

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Saint Mary's Health Care
200 Jefferson, S.E.
Grand Rapids, MI 49503
REPORT NUMBER(S) **2010-01**

2. NRC/REGIONAL OFFICE

U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532-4351

3. DOCKET NUMBER(S)

030-08291

4. LICENSEE NUMBER(S)

21-01078-01

5. DATE(S) OF INSPECTION

November 3, 2010

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:

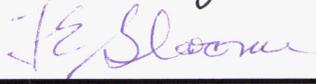
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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		11/3/10
Branch Chief	Tamara E. Bloomer		11/15/10

Docket File Information
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1. LICENSEE Saint Mary's Health Care Grand Rapids, MI 49503 REPORT NUMBER(S) 2010-01		2. NRC/REGIONAL OFFICE Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532-4351	
3. DOCKET NUMBER(S) 030-08291		4. LICENSE NUMBER(S) 21-01078-01	5. DATE(S) OF INSPECTION November 3, 2010
6. INSPECTION PROCEDURES 87131, 87132		7. INSPECTION FOCUS AREAS 03.01-03.07	
SUPPLEMENTAL INSPECTION INFORMATION			
1. PROGRAM 2230	2. PRIORITY 2	3. LICENSEE CONTACT Dale Schippers, M. S., RSO	4. TELEPHONE NUMBER 616-752-6744

◀ Main Office Inspection: 200 Jefferson SE, Grand Rapids, MI
 Next Inspection Date: November 2012
 ◀ Field Office Inspection : Lacks Cancer Center, 250 Cherry St., SE, Grand Rapids, MI Temporary Job Site Inspection ___

PROGRAM SCOPE

This 300 bed medical licensee performs approximately 120 diagnostic nuclear medicine procedures monthly. Five full-time and two part-time technologists perform patient procedures. The licensee performs about five iodine-131 treatments for hyperthyroid per week, and two iodine-131 ablation therapies weekly, both in capsule form. Whole-body scans are performed using iodine-125. Approximately three Yttrium-90 Zevalin treatments have been performed to date. The licensee maintains three authorized locations of use as indicated on the license. Locations inspected are noted above. Licensed material is received as needed from an area nuclear pharmacy.

The licensee's brachytherapy program consists of 12 iodine-125 permanent implants and about one cesium-137 treatment annually. Yttrium-90 treatments with TheraSpheres have also recently been performed. Cesium-137 implant sources were compared with the licensee's current inventory with no discrepancy noted.

The licensee performs about 80 fractionated treatments annually utilizing a High Dose Rate Afterloader (HDR) device containing type and quantity of licensed material as authorized. Three authorized users, two medical physicists, two dosimetrists and eight technicians are available for treatment administration, treatment planning, etc.

PERFORMANCE OBSERVATIONS

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 or observed at locations inspected. An actual iodine-131 administration was observed with no regulatory issues identified. 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. A daily QC check of the HDR unit was demonstrated during the review and included all appropriate safety verifications. Written directives, patient instructions and staff responses to QMP questions for the various treatment modalities performed were adequately completed and addressed with no issues noted.

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.