

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Memorial Hospital
615 North Michigan Street
South Bend, IN 46601

REPORT NUMBER(S) 2014-001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-17335

4. LICENSE NUMBER(S)

13-18881-01

5. DATE(S) OF INSPECTION

JULY 9-11, 2014

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:

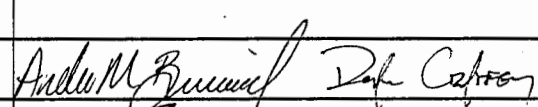
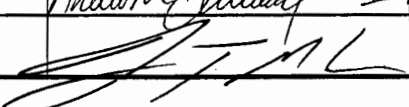
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☒ 2. Previous violation(s) closed. 12 03017335 / 2012001 (DNMS)
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, 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	Andrew Bramnik / Ryan Craffey		7/11/14
BRANCH CHIEF	Aaron McCraw		7/21/14

Docket File Information

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3. DOCKET NUMBER(S) 030-17335	4. LICENSE NUMBER(S) 13-18881-01	5. DATE(S) OF INSPECTION July 9-11, 2014
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6. INSPECTION PROCEDURES USED 87131, 87132	7. INSPECTION FOCUS AREAS All
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02240	2. PRIORITY 2	3. LICENSEE CONTACT Dan Archambeault, MS - RSO	4. TELEPHONE NUMBER (574) 647-7956
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- ☒ Main Office Inspection Next Inspection Date: July 2016
- ☒ Field Office Inspection South Bend, IN (Memorial Dr.); Miskawaka, IN
- ☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine inspection of a 400-bed hospital authorized to use byproduct material for medical uses under 10 CFR 35.100, 35.200, 35.300, 35.400, 35.600 and 35.1000 at three locations on the licensee's South Bend, Indiana campus and at an off-site facility in Mishawaka, Indiana. At the primary location, seven nuclear medicine technologists conducted 10-15 diagnostic administrations daily, approximately half of which were stress tests, and 15-30 I-131 administrations monthly. The licensee had only performed one Y-90 SIR-spheres treatment since the last inspection. The radiation oncology department, also located at the primary location, had treated nine patients with the Ir-192 HDR and three patients with manual brachytherapy in 2013. In 2014, the licensee had treated only two and one patients, respectively. At the Mishawaka facility, one technologist conducted approximately 30-40 diagnostic administrations of F-18 monthly. The licensee had not conducted any principal activities at the Memorial Drive location since acquiring the practice in November 2013. The location was only used to store sealed sources included in the acquisition. A medical physics consultant conducted quarterly audits at all of the licensee's nuclear medicine departments individually.

PERFORMANCE OBSERVATIONS

The inspectors toured the licensee's main facility and two additional locations of use to evaluate established measures for materials security, hazard communication and exposure control. Independent and confirmatory surveys of these facilities found no readings indicative of residual contamination or exposures in excess of 10 CFR Part 20 dose limits. The inspectors observed the administration of the licensee's first therapeutic administration of Ra-223 radium dichloride "Xofigo" at the main facility and two administrations of F-18 at the Mishawaka location. The RSO demonstrated daily spot checks of the HDR unit and discussed procedures for full HDR calibrations and treatments. The RSO also discussed the licensee's protocols for manual brachytherapy. The inspectors discussed with various staff procedures for Y-90 treatments, lung ventilation studies, release criteria and inpatient precautions, receipt of packages containing radioactive material, waste handling, and surveys. The inspectors also reviewed a selection of licensee records, including procedures, quarterly audits, a variety of written directives (closing out a previous violation for 10 CFR 35.41(a) in the process), brachytherapy treatment plans, inventories and personnel dosimetry.

No violations of NRC requirements were identified as a result of this inspection.