

## SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

## 1. LICENSEE/LOCATION INSPECTED:

St. Mary's of Michigan Medical Center  
800 S. Washington Street  
Saginaw, Michigan 48601

REPORT NUMBER(S) 2013001

## 2. NRC/REGIONAL OFFICE

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

## 3. DOCKET NUMBER(S)

030-02031

## 4. LICENSE NUMBER(S)

21-03646-03

## 5. DATE(S) OF INSPECTION

February 19-20, 2013

## 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:

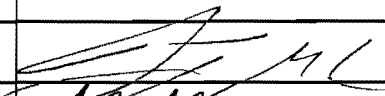
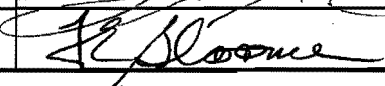
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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	Aaron T. McCraw		2/20/13
BRANCH CHIEF	Tamara E. Bloomer		2/25/13

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

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5. DATE(S) OF INSPECTION  February 19-20, 2013		6. INSPECTION PROCEDURES USED IP 87130, 87131, 87132	
7. INSPECTION FOCUS AREAS As appropriate			

**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S) 02240	2. PRIORITY 2	3. LICENSEE CONTACT Jacek Wierzbicki, Ph.D., RSO	4. TELEPHONE NUMBER (989) 776-8285
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- ☒ Main Office Inspection      Next Inspection Date: 02/20/2015
- ☒ Field Office Inspection    1015 S Washington Ave, Saginaw
- ☐ Temporary Job Site Inspection

**PROGRAM SCOPE**

This was a routine inspection of a hospital and satellite facilities in Saginaw, Michigan. The licensee was authorized to use licensed materials for medical uses under 10 CFR 35.100, 200, 300, 400, 600, and 1000. Since the last inspection, the licensee had not used any materials under 35.400 or 1000. The licensee conducted the spectrum of nuclear medicine studies at the main hospital, cardiac studies at the satellite cardiology facility, and lymphoscintigraphy at the outpatient surgery center. Under 35.600, the licensee used iridium-192 in a high dose-rate remote (HDR) afterloader unit. The licensee saw, on average, 4-5 patients per year for HDR treatments, primarily for gynecological treatments. The licensee also possessed a TechOps device with a nominal 200-millicurie, cesium-137 source for instrument calibrations.

**PERFORMANCE OBSERVATIONS**

The inspector reviewed the nuclear medicine and HDR brachytherapy programs through a combination of personnel interviews, records reviews, and performance observations. In the HDR brachytherapy program, the inspector reviewed patient treatment plans and written directives and determined that all treatments were in accordance with the written directives and treatment plans. No patients were scheduled for treatment during the inspection. The licensee demonstrated the periodic checks required for the HDR unit prior to use on a given day.

In the nuclear medicine program, the inspector interviewed available staff, observed patient three administrations, observed package receipt and surveys, reviewed records, and interviewed staff at the main hospital and the cardiology clinic. The inspector reviewed the circumstances of a "misadministration" that occurred when the licensee injected a patient with the wrong radiopharmaceutical. The inspector evaluated the licensee's dose determinations and conclusion that the "misadministration" did not meet the NRC's criteria as a reportable medical event.

No violations of regulatory requirements were identified during this inspection.