified an apparent violation of 10 CFR 35.41(a)(2) for the failure to implement written procedures to provide high confidence that each administration of microspheres is in accordance with the written directive.

6 Exit Meeting Summary

The NRC inspector presented preliminary inspection findings following the onsite inspection on May 3, 2016, and presented final inspection findings via telephone on October 18, 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

Evan J. Boote, Ph.D. – Director, Physics and Technology (Radiology), RSO
Michael Doherty, M.D. – Physician Authorized User
Todd Durham, M.D. – Physician Authorized User
Larry Genzink – Director, Radiology Services
Doreen Marcinek – Director, Inpatient Radiology Services
Donna Nawrocki – Interventional Radiology Technologist II
Melissa Pell – Interventional Radiology Technologist I
Kat Pyne – Imaging Applications Coordinator (Nuclear Medicine)
Greg Quiroz – Manager, CT & Nuclear Medicine
Edward Silberstein, M.D. – Medical Consultant (University of Cincinnati Medical Center)

INSPECTION PROCEDURES USED

87103: Inspection of Nuclear Material Licensees Involved in an Incident or Bankruptcy Filing
87131: Nuclear Medicine Programs – Written Directive Required
87132: Brachytherapy Programs