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

June 11, 2018

EA-18-047
EN 53187
NMED No. 180063 (Closed)

Mr. Garrett Allen
Director of Oncology
Missouri Baptist Medical Center
3015 N. Ballas Road
St. Louis, MO 63131

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03008325/2018001(DNMS) – MISSOURI BAPTIST MEDICAL CENTER

Dear Mr. Allen:

On February 5, 2018, 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 May 14, 2018. The purpose of the inspection was to review the facts and circumstances of a medical event reported to the NRC on January 29, 2018. The in-office review included a review of the licensee's written report provided to the NRC concerning the medical event, as well as a review of the written report from a medical consultant contracted by the NRC to independently review the circumstances of the 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 licensee's failure to develop written procedures to provide high confidence that each administration is in accordance with the written directive, as required by Title 10 of the *Code of Federal Regulations* (CFR) 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. Edward Harvey 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 Mr. Thomas Moenster of your staff during a final telephonic exit meeting on May 16, 2018.

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 this inspection report within 30 days of the date of this letter; (2) request a Predecisional Enforcement Conference (PEC); or (3) choose not to respond because corrective actions for this violation are already established and implemented and have been communicated to the NRC. **Please contact 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. 03008325/2018001(DNMS); EA-18-047," 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. Your response should be sent to the NRC's Document Control Center, with a copy mailed to the NRC Region III Office, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532, within 30 days of the date of this letter. 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, the NRC will issue a press release to announce the time and date of the PEC. The PEC will be open to public observation.

Because your facility has not been the subject of escalated enforcement action within the last two inspections, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. In addition, please be advised that the number and characterization of any 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, 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/

John B. Giessner, Director
Division of Nuclear Materials Safety

Docket No. 030-08325
License No. 24-11128-02

Enclosure:
IR No. 03008325/2018001(DNMS)

cc w/encl: Thomas Moenster, RSO
State of Missouri

Letter to Mr. Garrett Allen from John Giessner, dated June 11, 2018

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03008325/2018001(DNMS) – MISSOURI BAPTIST MEDICAL CENTER

DISTRIBUTION w/encl:
Steven West
Darrell Roberts
Christine Lipa
Richard Skokowski
Kenneth Lambert
Paul Pelke
MIB Inspectors

ADAMS Accession Number: ML18162A137

OFFICE	RIII-DNMS		RIII-DNMS		RIII-EICS		RIII	
NAME	EHarvey:cl (via-e-mail)		AMcCraw		RSkokowski		JGiessner	
DATE	6/4/2018		6/5/2018		6/8/2018		6/11/2018	

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U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.:	030-08325
License No.:	24-11128-02
Report No.:	03008325/2018001(DNMS)
EA No./NMED No.:	EA-18-047 / 180063
Licensee:	Missouri Baptist Medical Center
Facility:	3015 N. Ballas Road St. Louis, MO 63131
Inspection Date:	February 5, 2018, with continued in-office review through May 14, 2018
Exit Meeting Date:	May 16, 2018
Inspector:	Edward Harvey, Health Physicist
Approved by:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Missouri Baptist Medical Center
NRC Inspection Report 03008325/2018001(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 29, 2018. The medical event occurred at Missouri Baptist Medical Center in St. Louis, Missouri, and involved the administration of a high dose-rate remote afterloader (HDR) brachytherapy treatment using a strut-adjusted volume implant (SAVI) applicator. Specifically, a misidentification of the struts on the applicator caused a higher-than-intended radiation dose to the skin surrounding the treatment site.

The inspector reviewed the facts and circumstances of the medical event and identified one apparent violation of 10 CFR 35.41(a)(2) for the licensee's failure to develop written procedures to provide high confidence that each administration requiring a written directive is performed in accordance with the written directive. The inspector determined that the root cause of the apparent violation was that the licensee's written procedures did not include adequate verifications to ensure that no errors were made during the treatment planning process. As such, the misidentification of the struts was not identified prior to the administration.

