UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

April 22, 2019

EN 53814
NMED No. 190021 (closed)

Mr. Maxwell Amurao
Radiation Safety Officer
Washington University in St. Louis
Campus Box 8053
660 S. Euclid Avenue
St. Louis, MO 63110-1093

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03002271/2019001(DNMS) – WASHINGTON UNIVERSITY IN ST. LOUIS

Dear Mr. Amurao:

On January 10, 2019, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at your facility in St. Louis, Missouri, with continued in-office review through April 5, 2019. The purpose of the inspection was to review the circumstances surrounding a potential medical event that you reported to the NRC on January 4, 2019, and to ensure that activities were being performed in accordance with NRC requirements. The in-office review included a review of the written report you provided concerning the potential medical event and a review of the licensee's basis for ultimately retracting the report once the procedure was determined by the licensee to not meet the criteria for an NRC reportable medical event. The NRC agreed with this conclusion. Mr. Geoffrey Warren of my staff discussed the results of the inspection with you at the inspection exit meeting on April 5, 2019. The enclosed inspection report presents the results of the inspection.

During the 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 of NRC requirements were identified during this inspection, and the NRC has no further questions regarding this matter. Therefore, you are not required to respond to this letter unless the description in the enclosed inspection report does not accurately reflect your understanding or position. In that case, or if you choose to respond, clearly mark your response as a "Reply to NRC Reactive Inspection Report No. 03002271/2019001(DNMS)" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region III, within 30 days of the date of this letter.

In accordance with Title 10 of the *Code of Federal Regulations* 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and any response you provide 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. Warren 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. 030-02271
License No. 24-00167-11

Enclosure:
IR03002271/2019001(DNMS)

cc w/encl: State of Missouri

Letter to M. Amurao from Aaron T. McCraw, dated April 22, 2019.

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03002271/2019001(DNMS) – WASHINGTON UNIVERSITY IN ST. LOUIS

DISTRIBUTION w/encl:
Darrell Roberts
John Giessner
David Pelton
Christine Lipa
Kenneth Lambert
Paul Pelke
MIB Inspectors

ADAMS Accession Number: ML19112A203

OFFICE	RIII-DNMS	C	RIII-DNMS	C				
NAME	GWarren:ps		AMcCraw					
DATE	4/18/2019		4/22/2019					

OFFICIAL RECORD COPY

U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-02271
License No.	24-00167-11
Report No.	03002271/2019001(DNMS)
EN No. / NMED No.	53814 / 190021
Licensee:	Washington University in St. Louis
Facility:	Barnes-Jewish Hospital 1 Barnes Jewish Hospital Plaza St. Louis, Missouri
Inspection Dates:	January 10, 2019, with continued in-office review through April 5, 2019
Exit Meeting Date:	April 5, 2019
Inspector:	Geoffrey Warren, Senior Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Washington University in St. Louis
NRC Inspection Report 03002271/2019001(DNMS)

This was a reactive inspection performed in response to a potential medical event reported by Washington University in St. Louis (the licensee) on January 4, 2019. The licensee was authorized by U.S. Nuclear Regulatory Commission (NRC) Radioactive Materials License No. 24-00167-11 to use licensed material for a variety of uses, including medical procedures involving yttrium-90 (Y-90) microspheres.

The potential medical event was identified following a Y-90 microspheres procedure for treating liver cancer performed at Barnes-Jewish Hospital in St. Louis on January 3, 2019. It was identified as a result of a post-treatment scan that appeared to indicate that the administered material was delivered to the incorrect portion of the liver, and licensee staff reported it to the NRC in accordance with Title 10 of the *Code of Federal Regulations* (CFR) 35.3045(c). However, after further review, the licensee's physician authorizored user determined that the correct portion of the liver was treated, as intended, and the licensee retracted the event report. The NRC conducted a reactive inspection on January 10, 2019, to review the circumstances of the event and the basis for its ultimate retraction.

In addition, the inspector conducted a comprehensive review of the licensee's Y-90 microspheres program and closed two previously cited violations from 2017 inspections concerning Y-90 microspheres medical events. The inspector determined that the licensee had completed adequate corrective actions and the violations had not recurred. No violations were identified during this inspection.

REPORT DETAILS

1 Program Overview and Inspection History

Washington University in St. Louis (the licensee) is authorized under NRC Radioactive Materials License No. 24-00167-11 to use licensed material for a variety of uses, including medical procedures. Among these medical procedures are Y-90 microspheres procedures for treating liver cancer. These procedures are performed at Barnes-Jewish Hospital in St. Louis, Missouri.

