INSPECTION RECORD

Region: III **Inspection Report No.** 2018002 **License No.** 24-11128-02
Docket No. 030-08325

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

Locations Inspected: Same as above

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: January 9-10, 2017 **Date of This Inspection**: October 9-10, 2018

Next Inspection Date: October 9, 2020 (X) Normal ( ) Reduced

Summary of Findings and Actions:

( ) 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
(X) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspector: Zahid Sulaiman, Health Physicist

/RA/ Date ***11/06/2018***
Signature

Approved: Aaron T. McCraw, Chief, MIB

/RA/ Date: ***11/09/2018***
Signature

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
88	08/8/2017	added and/or deleted and/or modified other areas of use in the course of remodeling work.
89	11/15/2017	added four authorized users
90	3/28/2018	added new authorization for Y-90 microspheres program

2. INSPECTION AND ENFORCEMENT HISTORY:

The last routine inspection of this licensee was on January 9 and 10, 2017. No violations of NRC requirements were identified. The last inspection of this licensee was a reactive inspection conducted on February 5, 2018, to review the facts and circumstances of the event described below.

3. INCIDENT/EVENT HISTORY:

There was one medical event reported to the 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 identified a Severity Level III violation of Title 10 *Code of Federal Regulations* (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.

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Missouri Baptist Medical Center is authorized under NRC Materials License No. 24-11128-02 to use licensed material permitted by 10 CFR Sections 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000. The licensee was a 480-bed hospital. The nuclear medicine department was staffed with seven full-time and a part-time nuclear medicine technologists (NMTs), and three PRNs at four nuclear medicine areas: the main hospital, the cardiovascular diagnostic center, the outpatient cardiology center, and the PET clinic. The licensee performed approximately 600+ diagnostic nuclear medicine procedures monthly, primarily cardiac stress tests, lung scans using xenon-133, HIDA, gastric emptying, bone scans, gall bladder, renal, and PET imaging using flourine-18 (F-18). The licensee performed approximately 12 radium-223 (Ra-223) dichloride administrations, and 60 iodine-131 (I -131) hyperthyroid and cancer therapy treatments annually. The licensee received unit doses, bulk technetium-99m (Tc-99m), and I-131 in capsule form from a licensed radiopharmacy. The licensee consultant physicist conducted radiation safety program audits on a quarterly basis.

The radiation oncology department located at the main hospital was staffed with two oncologists, two authorized medical physicists (AMPs), and two dosimetrists. The licensee conducted approximately 10 HDR treatments per month, primarily gynecological and breast cancer treatments. The HDR source was exchanged every four months, with the most recent source exchanged on October 1, 2018. The licensee also performed approximately two manual brachytherapy procedures using iodine-125 (I-125) prostate seed implants annually. The licensee started its yttrium-90 (Y-90) microspheres program on May 9, 2018. The licensee performed nine Y-90 patient treatments as of October 9, 2018.

2. SCOPE OF INSPECTION:

Inspection Procedures Used: 87131 and 87132

Focus Areas Evaluated: All

The inspector observed that licensed radioactive materials were properly secured from unauthorized access. The inspector toured the licensee's the nuclear medicine, PET/CT clinic, and oncology departments. The inspector observed administration of Tc-99m doses to a patient for cardiac stress test, and F-18 for PET studies, with no issue noted. Interviews conducted with licensee staffs revealed an adequate level of understanding of radiation safety practices and emergency procedures. Nuclear medicine staff discussed and demonstrated to the inspector: (1) dose calibrator daily constancy checks; (2) radioactive material package receiving and check-in procedures, how the package was surveyed and the wipe test was counted; (3) end of the day area surveys; (4) weekly wipe surveys; and (5) radioactive material spill and waste disposal procedures. The inspectors observed nuclear medicine staff properly handle radioactive waste for decay-in-storage. The inspector had the NMT demonstrate the Y-90 dose preparation procedures, completion of dose preparation worksheet, and pre and post treatment survey procedures.

The inspector had the AMP demonstrate the HDR's: (1) security of licensed material; (2) daily spot checks; (3) emergency equipment and procedures; (4) safety procedures and instructions; (5) door interlock system; and (6) radiation monitoring equipment. The inspector reviewed five HDR, three manual brachytherapy, twelve I-131 therapy, and three Y-90 written directives, and pre- and post-treatment plans, with no issue noted.

The inspector reviewed the following records: radiation safety committee minutes, quarterly program audits conducted by an outside consultant, package receipts, waste disposal records, DOT Hazmat training, linearity and accuracy of the dose calibrator, and sealed source inventory and leak tests. The inspector reviewed the dosimetry records for 2017, and through July 31, 2018, indicating the maximum annual dose to be 333 mrem - DDE; and 2355 mrem - SDE. The inspector also reviewed the dosimetry records of two declared pregnant workers since the last inspection.

The inspector reviewed the licensee's corrective action to a SL III violation of 10 CFR 35.41 (a)(2) (Inspection Report No. 2018001) for 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 reviewed and verified the following licensee's corrective actions: (1) implemented new hospital policy for HDR program, requiring "a second check be performed by AMP or oncologist to review the HDR treatment plan", (2) created a HDR – plan review checklist to include a second independent review of the treatment plan, (3) added QMP monthly plan review to monthly audit, and (4) AMP and oncologist training completed on February 2, 2018. The inspector closed the inspection finding

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Using a Thermo Scientific RadEye detector calibrated on July 30, 2018, the inspector conducted independent surveys at each areas inspected. The inspector found no readings which would indicate residual contamination or exposures to members of the public in excess of regulatory limits.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

Title 10 CFR 35.92 requires that a licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if it monitors at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

During the inspection, the inspector identified a SL IV violation of 10 CFR 35.92, an unauthorized disposal of radioactive material sealed sources with a half-life greater than 120 days into normal trash. Specifically, On May 12, 2014, the licensee disposed of two ADAC gadolinium-153 (Gd-153) (North American Scientific, Inc., Model 3601) sources with a half-life of 240.4 days into the normal trash. The two Gd-153 sealed sources with a nominal activity of 250 mCi, each calibrated on August 1, 1998, were in storage for approximately 16 years prior to the disposal. The licensee conducted a survey at the surface with a GM survey meter, and the reading was at background. The wipe test result of the sources showed no detectable removable activity. The licensee calculated a residual activity of 0.015 microcuries at the time of disposal. The licensee removed the plastic radioactive symbol on the sources and disposed of them in the normal trash.

The inspector determined that the root cause of the violation was that the licensee was unaware that the decay-in-storage requirements were limited only to isotopes with a half-life less than 120 days. The licensee thought that the requirement for disposal of materials into a normal trash is that if the materials decayed over 10 half-lives and if the surveys result shows background reading. As corrective actions to restore compliance and to prevent recurrence, the licensee committed that any source with a half-life greater than 120 days, will be returned to the vendor or transferred to an authorized broker for proper disposal.

5. PERSONNEL CONTACTED:

Nancy Kimmel	Director, Quality and Patient Safety
Michelle Onder	Director, Diagnostic Services
Allen Garret	Director, Oncology Department
Zehra Kujundzic	Manager, Radiology
Amy Ettling	Authorized Medical Physicist
David Nelson	Authorized Medical Physicist
Mary Wojick	Manager, Radiation Oncology
Thomas Moenster#	Radiation Safety Officer

Attended exit meeting on November 1, 2018.

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