As corrective action to prevent recurrence, the licensee (1) updated its HDR policy to require a second physicist or physician to independently check and verify the identification of the catheter struts in the treatment planning system on February 1, 2018; (2) designed and added an HDR Plan Review checklist to include the second independent review of the HDR treatment plan, including the digitization of the catheter(s)/struts; (3) added the HDR Plan Review to the departmental quality monitoring program (QMP) audit; and (4) trained the physicists and radiation oncology physicians on the revised procedures on February 2, 2018, prior to any subsequent HDR treatments.

The NRC contracted the services of a medical consultant to review the facts and circumstances of this medical event. The medical consultant concluded that there have been no deterministic effects observed as of two months following the incident and that there is a small risk for late toxicity (e.g., subcutaneous fibrosis and scarring). The medical consultant agreed with the licensee's assessment of: (1) cause; (2) effect on the patient; (3) immediate action on discovery; and (4) corrective actions to prevent recurrence.

REPORT DETAILS

1.0 Program Overview

Missouri Baptist Medical Center (licensee) is authorized under NRC Materials License No. 24-11128-02 to use byproduct material for diagnostic and therapeutic medical procedures. Among these procedures, the licensee performs brachytherapy treatments using an HDR unit at its main hospital location in St. Louis, Missouri. The purpose of this announced reactive inspection was to review the facts and circumstances surrounding a medical event that occurred during an HDR treatment on January 29, 2018.

The NRC last conducted a routine inspection of this licensee on January 9 and 10, 2017, with no violations identified this inspection. The previous inspection was performed on December 17 and 18, 2014, which resulted in the NRC's use of enforcement discretion to disposition a Severity Level IV violation of 10 CFR 30.3(c)(2) for unauthorized possession of radium as a non-cited violation (NCV) in accordance with Enforcement Guidance Memorandum 09-004, "Interim Guidance for Dispositioning of Naturally Occurring and Accelerator Produced Radioactive Materials (NARM) Requirements."

2.0 Sequence of Events and Event Assessment

2.1 Inspection Scope

On February 5, 2018, an NRC inspector performed a reactive inspection at the licensee's facility in St. Louis, Missouri. The inspector interviewed licensee staff and management personnel concerning the medical event that occurred on January 29, 2018, and reviewed pertinent documentation related to the treatment.

2.2 Observations and Findings

On January 29, 2018, the licensee performed an HDR treatment to a patient's left breast using a SAVI applicator. This particular treatment was the first of ten fractions, and there were no apparent complications identified during the administration.

Following the delivery of the first fraction, a medical physicist employed by the licensee noticed an abnormality in the dwell times within the struts of the SAVI applicator during a review of the post-treatment report. The physicist then compared the post-treatment report to the initial treatment plan, which was performed on January 26, 2018, and discovered that the dwell times and positions in the post-treatment report did not correlate to those in the treatment plan.

After further investigation, the licensee discovered that two of the seven struts on the SAVI applicator were misidentified during the three-dimensional treatment planning process that took place on January 26, 2018. This error caused the digital orientation of the applicator recognized by the treatment planning software to differ from the physical orientation of the applicator within the patient's left breast. As a result, the higher dwell times intended to deliver a higher dose to the treatment site were shifted such that a higher dose was delivered to the patient's surrounding skin tissue.

The licensee calculated that the patient received 190 centigray (cGy) of the prescribed 340 cGy dose, which equates to approximately 56 percent of the prescribed dose. The licensee also calculated that the surrounding skin tissue received doses from 850 cGy to 1,899 cGy to volumes ranging from 1 cubic centimeter (cc) to 0.03 cc, respectively. The intended maximum skin dose to the patient should not have exceeded 425 cGy, per the treatment plan. The licensee determined that this incident is therefore reportable to the NRC as a medical event under 10 CFR 35.3045(a)(3) because the dose to the skin exceeded both 0.5 Sieverts (Sv) and 50 percent or more of the dose expected from the administration as defined in the written directive. The licensee identified the error after the first of 10 planned fractions. The licensee aborted the remainder of the procedure after the discovery of the error.

