December 16, 2010

EA-10-239
NMED No: 080548 (CLOSED)

Mr. Doug Black, Vice President
Operations
Missouri Baptist Medical Center
3015 North Ballas Road
St. Louis, MO 63131

SUBJECT: NRC INSPECTION REPORT 030-08325/2010-001 (DNMS)
AND NOTICE OF VIOLATION - MISSOURI BAPTIST MEDICAL CENTER

Dear Mr. Black:

On November 1 through 17, 2010, the U.S. Nuclear Regulatory Commission (NRC) inspector conducted a routine inspection at the Missouri Baptist Medical Center. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. The inspection included a review of the circumstances surrounding the loss of an iodine-125 seed that your institution reported to us on September 5, 2008, with a follow up letter dated October 10, 2008. Our inspection also included a review of additional information you provided on November 17, 2010, concerning your corrective actions. The findings were discussed with you and members of your staff during a telephonic exit meeting on November 17.

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, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violations are cited in the enclosed Notice of Violation (Notice) and involve the loss of one iodine-125 seed that occurred on August 14, 2008, and the failure to report the lost seed.

The violations are being cited in the Notice because lost sources are of concern to the NRC and the NRC continues to emphasize the importance of maintaining control of all licensed material. The NRC also wants to emphasize the importance of reporting incidents to our agency in the required time-frame specified our regulations.

Upon completion of a prostate implant procedure on August 14, 2008, your staff could not account for one iodine-125 seed. A quantity of 100 seeds was ordered for the procedure; 94 seeds were to be implanted into the patient with six extra seeds. During the implant one

seed became jammed and was removed and replaced with another seed. At the conclusion of the implant, the authorized user left the operating room (OR) and it is uncertain if a personnel survey was performed. The staff surveyed the patient and the operating room and found no missing/dropped seeds. The staff transported the wings (containing the extra seeds) and associated equipment to the hot lab for inventory. The staff expected six seeds, five of the "extra" seeds that were not used and the jammed seed; however, the final seed count only identified five seeds.

Once the staff determined that one seed was missing, the staff returned to the operating room in attempt to perform surveys to locate the seed. However, the operating room had been decontaminated by housekeeping; it is unknown how many individuals entered the operating room during this time. The staff's surveys of the operating room did not locate the missing seed. Patient radiographs were taken and the staff counted the seeds on the radiographs; the staff determined that 94 seeds could be seen on the images. At this point, the staff concluded that the unaccounted seed was lost and most likely disposed in a metal container (located in the OR) as waste.

According to your radiation safety officer, the physics staff forgot to inform him of the missing seed. On Friday, September 12, 2008, a patient provided the lead physicist a newspaper article discussing another NRC licensee that had been fined for losing I-125 seeds. The physicist recalled that their department recently lost an I-125 seed. He informed the Radiation Safety Officer (RSO) of the incident on Monday, September 15, 2008. The RSO notified the NRC by telephone the same day.

On September 30, 2008, your staff convened a special Radiation Safety Committee meeting to review the incident and discuss your corrective actions. Your corrective actions included revising your departmental procedures to require an immediate source inventory in the operating room at the completion of an implant. The policy required surveys of the operating room to be performed immediately when a source/seed is suspected to be missing, including isolating the room so that surveys could be conducted to locate any missing seeds. The procedure also included instruction on the reporting and timeliness requirements for lost/missing licensed material. The RSO's name and phone number was included in the procedure for reference by the medical physics staff.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken to correct the violations and prevent recurrence are already adequately addressed on the docket in this letter and in your letter dated October 10, 2008. 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, 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 you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from 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. 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.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

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

Enclosure:
Notice of Violation

cc w/encl: State of MO

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Materials Inspection Branch
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Enclosure:
Notice of Violation

cc w/encl: State of MO

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NOTICE OF VIOLATION

Missouri Baptist Medical Center
St. Louis, Missouri

Docket No.: 030-08325
License No.: 24-11128-02
EA-10-239

During an NRC inspection conducted on November 1 through 17, 2010, violations of NRC requirements were identified. In accordance with the Enforcement Policy, the violations are listed below:

A. Title 10 of the Code of Federal Regulations (CFR) 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Contrary to the above, on August 14, 2008, the licensee did not control one seed containing iodine-125 located a surgical suite, which is a controlled area. Specifically, the licensee lost the iodine-125 seed during a patient implant procedure and cannot account for the seed.

This is a Severity Level IV Violation (Section 6.2).

B. 10 CFR 20.2201(a)(ii), requires that each licensee shall report by telephone within 30 days of the occurrence of any lost, stolen or missing licensed material becomes known to the licensee, any licensed material in a quantity greater than 10 times the quantity specified in Appendix C to Part 20. The Appendix C quantity for iodine-125 is 1 microcurie.

Contrary to the above, the licensee failed to report by telephone, within 30 days of the occurrence of a lost source, containing licensed material in a quantity greater than 10 times the quantity specified in Appendix C to Part 20, which became known to the licensee on August 14, 2008. Specifically, the licensee did not report the lost of an iodine-125 seed until September 15, 2008, 32 days following the occurrence of the lost source.

This is a Severity Level IV Violation (Section 6.2).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in this letter and in your letter dated October 10, 2008. 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-10-239), 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 the letter transmitting this Notice of Violation (Notice)."

Enclosure

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from 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. 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.

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

Dated this 16th day of December 2010