

(07-2012)
10 CFR 2.201

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

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

REPORT NUMBER(S) 2017001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Rd, Suite 210
Lisle, IL 60532

3. DOCKET NUMBER(S)

030-08325

4. LICENSE NUMBER(S)

24-11128-02

5. DATE(S) OF INSPECTION

January 9 & 10, 2017

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- ☒ 1. Based on the inspection findings, no violations were identified.
- ☒ 2. Previous violation(s) closed. *IR 2014001*
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

_____ Non-cited violation(s) were discussed involving the following requirement(s):

- ☐ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Zahid Sulaiman, Health Physicist	<i>Zahid Sulaiman</i>	1/10/2017
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB	<i>[Signature]</i>	2/3/17

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Docket File Information

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3. DOCKET NUMBER(S) 030-08325	4. LICENSE NUMBER(S) 24-11128-02	5. DATE(S) OF INSPECTION January 9 & 10, 2017	
6. INSPECTION PROCEDURES USED 87130, 87131 & 87132	7. INSPECTION FOCUS AREAS 03.01-03.07		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02230	2. PRIORITY 2	3. LICENSEE CONTACT Thomas Moenster, RSO	4. TELEPHONE NUMBER (314) 996-5397
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☒ Main Office Inspection Next Inspection Date: 01/09/2019

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine inspection of a 480-bed hospital authorized to use licensed materials under 10 CFR 35.100, 35.200, 35.300, 35.400, and 35.600. The licensee employed six full-time nuclear medicine technologists (NMTs), two PRNs, and one part-time NMT at four nuclear medicine areas; main hospital nuclear medicine department, PET/CT clinic, cardiovascular diagnostic center, and outpatient cardiology clinic. The licensee performed approximately 600+ diagnostic nuclear medicine procedures monthly, primarily cardiac stress tests, lung scans using Xe-133, HIDA, gastric emptying, bone scans, gall bladder, renal, and PET imaging using F-18. The licensee received unit doses, bulk Tc-99m, and I-131 in capsule form from a licensed radiopharmacy. The licensee performed approximately 6 Ra-223 Xofigo, and 60 iodine-131 (I-131) hyperthyroid and cancer therapy treatments annually. The licensee consultant physicist conducted the 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 (AMP), and two dosimetrists. The licensee conducted approximately 30 high dose-rate brachytherapy (HDR) treatments per month, primarily gynecological and some bronchial and breast cancer treatments. The HDR sources were exchanged every four months, with the most recent source exchanged on October 5, 2016. The licensee also performed approximately 2 manual brachytherapy procedures using I-125 for prostate seed implants annually. The licensee planned to move the PET/CT clinic from 3023 N Ballas Rd to the main hospital at 3015 N Ballas Rd, next to the main hospital nuclear medicine department by April 2017. The licensee was in the process of submitting the license amendment request to the NRC.

Performance Observations:

The inspection consisted of interviews with select licensee personnel; review of select records; and tours of the nuclear medicine, PET/CT clinic, and oncology department. The inspector observed administration of Tc-99 doses to a patient for cardiac stress test, and F-18 for PET/CT studies. The inspector also observed one HDR treatment procedure to a patient, with no issue noted. The inspector: (1) observed the NMT conduct a physical inventory of sealed sources, and all sources were accounted for; (2) had the NMT demonstrate the dose calibrator constancy check, package receiving and check-in procedures, the end of the day daily area surveys, and proper handling of radioactive waste and disposal procedures. The inspector had the AMP demonstrate the HDR unit's: (1) security of licensed material;

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(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 6 HDR, 3 manual brachytherapy, and 15 I-131 therapy written directives and treatment plans.

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 leak tests. The inspector reviewed the dosimetry records for 2015, and till September 31, 2016 indicating the maximum annual dose to be 528 mrem - DDE; and 2470 mrem - SDE. The inspector also reviewed the dosimetry records of three declared pregnant workers since the last inspection and observed one pregnant worker wearing the fetal badge properly.

The inspector reviewed the licensee's corrective action to one non-cited violation of 10 CFR 30.3(c)(2) for failure to obtain a license amendment to possess radium-226. The inspector verified the licensee's corrective action, determined that the license was amended to add the authorization for radium-226, and closed the violation. The inspector also reviewed the disposal record dated June 11, 2015, of a box contaminated with radium-226 that was properly disposed to an authorized vendor.

In addition, the inspector followed up on the NMED event #130599, pertaining to the licensee's receipt of an unlabeled package that contained two (50 uCi) Co-57 spot markers and the licensee determined that the radiation reading outside the package was 1 mR/hr. The inspector reviewed the package receipt procedures and the licensee's corrective actions. Based on these observations, the event is closed.

No violations of NRC requirements were identified during this inspection.