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 1015 S. Washington Ave. Saginaw, MI 48601 REPORT NUMBER(S) 2019-001	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 12, 2019

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	Kevin G. Null	K-D Null	02/27/2019
BRANCH CHIEF	Aaron McCraw	for ATM	2/27/19

NRC FORM 591M PART 3
(07-2012)
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Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131 and 87132	All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02230	2	Tracy King	(989) 907-8000

☑ Main Office Inspection Next Inspection Date: 02/12/2021

☑ Field Office Inspection 4599 Towne Centre, Saginaw, Michigan

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, unannounced inspection of a large medical center that was authorized for material described in 10 CFR 35.100, 200, 300, 400, and 600. The licensee was authorized to use material at 3 locations of use in Saginaw, Michigan. At the 800 S. Washington address the licensee performed diagnostic imaging studies, radiphiopharmaceutical therapy procedures, and high dose rate remote afterloader treatments. Lymphoscintigraphy procedures using millicurie quantities of technetium-99m (Tc-99m) were performed at 4599 Towne Centre 3-4 times per month. The therapy department was staffed with 3 medical physicists (MP). The MP responsible for the HDR program was unavailable for the inspection, which resulted in a limited review by the inspector. Sealed source and permanent implant therapy had not been performed since the last inspection. The nuclear medicine department was staffed with a manager and 2 full time certified nuclear medicine technologists (CNMT's), and included 1 hot lab and 2 imaging rooms. Unit doses were received from a local radiopharmacy, and a contracted consultant performed quarterly audits. The nuclear medicine department performed 50-60 diagnostic studies per month and 4-6 iodine-131 therapy treatments per year using iodine-131 capsules. The licensee had not performed any radium-223 xofigo studies since the last inspection.

Performance Observations

The inspector interviewed an MP and the manager of the therapy department and toured the HDR treatment room. The MP was not familiar with details of the HDR program but was able to demonstrate security of the room, and functioning audio/video and treatment room door interlock systems. The inspector reviewed a random selection of HDR written directives and treatment plans, calibration records of the dosimetry equipment, and records of training provided by the HDR manufacturer. The inspector toured the nuclear medicine department and interviewed the manger and a CNMT. The CNMT demonstrated radioactive material package receipt procedures, daily dose calibrator constancy checks, and daily and weekly area surveys. The inspector visited 4599 Towne Centre where Tc-99m labeled sulfur colloid lymphoscintigraphy procedures were conducted, and observed security of the hot lab where unit doses were stored and received, and the dose calibrator that was used to prepare and measure unit doses received from a local radiopharmacy. The inspector reviewed dosimetry reports, and records of package receipts and surveys, area surveys, survey meter calibration, and training.

No violations of NRC requirements were identified.

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