On October 20, 2017, the licensee was cited for the failure to implement its written procedure for Y-90 microsphere procedures, in that, during a procedure on August 18, 2017, licensee staff failed to prepare the patient for dose delivery by placing the infusion catheter into the proper treatment location, as required by 10 CFR 35.41(a). This violation was closed during this inspection as described in Section 4 of this report.

On September 21, 2017, the licensee was cited for the failure to notify the NRC Operations Center by telephone no later than the next calendar day after discovery of a medical event resulting from a Y-90 microsphere procedure performed on April 8, 2016, as required by 10 CFR 35.3045(c). This violation was closed during this inspection as described in Section 4 of this report.

No violations were cited as a result of the two most recent routine inspections of the licensee performed in March 2016 and March 2017.

2 Events Surrounding Potential Medical Event and Licensee Response

2.1 Inspection Scope

The inspector reviewed the circumstances surrounding and following a potential medical event that occurred on January 3, 2019, by interviewing licensee staff and reviewing documentation concerning the medical procedure.

2.2 Observations and Findings

On January 3, 2019, the licensee performed a Y-90 microsphere procedure on a patient to treat liver cancer. This was the fourth administration of microspheres for the patient, and was intended to treat segments 6 and 7 of the left lobe of the liver. The oncologist signed a written directive for the procedure on January 3, with a prescribed dose of 125.3 Gray (Gy) to the two segments and a corresponding dosage of 1.06 gigabecquerels (GBq) of Y-90 to provide that dose. Licensee staff verified the patient's identity and prepared the patient for the procedure. Before administering the microspheres dosage, licensee staff performed a spot x-ray with angiography contrast to verify treatment of the correct liver segments, and another spot x-ray following attachment of the microspheres apparatus to verify correct placement of the catheter. Licensee staff then administered the microspheres material slowly because of fibrosis from previous Y-90 adminstrations. According to licensee staff, there were no indications of any issues, such as movement of the catheter during the administration, and post-treatment calculations showed that 1.02 GBq, or 96 percent, of the prescribed 1.06 GBq was administered.

Following the procedure, the patient was taken to a nuclear medicine area for a post-treatment SPECT-CT scan in order to verify the treatment. The initial review of this scan indicated that, instead of treating segments 6 and 7 of the left lobe of the liver as planned, the microspheres appeared to have been administered to segments 5 and 8. Based on this determination, licensee staff recognized that the treatment appeared to have met the criteria for a medical event, as specified in 10 CFR 35.3045(a)(3), and notified the NRC's Operations Center by telephone on January 4.

Soon after this notification occurred, further review by licensee physician authorized users who were familiar with the patient's anatomy reviewed the post-treatment scan and provided a different interpretation of the scan. Their evaluation determined that the image showed treatment of the correct segments of the liver, and therefore, the administration was as intended and in accordance with the written directive.

During the inspection, licensee staff described how the catheter would have had to slip several centimeters and move into another artery in order to treat segments 5 and 8, but that no movement of the catheter was observed. Because (1) the spot x-rays showed the catheter was properly placed to treat the correct segments, (2) there was no indication of movement of the catheter during the procedure, and (3) evaluation of the post-treatment SPECT-CT image by personnel familiar with the patient's anatomy indicated that the correct segments were treated, the licensee determined that no medical event occurred. Based on this, the licensee retracted its report of a medical event on January 14, 2019.

The licensee stated that the potential medical event was initially reported based on two factors. First, licensee staff believed that reporting was required no later than the next calendar day after occurrence of the medical event, rather than discovery of the medical event. Second, the initial evaluation of the post-treatment SPECT-CT scan was made using a software program; incorrect registration of the images resulted in an incorrect determination of the segments treated. In future cases, the licensee will conduct a more extensive process of discovery, including review by appropriate personnel, before determination of a reportable medical event.

2.3 Conclusions

The inspector had no findings concerning the events surrounding or following the potential medical event.

3 Reporting of Suspected Medical Event

3.1 Inspection Scope

The inspector reviewed notifications and reports concerning the suspected medical event by interviewing staff and reviewing the written report that the licensee provided to the NRC.

3.2 Observations and Findings

The licensee reported the potential medical event in accordance with 10 CFR 35.3045(c), which requires that the report be provided no later than the next calendar day after discovery of the medical event, based on the evaluation criteria

in 10 CFR 35.3045(a)(3), for a suspected dose to an organ or tissue other than the treatment site that exceeded 50 rem to an organ or tissue. The licensee provided this report telephonically to the NRC Operations Center the next calendar day after the event, January 4, 2019.

