

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

<b>1. LICENSEE/LOCATION INSPECTED:</b> <b>St. Mary's of Michigan Medical Center</b> <b>800 South Washington Street</b> <b>Saginaw, MI 48601</b> REPORT NUMBER(S) <b>2010-01</b>	<b>2. NRC/REGIONAL OFFICE</b> <b>U.S. Nuclear Regulatory Commission</b> <b>Region III</b> <b>2443 Warrenville Road</b> <b>Suite 210</b> <b>Lisle, Illinois 60532-4351</b>
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<b>3. DOCKET NUMBER(S)</b> <b>030-02031</b>	<b>4. LICENSEE NUMBER(S)</b> <b>21-03646-03</b>	<b>5. DATE(S) OF INSPECTION</b> <b>November 1-2, 2010</b>
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**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

**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	S. J. Mulay		11/2/10
Branch Chief	Tamara E. Bloomer		11/16/10

NRC FORM 591 M PART 3  
(06-2010)  
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

*Docket File Information*  
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1. LICENSEE  
St. Mary's of Michigan Medical Center  
Saginaw, MI 48601

2. NRC/REGIONAL OFFICE  
Region III  
2443 Warrenville Road, Suite 210  
Lisle, Illinois 60532-4351

REPORT NUMBER(S) 2010-01

3. DOCKET NUMBER(S)

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4. LICENSE NUMBER(S)

21-03646-03

5. DATE(S) OF INSPECTION

November 1-2, 2010

6. INSPECTION PROCEDURES

87131, 87132

7. INSPECTION FOCUS AREAS

03.01-03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM

2240

2. PRIORITY

2

3. LICENSEE CONTACT

J.G. Wierzbicki, Ph.D., RSO

4. TELEPHONE NUMBER

989-907-8285

Main Office Inspection

800 S. Washington St., Saginaw, MI

Next Inspection Date: November 2012

Field Office Inspection:

4599 Towne Ctr., Saginaw, MI

Temporary Job Site Inspection

PROGRAM SCOPE

This large medical licensee performs approximately 400 diagnostic nuclear medicine procedures monthly. Five full-time and one part-time technologists perform patient procedures. The licensee performs about two iodine-131 treatments for hyperthyroid, one iodine-131 ablation therapy, and two whole-body iodine-131 administrations monthly. The inspection included a review of an authorized off-site location as indicated above and used to perform about one outpatient lymphoscintigraphy monthly. Licensed material is received as unit doses at both locations from an area nuclear pharmacy.

The licensee's conventional brachytherapy program is currently inactive with no therapeutic implant procedures performed since the last inspection. The licensee maintains 10 Hyman applicator sources, one survey meter calibration device and one strontium-90 source in locked storage. All other sources were disposed of through an authorized vender on 12/13/08. Brachytherapy treatments are done with a High Dose Rate Afterloader (HDR) device containing the type/amount of licensed material as authorized. Approximately 18 fractionated treatments are performed monthly. Five authorized users, three medical physicists and two dosimetrists are available.

Interviews conducted with available nuclear medicine staff revealed an adequate level of understanding of emergency and material handling procedures and techniques. Dose calibrator constancy checks, injection technique, daily surveys, waste handling and disposal, and package receipt procedures, were successfully demonstrated, observed and/or described at both locations. A daily HDR daily check was demonstrated and included all required parameters prior to patient treatments with no problems noted. An outside consultant performs quarterly program audits which appear to adequately oversee licensed activities.

Licensed material was observed adequately secured during the review and was not readily accessible to members of the general public. Survey meters were found to be calibrated and operational and compared well in side-by-side comparison with the NRC instrument. Written directives, patient instructions and staff responses to QMP questions were adequately addressed with no issues identified.

Independent measurements taken did not indicate readings in excess of 10 CFR Pt. 20 limits in restricted or unrestricted areas. In addition, personal dosimetry records reviewed for 2009 and YTD 2010 for nuclear medicine and brachytherapy staff did not reveal whole-body and extremity readings in excess of regulatory limits.