

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Metro Health - University of Michigan Health 5900 Byron Center Ave. S.W. Wyoming, MI 49519 REPORT NUMBER(S) 2019001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Rd, Suite 210 Lisle, IL 60532	
3. DOCKET NUMBER(S) 030-02134	4. LICENSE NUMBER(S) 21-12829-01	5. DATE(S) OF INSPECTION July 26, 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 violation(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	<i>Zahid Sulaiman</i>	7/26/19
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB	<i>ATM</i>	8/23/19

Docket File Information
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6. INSPECTION PROCEDURES USED 87131 & 87132	7. INSPECTION FOCUS AREAS 03.01 - 03.07		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02240	2. PRIORITY 2	3. LICENSEE CONTACT Suzanne Kasper, Radiology Manager	4. TELEPHONE NUMBER (616) 252-7355
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☒ Main Office Inspection Next Inspection Date: 07/26/2021

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced, routine inspection of a 127-bed hospital authorized to use byproduct materials under 10 CFR Sections 35.100, 35.200, 35.300, 35.500 and 35.1000 (using yttrium-90 (Y-90) microspheres) at its facility in Wyoming, Michigan. The nuclear medicine department was staffed with four full-time nuclear medicine technologists (NMTs) and three PRNs. The NMTs typically administered approximately 120 diagnostic doses monthly, two radium-223 Xofigo treatments, and 12 iodine-131 (in capsules form) therapies annually. The diagnostic procedures using technetium-99m (Tc-99m) included a variety of imaging and uptake procedures. The Greenville, MI facility was staffed with a NMT and conducts cardiac stress test on Tuesdays and Wednesdays. The licensee conducted their first Y-90 SIR-Spheres patient treatment on April 25, 2019. The licensee has removed and disposed of the Gadolinium-153 sources on March 13, 2019, and submitted an amendment request to remove the 35.500 program from its license. The licensee is planning to change their dosimetry program to issuing digital monitoring badges by end of 2019.

PERFORMANCE OBSERVATIONS

The inspection consisted of interviews with select licensee personnel, a review of selected records, and a tour of the nuclear medicine department. The inspector observed preparation and administration of Tc-99m for diagnostic procedures on a patient. The inspector: (1) observed the NMT conduct a physical inventory of sealed sources, and all sources were accounted for, (2) had the NMT demonstrate the package receipt surveys and wipes, dose calibrator constancy check, daily area surveys and weekly wipe tests, and proper handling of radioactive waste and disposal procedures, (3) had the NMT demonstrate the Y-90 SIR-Spheres dose preparation, pre & post dose assays, and post operation procedures. The inspector reviewed written directives for Y-90 and I-131 therapies, with no issues noted. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. The inspector reviewed the following selected records: RSC minutes, quarterly program audits, package receipts, waste disposal records, DOT Hazmat training, linearity and accuracy of the dose calibrator, instrument calibration, sealed source leak tests, daily area surveys, and weekly wipe tests. The inspector reviewed one fetal monitoring report and the dosimetry records for 2018 indicating the maximum annual dose to be 278 mrem - DDE; and 933 mrem - SDE. The inspector performed independent surveys and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

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