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) 2015-001	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	June 8-9, 2015

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)

as of June 8, 2015, GW

Contrary to 10 CFR 35.643 (a)(1), (d)(1), and (d)(6), the licensee failed to perform adequate periodic spot checks for a high dose rate (HDR) remote afterloader facility GW before the first use of the HDR unit each day of use in that the spot checks did not include (1) checking electrical interlocks at both HDR unit room entrances, and (2) verifying timer accuracy. The root cause of the violation was that the licensee was not aware of the requirements. As corrective action, the licensee will ~~will~~ GW revise the checklist to include the timer accuracy test, retrain the additional physicist on the additional requirements, and begin testing both room entrances and the timer before the next patient treatment is performed.

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	SHARON LEAMAN CASE	Sharon L Case	9 June 2015
NRC INSPECTOR	Geoffrey M. Warren	GW Warren	6/9/15
BRANCH CHIEF	Aaron T. McCraw	ATM	6/22/15

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

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Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131, 87132	03.01 - 03.08; 03.01 - 03.08

SUPPLEMENTAL INSPECTION INFORMATION

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

☑ Main Office Inspection Next Inspection Date: June 2017

☑ Field Office Inspection 4599 Towne Center, Saginaw, MI

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, unannounced, inspection. The licensee was a 190-bed hospital located in Saginaw, Michigan, that used byproduct materials in Sections 35.100, 35.200, 35.300, and HDR under 35.600. The licensee also operated two other facilities in Saginaw under the license - a cardiology clinic and a facility where lymphoscintigraphy procedures were performed. While authorized to perform calibration procedures and brachytherapy procedures under 35.400, none had been performed in several years. Licensed activities were conducted only at the facilities identified on the license.

The nuclear medicine department was staffed with three full-time nuclear medicine technologists at this site, who typically administered 250 diagnostic doses monthly, received as unit doses from a licensed nuclear pharmacy or prepared from bulk technetium-99m. Diagnostic procedures were mostly cardiac and bone imaging, but included a variety of procedures. The staff performed around 20 iodine-131 procedures requiring written directives annually, and had treated five radium-223 patients to date. The radiation therapy department was staffed with three physician authorized users and two medical physicists, who treated around 7 to 8 patients annually using HDR, limited to gynecological procedures. The licensee possessed cesium-137 brachytherapy seeds and a calibration source in storage.

Nuclear medicine technologists went to the Towne Center site around twice monthly to receive and prepare lymphoscintigraphy procedures there; the doses were administered by trained physicians. At this site, PET/CT procedures were performed Thursdays and Fridays under another license.

Performance Observations: The inspector observed two diagnostic administrations of licensed materials, including dose preparation and disposal; and daily checks in nuclear medicine, including dose calibrator constancy, survey meter and wipe counter QC, and package receipt surveys. Licensee staff demonstrated or described HDR daily checks, HDR planning and administration, a variety of diagnostic procedures, iodine-131 and radium-223 therapy procedures, kit preparation, daily and weekly contamination surveys, and other procedures. The inspector noted no concerns with these activities except as described below. The inspector reviewed written directives for radiopharmaceutical therapies and HDR treatments and identified no concerns. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of dosimetry records indicated no exposures of regulatory concern.

(continued on Part 2)

NRC FORM 591M PART 2
(07-2012)
10 CFR 2.201

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(Continued)

The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings. Review of radiation safety committee minutes indicated good attendance and discussion of appropriate topics.

The inspector observed that, during HDR daily checks, the licensee did not check timer accuracy and interlocks on both doors into the HDR suite. They did check one door into the HDR suite, but not the other. Prior to the exit meeting, the physicist had updated the checklist to include checking both entrances and the timer accuracy.