Title 10 CFR 35.3045(e) requires that the licensee contact the referring physician and the individual who is the subject of the medical event no later than 24 hours after its discovery. The licensee notified both the referring physician and the patient within 24 hours, the next day after the medical event, on January 4, 2019. Both were also notified of the retraction of the report on January 14, 2019.

Title 10 CFR 35.3045(d) requires the licensee to submit a written report to the NRC Region III office within 15 days after discovery of the event and specifies what information the report must include. The event occurred on January 3, 2019, and the NRC received the written report on January 17, 2019, within 15 days of the medical event. The inspector determined that the written report contained all required information.

3.3 Conclusions

The inspector had no findings concerning the notifications and report made by the licensee.

4 Review of Previous Violations

4.1 Inspection Scope

The inspector reviewed corrective actions for previously cited violations through interviewing licensee staff and reviewing records concerning the violations.

4.2 Observations and Findings

On October 20, 2017, the licensee was cited for a violation of 10 CFR 35.41(a) concerning the failure to implement its written procedure for Y-90 microsphere procedures, in that, during a procedure on August 18, 2017, licensee staff failed to prepare the patient for dose delivery by placing the infusion catheter into the proper treatment location, resulting in a medical event. In particular, licensee personnel placed the infusion catheter in an artery that resulted in delivering the dose to an improper treatment location.

As corrective action, the licensee committed to (1) revising its written procedure to require that the interventional radiologist (IR) to state during the “Time Out”, without prompting, the treatment site and artery catheterized instead of stating “yes” or “no” and to require the brachytherapist to confirm this information with the written directive; (2) reminding the IRs listed as approved physicians to review the patient plan just prior to beginning their preparation for the procedure; and (3) having IRs document the treatment site on their patient consent form and read it aloud during the Time Out. The inspector determined that the licensee has completed these corrective actions as described and the violation has not recurred. Based on this, the violation is closed.

On September 21, 2017, the licensee was cited for a violation of 10 CFR 35.3045(c) concerning the failure to notify the NRC Operations Center by telephone no later than the next calendar day after discovery of a medical event resulting from a Y-90 microsphere procedure performed on April 8, 2016. In particular, the licensee had sufficient information to recognize that this procedure met the definition of a medical event but did not recognize the medical event at the time or report it until January 2017.

As corrective action, the licensee committed to reporting Y-90 microsphere medical administration incidents as described in the medical event reporting section of current NRC guidance, if licensee staff have not observed a patient action which led to movement of the catheter tip. The inspector determined that the licensee has completed these corrective actions, as demonstrated by the reporting of the medical event described in Section 2 of this report, and the violation has not recurred. Based on this, the violation is closed.

4.3 Conclusions

Two violations concerning previous Y-90 microspheres medical events were closed.

5 Other Areas Inspected

5.1 Inspection Scope

The inspector reviewed the licensee's implementation of the radiation safety program as it pertained to Y-90 microspheres procedures performed at Barnes-Jewish Hospital in St. Louis, Missouri, through interviews with licensee staff, demonstrations of licensed activities, and documentation of ordering licensed materials, performance of patient treaments, and patient followup.

5.2 Observations and Findings

Licensee personnel at Barnes-Jewish Hospital performed around 150 to 200 Y-90 microspheres procedures annually. Three oncologists, three dosimetrists, and four physicists were involved in these procedures. Licensee staff described the planning and administration of these procedures, including, for example, performing nuclear medicine scans to evaluate shunting, preparation of written directives, spot x-ray imaging to verify placement of catheters, and use of post-treatment scans to verify placement. Review of written directives indicated no concern with treatments.

5.3 Conclusions

The inspector had no findings concerning the Y-90 microspheres program at Barnes-Jewish Hospital in St. Louis, Missouri.

6 Exit Meeting Summary

The NRC inspector presented preliminary inspection findings following the onsite inspection on January 10, 2019. 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

Michael Altmen, Physicist, Radiation Oncology
#^ Maxwell Amurao, Ph.D., Radiation Safety Officer
Bruce Backus, Assistant Vice Chancellor, Environmental Health and Safety
Andy Bierhals, Radiology Quality and Safety
Briana Davis, Health Physicist
Dan Gardina, M.D., Interventional Radiologist
Mike Harrod, Radiology Quality and Safety
Hyun Kim, M.D, Radiation Oncology, Authorized User
David Luechtefeld, Health Physicist
Sajid Omar Shaikh, Radiology Technical Manager

Attended preliminary exit meeting on January 10, 2019
^ Attended final exit meeting on April 5, 2019.

INSPECTION PROCEDURES USED

87103 – Materials Licensees Involved in an Incident or Bankruptcy Filing
87134 – Medical Broad-Scope Programs