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
Mercy Health Saint Mary's 200 Jefferson Ave. SE Grand Rapids, MI 49503 REPORT NUMBER(S) 2017001	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
030-08291	21-01078-01	July 31-August 1, 2017

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)

Contrary to 10 CFR 35.643(d)(6), as of July 31, 2017, the licensee failed to assure proper timer accuracy of the licensee's high dose-rate remote afterloader (HDR) unit during spot-checks, which are required by 10 CFR 35.643(a)(1) to be performed before the first use of the HDR on a given day. This is a Severity Level IV violation.

As corrective action, on August 3, 2017, prior to the next use of the HDR, the licensee updated its HDR warmup procedure and daily quality assurance checklist to include a timer accuracy test.

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	Triston W. Dougall, RSO	Triston Dougall	8/15/17
NRC INSPECTOR	Edward F. Harvey/Jason D. Draper	Edward Harvey / for O.Gyn	8/11/17
BRANCH CHIEF	Aaron T. McCraw		8/14/17

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
87131, 87132	All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02240	2	Triston W. Dougall, RSO	(616) 685-5000

☑ Main Office Inspection Next Inspection Date: July 31, 2019

☑ Field Office Inspection 250 Cherry Street SE, Grand Rapids, MI

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced, routine inspection of a hospital authorized to use byproduct material to perform diagnostic and therapeutic administrations of radiopharmaceuticals, manual brachytherapy, HDR treatments, administrations of Y-90 microspheres, and temporary implants to localize non-palpable lesions at its campus in Grand Rapids, Michigan. In the nuclear medicine department the licensee performed approximately ten diagnostic studies per day, and approximately four therapeutic administrations of I-131 per month. The licensee also performed approximately three administrations of Ra-223 dichloride (Xofigo®) per year. In the radiation oncology department, the licensee performed approximately five prostate seed implants per year, and treated approximately 30 patients per year using the HDR unit (mostly gynecological).

The inspectors observed nuclear medicine staff demonstrate package receipt and surveying procedures, daily dose calibrator constancy checks, daily surveys, and waste disposal procedures. In addition, the inspectors observed both the administration of a therapeutic dose of Ra-223 Xofigo® and a diagnostic dose of F-18 for a PET scan. The inspectors noted that the NMT wore the appropriate personal protective equipment, assayed the doses, and verified patient identity prior to administering the doses. The nuclear medicine staff also demonstrated adequate knowledge of radiation protection principles and emergency procedures in the event of a spill through interviews with the inspectors.

In the radiation oncology department, the inspectors observed licensee staff demonstrate their procedures for daily spot checks of the HDR unit. The inspectors also verified the licensee's implementation of corrective actions for a previous violation involving the licensee's failure to have a copy of the emergency procedures located at the HDR treatment console. No additional violations of this requirement were identified; therefore, the previous violation is closed.

The inspectors also observed an authorized user perform an I-125 seed implant for a non-palpable lesion localization study. The activity of the I-125 seed was verified in the nuclear medicine department prior to being transported to the implant room. The inspectors noted that the authorized user wore the appropriate personal protective equipment, verified patient identity prior to starting the procedure, and verified the seed location using ultrasound prior to finishing the procedure.

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(Continued)

{Part 3 Continued}

The inspectors reviewed a selection of licensee records, including written directives, treatment plans, quarterly audits, source inventories, equipment calibration records, package receipt logs, dosimetry, and RSC meeting minutes with no issues noted. In addition, the inspectors performed independent surveys, which revealed no readings that would indicate residual contamination or exposures to members of the public in excess of regulatory limits.

One Severity Level IV violation, described in Part 1 of this report, was identified during this inspection.