

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Saint Joseph Regional Medical Center  
5215 Holy Cross Parkway  
Mishawaka, Indiana 46545

REPORT NUMBER(S) 2014001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-13685

4. LICENSE NUMBER(S)

13-02650-02

5. DATE(S) OF INSPECTION

July 8-9, 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.
- ☐ 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 M. Bramnik / Ryan J. Craffey	<i>Andrew M. Bramnik / Ryan J. Craffey</i>	7/9/14
BRANCH CHIEF	Aaron T. McCraw	<i>Aaron T. McCraw</i>	7/21/14

## Docket File Information

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6. INSPECTION PROCEDURES USED

87131, 87132

7. INSPECTION FOCUS AREAS

All

## SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02240

2. PRIORITY

2

3. LICENSEE CONTACT

Sharon Updike, MHP - RSO

4. TELEPHONE NUMBER

(734) 662-3197

☒ Main Office Inspection Next Inspection Date: July 2016☒ Field Office Inspection All except 53940 Carmichael Dr., South Bend☐ Temporary Job Site Inspection

## PROGRAM SCOPE

This was a routine inspection of a 254-bed hospital authorized to use byproduct material for medical uses under 10 CFR 35.100, 35.200, 35.300, 35.400, and 35.1000 at two locations on the licensee's Mishawaka, Indiana campus, at two facilities in Plymouth and at one in South Bend, Indiana. At the primary location, a staff of five nuclear medicine technologists conducted a full spectrum of diagnostic administrations using unit doses obtained from an area nuclear pharmacy. The licensee conducted approximately 12 administrations daily in addition to 2-3 administrations of I-131 requiring a written directive per month. The department had performed seven Y-90 SIR-spheres treatments since receiving authorization in July 2013 and the radiation oncology department had performed three manual brachytherapy treatments since the last inspection, using an external medical physics group for treatment planning. Two nuclear medicine technologists administered approximately 80 administrations per month at the locations in Plymouth, as well as 2-3 administrations of I-131 requiring a written directive per month. A Radiation Safety Committee reviewed the content and implementation of the program quarterly.

## PERFORMANCE OBSERVATIONS

The inspectors toured the licensee's main facility and three 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 preparation and administration of one Y-90 SIR-spheres treatment and one Tc-99m cardiac stress test at both the main facility and Plymouth location. The inspectors reviewed the licensee's protocols for manual brachytherapy with an AMP, as well as the written directives, treatment plans, and other associated documentation for the two most recent brachytherapy procedures. The inspectors also discussed with various other nuclear medicine and interventional radiology staff procedures and training for Y-90 treatments, patient release criteria and inpatient precautions, receipt of packages containing radioactive material, waste handling, and spill response. The inspectors also reviewed a selection of Radiation Safety Committee meeting minutes, I-131 written directives with associated patient release calculations, and personnel dosimetry.

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