The licensee conducted an extent of condition review and determined that no other HDR administrations involving a SAVI applicator included a similar error. The licensee determined, and the inspector agreed, that the cause of the medical event was operator error in the labeling of the struts during catheter reconstruction in the treatment planning software. As a root cause of the medical event, the inspector determined that the licensee's written procedures did not include adequate verifications to ensure that no errors were made during the treatment planning process, preventing the error from being identified prior to administration. As such, the inspector identified an apparent violation of 10 CFR 35.41(a)(2) for the licensee's failure to develop written procedures to provide high confidence that each administration requiring a written directive is performed in accordance with the written directive. Although the licensee did not identify any additional errors during its extent of condition review, the inspector determined that the apparent violation was of a programmatic nature because, until the licensee took corrective action, the potential existed for other similar errors to occur.

As corrective action to prevent recurrence of a similar medical event and apparent violation, the licensee: (1) updated their HDR policy to require a second physicist or physician to independently check and verify the identification of the catheter struts in the treatment planning system on February 1, 2018; (2) designed and added an HDR Plan Review checklist to include the second independent review of the HDR treatment plan, including the digitization of the catheter(s)/struts; (3) added the HDR Plan Review to the departmental quality monitoring program (QMP) audit; and (4) trained the physicists and radiation oncology physicians on the revised procedures on February 2, prior to any subsequent HDR treatments.

2.3 Conclusions

The inspector found the licensee's response to and assessment of the medical event to be adequate. The inspector identified one apparent violation of 10 CFR 35.41(a)(2) for the licensee's failure to develop written procedures to provide high confidence that each administration requiring a written directive is performed in accordance with the written directive. The licensee took prompt and appropriate corrective action to prevent recurrence of a similar medical event and apparent violation.

3.0 Licensee Notifications

3.1 Inspection Scope

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

3.2 Observations and Findings

The licensee discovered that the HDR brachytherapy treatment resulted in a medical event in January 29, 2018, and subsequently notified the NRC Headquarters Operations Center on the same day. This met the requirement to report the medical event to the NRC by no later than the next calendar day after discovery, in accordance with 10 CFR 35.3045(c).

In addition, the licensee notified the patient and the patient's referring physician of the medical event the same day of discovery. This met the 24-hour reporting requirement described under 10 CFR 35.3045(e).

The NRC received the licensee's written report on February 8, 2018. The licensee's written report was received within 15 days of the discovery of the medical event, as required by 10 CFR 35.3045(c). The inspector reviewed the report and determined that it contained all the required information. A copy of the licensee's written report can be found in the NRC's Agencywide Document Access and Management System (ADAMS) using Accession Number ML18116A585.

3.3 Conclusions

The inspector determined that the licensee made all required notifications in a timely manner.

4.0 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 April 19, 2018.

4.2 Observations and Findings

The medical consultant concluded that there have been no deterministic effects observed as of two months following the incident and that there is a small risk for late toxicity (e.g., subcutaneous fibrosis and scarring). The medical consultant agreed with the licensee's assessment of: (1) cause; (2) effect on the patient; (3) immediate action on discovery; and (4) corrective actions to prevent recurrence. A copy of the medical consultant's report can be found in ADAMS using Accession Number ML18110A675.

4.3 Conclusions

The NRC's medical consultant agreed with the licensee's assessment of the medical event and determined that that there is a small risk for late toxicity (e.g., subcutaneous fibrosis and scarring).

5.0 Exit Meeting Summary

The inspector conducted a final exit meeting by telephone with the licensee's radiation safety officer (RSO) to present the inspection findings on May 16, 2018. The licensee acknowledged the findings presented.

LIST OF PERSONNEL CONTACTED

Garrett Allen, Director of Oncology
Amy Ettling, Medical Physicist
Nancy Kimmel, Director of Quality & Patient Safety
Kara Mirian, Patient Safety/Regulatory Manger
Thomas Moenster, RSO
David Nelson, Medical Physicist
Tony Pixton, Medical Physicist
Mary Wojcik, Radiation Oncology Manager

Participated in final, telephonic exit meeting on May 16, 2018.

INSPECTION PROCEDURES USED

87103: Inspection of Nuclear Material Licensees Involved in an Incident or Bankruptcy Filing

87132: Brachytherapy Programs