

(10-2010)  
10 CFR 2.201

## SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

## 1. LICENSEE/LOCATION INSPECTED:

Saint Joseph Regional Medical Center  
5215 Holy Cross Parkway, Mishawaka, IN and  
53940 Carmichael Drive, South Bend, IN

## 2. NRC/REGIONAL OFFICE

Region III  
2443 Warrenville Rd.  
Lisle, IL 60532

REPORT NUMBER(S) 2011-001

## 3. DOCKET NUMBER(S)

030-13685

## 4. LICENSE NUMBER(S)

13-02650-02

## 5. DATE(S) OF INSPECTION

8/1-2/11

## 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, NUREG-1600, 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. 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	Robert G. Gattone, Jr.	Robert G. Gattone, Jr.	8/2/11
BRANCH CHIEF	Tamara Bloomer	Ker Lambert for	8/11/11

*Docket File Information*  
**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

<b>1. LICENSEE</b> Saint Joseph Regional Medical Center 53940 Carmichael Dr., South Bend, IN and 5215 Holy Cross Parkway, Mishawaka, IN REPORT NUMBER(S) 2011-001		<b>2. NRC/REGIONAL OFFICE</b> Region III 2443 Warrenville Road Lisle, IL	
<b>3. DOCKET NUMBER(S)</b> 03013685	<b>4. LICENSE NUMBER(S)</b> 13-02650-02	<b>5. DATE(S) OF INSPECTION</b> 8/1-2/11	
<b>6. INSPECTION PROCEDURES</b> 87130, 87131, and 87132		<b>7. INSPECTION FOCUS AREAS</b> 02.01-02.07	

**SUPPLEMENTAL INSPECTION INFORMATION**

<b>1. PROGRAM</b> 02120	<b>2. PRIORITY</b> 3	<b>3. LICENSEE CONTACT</b> Patrick Byrne	<b>4. TELEPHONE NUMBER</b> 734-717-8731
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☒ Main Office Inspection      Next Inspection Date: 08/02/14  
☒ Field Office Inspection 53940 Carmichael Dr., South Bend, IN  
☐ Temporary Job Site Inspection \_\_\_\_\_

**PROGRAM SCOPE**

Diagnostic nuclear medicine included the full spectrum of studies Mondays through Fridays from 6:30 am to 5:00 pm at the Holy Cross Parkway facility. No generators were used. Only unit dosages were used. The licensee used iodine-131 about twice a month for treating carcinoma with about 150 millicuries and for treating hyperthyroidism with about 20 millicuries at the Holy Cross Parkway facility. The licensee re-started brachytherapy at the Holy Cross Parkway facility in late 2010. As of the inspection, the licensee completed only three permanent prostate implants using iodine-125. The licensee used the services of two physicists for brachytherapy. PET imaging was conducted at the Carmichael Drive facility using unit dosages only (CardioGen-82 generators weren't used). About 5 FDG studies per week were conducted there using up to 12 millicuries per dosage. The Carmichael Drive facility was open from 7:30 am to 11:00 am. The licensee did rare sentinel node injections at the East Douglas Rd. facility. Therapeutic and diagnostic nuclear medicine was done at the 1915 Lake Avenue facility. In accordance with the license, the RSO visited the licensee's facilities one day per quarter. When present, the RSO reviewed administrations requiring written directives, interviewed staff, reviewed dosimetry records, and attended the RSC meetings. In addition, a medical consultant visited the facilities monthly to audit the radiation safety program, including administrations requiring written directives. No therapeutic administrations were conducted during the inspection.

**PERFORMANCE OBSERVATIONS**

The inspector observed: (1) that licensed material was secured as required; (2) that selected staff wore appropriate PPE and dosimetry badges; (3) records showing the licensee held quarterly RSC meetings with the required quorum; (4) a maximum of 0.1 mR/hr at 30 cm from the exterior surface of a hot lab wall at the Holy Cross Parkway location, 0.05 mR/hr at selected hot lab surfaces, and 1.4 mR/hr at a radioactive waste receptacle in a hot lab based on independent surveys using the NRC's Ludlum Model 2403, Serial No. 161609 that was calibrated on 10/29/10; (5) that the RSO conducted an adequate evaluation to determine that the erroneous administration of technetium-99m pertechnetate on 3/15/11 did not result in a medical event; (6) that, based on an interview with the RSO, the Wang applicator that was involved with medical events years ago was returned to the medical physicist consultant group that was involved with those medical events, and the licensee no longer possessed it; (7) an NMT conduct end of day ambient exposure rate surveys and wipe surveys; (8) selected NMTs demonstrate how daily survey instrument operability checks were done; (9) that appropriate shielding was used at the facilities; (10) preparation and administration of diagnostic dosages; (11) records showing that survey instruments were calibrated as required; (12) an NMT conduct package receipt surveys; (13) an NMT demonstrate response to a radioactive spill based on a scenario posed by the inspector; (14) an NMT describe implementation of procedures to provide high confidence that 35,300 administrations are in accordance with written directives; (15) records of several 35,300 administrations and the three 35,400 administrations; (16) a physicist describe implementation of procedures to provide high confidence that 35,400 administrations are in accordance with written directives; (17) dosimetry records; (18) records showing that the last HDR Ir-192 source was leak tested as required prior to authorized transfer; (19) an NMT conduct a sealed source inventory; (20) leak test records; (21) that, to ensure that the licensee is overseeing the contracted physicists' work to ensure safety and compliance, the licensee audited the physicists' work, observed the physicists conduct their work, interviewed the physicists about the work they did, had its COO as the RSC Chair, and had the physicists attend the RSC meetings.

*MRJ*