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

July 12, 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: NOTICE OF VIOLATION; NRC REACTIVE INSPECTION REPORT NO. 03008325/2018001(DNMS) - MISSOURI BAPTIST MEDICAL CENTER

Dear Mr. Allen:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) reactive inspection conducted on February 5, 2018, at your St. Louis, Missouri, facility 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. During the inspection, an apparent violation of NRC requirements was identified. The circumstances surrounding this apparent violation, the significance of the issue, and the need for lasting and effective corrective actions were discussed with Mr. Thomas Moenster, of your staff, during a telephone exit meeting on May 16, 2018. Details regarding the apparent violation were provided in NRC Inspection Report No. 03008325/2018001(DNMS), dated June 11, 2018. The inspection report can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at Accession Number ML18162A137. ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation identified in the report before we made a final enforcement decision by: (1) attending a predecisional enforcement conference (PEC); (2) providing a written response; or (3) not providing a written response because the corrective actions were already communicated to the NRC. In a telephone call with Mr. Aaron McCraw, of my staff, on June 22, 2018, you indicated that you declined to attend a PEC or provide a written response.

Based on the information developed during the inspection and the information that was provided in the written medical event report, dated February 8, 2018, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation involved the failure to develop a procedure to provide high confidence that an administration of iridium-192 in a high dose-rate remote afterloader (HDR) was in accordance with the written directive. Specifically, written procedures did not include a verification that the treatment plan would deliver the dose specified by the written directive.

The failure to have procedures that provide high confidence that administrations are in accordance with the written directive is of concern to the NRC because of the potential for a patient to have received a dose to an unintended location without anyone being aware of the event, as well as the potential for the intended treatment site not being treated as prescribed in the written directive. In this case, had an authorized medical physicist not recognized the dwell time abnormality, the event may not have been detected. The root cause of the medical event was that written procedures did not include verifications to ensure that no errors were made during the treatment planning process. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III. In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of $7,250 is considered for a Severity Level III violation. The NRC also includes significant enforcement actions on its Web site at http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/.

Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for Corrective Action in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. Corrective actions included: (1) revising the HDR Policy to require a second physicist or physician to independently check and verify the identification of the catheter strut in the treatment planning system; (2) designing an HDR Plan Review checklist to include a second independent review of the HDR treatment plan; (3) adding the HDR plan review to the departmental monthly quality management program (QMP) audit; and (4) training the physicists and radiation oncology physicians on February 2, 2018, on the updated HDR policy, the HDR Plan Review check list, the QMP and the QMP audit tool. Based on these corrective actions, credit for Corrective Action is warranted. Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 03008325/2018001(DNMS), and your written medical event report, dated February 28, 2018. Therefore, you are not required to respond to this letter 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, you should follow the instructions specified in the enclosed Notice.

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 any, will be made available electronically for public inspection in ADAMS, To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion

of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information.

Sincerely,

/RA/

K. Steven West
Regional Administrator

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

Enclosure:
Notice of Violation

cc: State of Missouri

Letter to G. Allen from K. Steven West dated July 12, 2018

SUBJECT: NOTICE OF VIOLATION; NRC REACTIVE INSPECTION REPORT NO. 03008325/2018001(DNMS) - MISSOURI BAPTIST MEDICAL CENTER

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SEE PREVIOUS CONCURRENCE

OFC	RIII/EICS	RIII/DNMS	RIII/DNMS	OE	RIII/EICS	RIII/ORA
NAME	KLambert:jc	AMcCraw	JGiessner CAL for	ABoland[1]	RSkokowski	KWest
DATE	6/29/18	7/2/18	7/2/18	7/3/18	7/10/18	7/12/18

OFFICIAL RECORD COPY

[1] OE Concurrence by e-mail from L. Sreenivas dated July 3, 2018

NOTICE OF VIOLATION

Missouri Baptist Medical Center
St. Louis, Missouri

Docket No. 030-08325
License No. 24-11128-02
EA-18-047

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on February 5, 2018, with continued in-office review through May 14, 2018, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> Title 10 of the *Code of Federal Regulations* (CFR) 35.41(a)(2) requires that for each 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.
>
> Title 10 CFR 35.41(b)(2) requires, in part, that the procedures required by paragraph (a) of this section must address verifying that the administration is in accordance with the treatment plan and the written directive.
>
> Contrary to the above, as of January 29, 2018, the licensee failed to develop, implement, and maintain procedures to provide high confidence that an administration requiring a written directive was performed in accordance with the written directive. Specifically, the licensee's procedures for administrations using a high dose-rate remote afterloader (HDR) unit did not include a verification that the treatment plan would deliver the dose specified by the written directive.

This is a Severity Level III violation (Section 6.3).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03008325/2018001(DNMS) and the licensee's written medical event report, dated February 22, 2018. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-18-047," 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, 2443 Warrenville Road, Lisle, IL 60532 within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 12th day of July 2018