

## INSPECTION RECORD

Region III Inspection Report No. 030-13685/2009-001  
License No. 13-02650-02 Docket No. 030-13685

**Licensee (Name and Address):**  
Saint Joseph Regional Medical Center  
801 East LaSalle St.  
South Bend, Indiana 46617-1935

**Licensee Contact:** Joni Pintada - RSO Telephone No. 574-837-8000

**Priority:** 2 **Program Code:** 2230

**Date of Last Inspection:** 6/11-12/08 **Date of This Inspection:** 2/19/2009

This inspection was a specific inspection of the licensee's HDR program. During a routine inspection conducted in June 2008, the licensee did not possess an HDR unit.

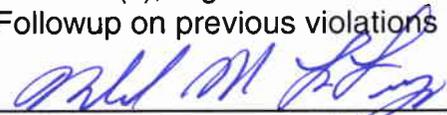
**Type of Inspection:**         Initial         Announced         Unannounced  
                                  Routine         Special

**Next Inspection Date:** 2/2011  Normal     Reduced

**Justification for reducing the routine inspection interval:**

**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
- Violation(s), regional letter issued
- Followup on previous violations

Inspector(s)   
Michael LaFranzo, Health Physicist

Date 3/12/09

Approved   
Kenneth Lambert, Chief, MIB  
*Acting*

Date 3/12/09

## **PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY**

### **1. AMENDMENTS AND PROGRAM CHANGES:**

<u>Amendment No.</u>	<u>Date</u>	<u>Subject</u>
41	8/4/08	Addition of authorized activities and change in RSO
42	10/8/08	Additional locations of use for specific activities
43	1/12/09	Additional authorized activities and locations of Use
44	2/24/09	Add authorized user
45	3/6/09	Addition of NARM on license

### **2. INSPECTION AND ENFORCEMENT HISTORY:**

During the last routine inspection on 6/11-12/08, a SL IV violation was identified regarding the failure to conduct leak tests in accordance with 10 CFR 35.67(f).

On November 16, 2005, the NRC conducted a special inspection to review the licensee's corrective actions implemented in response to the findings identified during our March 30 through April 21, 2005, Augmented Inspection Team inspection and the violations identified during our May 23 through 25, 2005, special follow-up inspection. No violations of NRC requirements were identified.

### **3. INCIDENT/EVENT HISTORY:**

(List any incidents, or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

None

## **PART II - INSPECTION DOCUMENTATION**

### **1. ORGANIZATION AND SCOPE OF PROGRAM:**

Lori Price, Chief Operating Officer  
Chris Karam, Administrator  
Joni Pintado, Radiation Safety Officer

This inspection only focused on the licensee's implementation of activities permitted under 10 CFR 35.600 (HDR) as during the last routine inspection conducted in June 2008, the licensee did not possess the unit. The licensee possesses one HDR unit but, at the time of the inspection, the licensee had not administered a dose to a patient. The licensee had the unit fully installed and all hardware and software had been tested. The licensee planned its first patient using the HDR in March 2009.

### **2. SCOPE OF INSPECTION:**

Inspection Procedure(s) Used: 87132

Focus Areas Evaluated: 03.01 through 03.07

### **3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:**

The inspector conducted radiological surveys around the HDR unit when in storage and on the exterior portion of the treatment room while the source on the HDR unit was exposed; the inspector did not identify any abnormal radiation readings. The inspector performed side-by-side comparison radiation measurements between the NRC and licensee radiation detection instrumentation; radiation measurement differences were within acceptable limits.

#### 4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

During the inspection, the licensee informed the inspector that, during a physical inventory search, the new Radiation Safety Officer had identified a lead pig contaminated with radium-226 that had not been identified during previous physical inventories. The licensee was unable to determine the quantity of radium-226 contamination but believes it is in the sub-microcurie range. The licensee contacted their consultant which informed them to contact the State of Indiana as Radium, they believed, was under the regulatory jurisdiction of the State. The licensee had contacted the State of Indiana but had not received a reply as of the day of the NRC inspection. In interviews with the licensee, the inspector does not believe that the licensee was aware that NRC had regulatory jurisdiction over radium-226. The inspector did not identify elevated radiation levels while the lead pig was sealed. The licensee believes that the radium was from a sealed radioactive source that they previously possessed as part of the medical program. The licensee does not believe they possess any additional radium sources. At the time of the inspection, the licensee was in the process of determining how best to properly dispose of the radium source.

On November 30, 2007, regulatory jurisdiction of NARM and radium-226 within the State of Indiana was transferred to the NRC. In accordance with the NRC regulations, a program which already had an NRC license and also possessed either NARM or radium-226 was required to submit an amendment to the NRC, within 6 months, requesting the NARM and/or radium-226 radioactive material and activities associated with that possession be placed on the license. Due to the circumstances surrounding the violation, the NRC had decided to exercise enforcement discretion in this case in accordance with Section VII.B.6 of the Enforcement Policy and not cite the violation because the licensee: (1) did not realize the requirement was in effect; (2) was in the process of determining the appropriate regulatory body after the radioactive material was discovered; and (3) was in the process to determine an appropriate means to dispose of the radioactive material. The licensee's corrective actions included an amendment submission to NRC, which was received on March 5, 2009, requesting the radium be placed on the license. The NRC approved such a request and Amendment 45 was issued which authorized the possession of radium.

No violations of NRC requirements were identified regarding the High-Dose Rate Afterloader.

5. **PARTIAL LIST OF PERSONNEL CONTACTED:**

- \*& Chris Karam, Administrator
- \*#& Joni Pintado, Radiation Safety Officer

Use the following identification symbols:

# Individual(s) present at entrance meeting

\* Individual(s) present at exit meeting

& Individuals contacted via telephone on February 25, 2009

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