NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
St. Mary's of Michigan Medical Center 800 S. Washington Street Saginaw, Michigan 48601 REPORT NUMBER(S) 2013001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-02031	21-03646-03	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 violations(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

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
IP 87130, 87131, 87132	As appropriate

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02240	2	Jacek Wierzbicki, Ph.D., RSO	(989) 776-8285

☑ 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.