INSPECTION RECORD

Region: III **Inspection Report No.** 2014001 **License No.** 24-11128-02
Docket No. 030-08325

Licensee: Missouri Baptist Medical Center
3015 North Ballas Road
St. Louis, MO 63131

Locations Inspected: All four authorized addresses

Licensee Contact: Thomas Moenster, RSO **Telephone No**. 314-996-5397

Program Code: 02230 **Priority**: 2

Type of Inspection: ( ) Initial (X) Routine ( ) Announced
( ) Special (X) Unannounced

Last Inspection Date: 04/18/2013 **Date of This Inspection**: December 17 and 18, 2014 with in-office review through March 12, 2015. Exited on April 7, 2015.

Next Inspection Date: 12/18/2016 (X) Normal ( ) Reduced

Justification for reducing the routine inspection interval: N/A

Summary of Findings and Actions:

(X) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
( ) Non-cited violations (NCVs)
( ) Violation(s), Form 591 issued
( ) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspector(s) Geoffrey Warren, Senior Health Physicist

/RA/ Date ***04/10/2015***
Signature

Approved Aaron T. McCraw, Chief, MIB

/RA/ Date: ***04/15/2015***
Signature

PART I - LICENSE, INSPECTION, INCIDENT/EVENT AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
83	Aug. 2014	Renewed license
82	June 2014	Added authorized user
81	Jan. 2014	Added authorization for Cs-131 seeds for permanent implants
80	March 2013	Changed room numbers for authorized site
79	Dec. 2012	Corrected street address for one location
78	Oct. 2012	Added and removed authorized users

2. INSPECTION AND ENFORCEMENT HISTORY:

The last inspection of this licensee was on April 18, 2014. This limited inspection closed a Severity Level III violation from the previous inspection, conducted October 18 and 19, 2013. The violation concerned the licensee's inadequate procedure for radiopharmaceutical therapies performed in radiation oncology.

3. INCIDENT/EVENT HISTORY:

No open items or events since the last routine inspection.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Missouri Baptist Medical Center, a 489-bed hospital, is authorized under NRC Materials License No. 24-11128-02 to use licensed material for medical purposes at facilities in St. Louis, Missouri. The licensee employed nine nuclear medicine technologists at four nuclear medicine areas, including the main nuclear medicine area, a nuclear cardiology laboratory, a positron emission tomography and computed tomography (PET/CT) laboratory, and an outpatient cardiology clinic. At the main nuclear medicine area, licensee technologists performed treatments for hyperthyroidism and a wide range of diagnostic procedures.

The radiation oncology department was staffed with one radiation oncologist, two physicists, and two dosimetrists who performed therapeutic treatments using licensed materials. The oncology staff performed radiopharmaceutical treatments, treatments using a high dose rate remote afterloader system (HDR), and permanent prostate implant procedures.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87131 and 87132

Focus Areas Evaluated: 03.01 – 03.08; 03.01 – 03.08

The inspector toured all nuclear medicine areas and radiation oncology, the ward where in-house oncology patients are housed, the long-term waste storage facility, and other areas. The inspector observed one therapeutic administration and five diagnostic administrations of unsealed licensed materials, including dose preparation and disposal, as well as package receipts surveys. Licensee personnel demonstrated dose calibrator constancy, wipe counter and survey meter QC, daily and weekly contamination surveys, and daily checks of the HDR unit; and described a variety of diagnostic procedures, waste handling and disposal, preparation and use of written directives, and other procedures. The inspector noted no concerns with these activities.

The inspector reviewed written directives for radiopharmaceutical therapies in nuclear medicine and radiation oncology, HDR treatments, and permanent implant brachytherapy procedures, and identified no concerns. In addition, the inspector reviewed a selection of licensee records for radiation safety committee meetings, inventories, leak tests, audits, dosimetry, public dose assessment, and training materials. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of dosimetry information indicated no exposures of regulatory concern.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspector conducted independent and confirmatory surveys in each of the areas inspected. The inspector found no readings which would indicate residual contamination or exposures to members of the public in excess of regulatory limits. Readings were consistent with licensee inspection records and postings.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

During a tour of the licensee's long-term waste storage area, the RSO pointed out a box that he stated was contaminated with radium-226. The box was sealed in multiple layers of plastic bags. The RSO stated that the box had been previously used to store radium needles, but that it had not been disposed when the radium needles were disposed. He further stated that the contamination was centered around the hinges for the box, and that the box had been in the waste storage area for decades.

The inspector noted that the licensee was not authorized to possess radium-226 in any form, and had not requested the material be added to the license as of the time of the onsite inspection. The licensee's possession of such material is a violation of 10 CFR 30.3(c)(2), which requires that all licensees who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for which a license amendment is required to authorize the activities may continue to use these materials until the date of the NRC's final licensing determination, provided that the person submits an amendment request within six months of the waiver expiration. For the State of Missouri, the waiver expired on September 30, 2008, so any amendment request would be required no later than March 30, 2009.

The licensee had submitted a request to add the PET/CT clinic as a location of use at the hospital within the required time period, but had not considered that they also needed to add this radium-contaminated box to the license. The inspector notified the licensee's RSO that the box must be added to the license on February 23, 2015. As corrective actions to restore compliance and to prevent recurrence, the licensee

submitted an amendment request dated March 5, 2015, to add the authorization to the license. The NRC received the request on March 11, 2015.

The licensee's failure to submit an amendment request to the NRC by March 30, 2009, to add the box contaminated with radium-226 is a violation of 10 CFR 30.3(c)(2). Because (1) this was the first occurrence of a violation of this requirement by the licensee after the termination date of the waiver, (2) the failure to add this material to the license did not result in any safety or health consequence, (3) the failure was not willful, (4) the explanation that the licensee had not considered that this material required authorization on the license appears to be reasonable, and (5) the licensee submitted an amendment request within 30 days after the RSO was notified that such an amendment was required, the NRC is using discretion to disposition this violation 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." However, any future violations of 10 CFR 30.3(c)(2) will be categorized as cited violations and evaluated as such.

5. PARTIAL LIST OF PERSONNEL CONTACTED:

Victoria M. Jackson, Manager, Patient Safety and Regulatory Compliance
Thomas J. Moenster, RSO

Attended preliminary exit meeting on December 18, 2014

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