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, Ml 49503 REPORT NUMBER(S) 2022001	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 7, 2022

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	Zahid Sulaiman, Health Physicist	Zahid M. Sulaiman Digitally signed by Zahid M. Sulaiman Date: 2022.07.29 13:43:15 -05'00'	
BRANCH CHIEF	Michael Kunowski, Chief, MIB	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2022.08.02 07:20:10 -05'00'	

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Mercy Health Saint Mary's	030-08291	21-01078-01

4. Report Number(s):	5. Date(s) of Inspection:
2022001	July 7, 2022

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Zahid Sulaiman, Health Physicist	02240	2	87131 & 87132

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Dale Schippers, RSO Alan Mayville, AMP	dale.schippers@mercyhealth.com alan.mayville@mercyhealth.com	Work: (616) 685-6744 Work: (616) 685-6218

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial ☑ Routine ☐ Announced ☐ Non-Routine ☑ Unannounced	☑ Main Office ☐ Field Office ☐ Temporary Job Site ☐ Remote	07/07/2024 ☑ Normal ☐ Extended ☐ Reduced ☐ No change

16. Scope and Observations:

This was a routine, unannounced, inspection of a 800-bed hospital located in Grand Rapids, Michigan, with authorization to use byproduct materials under 10 CFR Sections 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 (Iridium-192, high dose rate (HDR) remote afterloader), and 35.1000 (yttrium-90 (Y-90) microspheres and iodine-125 non-palpable lesion seed implants). The nuclear medicine department at the main hospital was staffed with two full-time and five part-time nuclear medicine technologists (NMTs). The NMTs typically administered approximately 15 diagnostic doses per day using Technicium-99m (Tc-99m), primarily for cardiac, HIDA, bone scan, gastric emptying, renal, and lung scan. The NMTs performed approximately 7 PET doses using F-18 and gallium-68 dotatate daily. The licensee also performed approximately 12 Y-90 microspheres, 8 radium-223 Xofigo, and 8 iodine-131 (capsules form) therapeutic procedures annually.

The cancer center was staffed with two oncologists, authorized medical physicists (AMPs), dosimetrists, and nine therapists, who performed approximately 12 HDR gynecologic treatments annually. Licensee has not performed manual brachytherapy procedures since the last inspection. The licensee has not used the I-125 non-palpable lesion seed implants since October 16, 2020. The licensee submitted an exemption request to 10 CFR 35.615(a) & (b) in June 25, 2019. The exemption requested was to keep the HDR treatment room door open and the access to HDR treatment room was controlled by three motions sensors, optical sensors placed at the entrance and inside the maze of the HDR treatment room, and a "pre-entrance" audible and visual warning system, instead of a physical door with an interlock system. The licensee agreed to keep the HDR treatment door closed with electronic door interlock system activated during HDR treatments until resolution of the exemption request. This item remains open pending review of the licensee's exemption request.

PERFORMANCE OBSERVATIONS

This inspection consisted of a tour of the hospitals, cancer center, nuclear medicine department, interviews with select licensee personnel, a review of select records, an observation of security of the materials, and independent measurements. The inspector had an NMT and an AMP conduct a physical inventory of sealed sources, and all sources were accounted for. The inspector had the NMT demonstrate the dose calibrator constancy check, package receipt procedures, the end of the day daily and weekly area surveys, proper handling of radioactive waste and disposal procedures, with no issue noted. The inspector observed the licensee staff prepare and administer several diagnostic dosages. The inspector had the NMT demonstrate the preparation and assay of a Y-90 TheraSpheres dosage. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

Materials Inspection Record (Continued)

The inspector had the AMP demonstrate the HDR unit's: (1) security; (2) daily spot checks; (3) emergency equipment and procedures; (4) safety procedures and instructions; (5) door interlock system; (6) radiation monitoring equipment checks; and (7) full calibration measurement. The inspector reviewed select HDR, I-131, Y-90, and Ra-223 written directives, treatment plans, and patient release calculations for therapeutic administrations. The inspector had the AMP test the HDR treatment room electronic door interlock system, with no issue noted. Through these observations, demonstrations and other discussions, the inspector found that the licensee personnel were knowledgeable of radiation protection principles, licensee procedures, and regulatory requirements.

The inspector reviewed the following records: radiation safety committee minutes, quarterly program audits, package receipts, waste disposal records, DOT hazmat training, constancy, linearity, and accuracy tests of the dose calibrator, sealed source leak tests and inventory, daily area surveys, and weekly wipe tests. The inspector reviewed the dosimetry records for 2021 through Mar 31, 2022, indicating the maximum annual dose to be 207 mrem - DDE, and 829 mrem - SDE.

No violations of NRC requirements were identified as a result of this inspection.