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
Metropolitan Hospital d/b/a Metro Health Hospital 5900 Byron Center Avenue SW Wyoming, MI 49519 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
030-02134	21-12829-01	November 19, 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.

One Non-cited violation(s) were discussed involving the following requirement(s):

10 CFR 35.63(d), which states that unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or it the dosage differs from the prescribed dosage by more than 20 percent.

☐ 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	Ryan Craffey	Ryan Craffey	11/24/15
BRANCH CHIEF	Aaron McCraw		11/25/15

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	All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02240	2	Jeffrey J. McClure, MD - RSO	(616) 252-7200

☑ Main Office Inspection Next Inspection Date: 11/19/2017

☑ Field Office Inspection 1915 Washington Street, Greenville, Michigan

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced routine inspection of a hospital authorized to use byproduct material for medical purposes at its main campus in Wyoming, Michigan, and at an affiliated cardiology clinic in Greenville, Michigan. At the time of the inspection, two full-time technologists at a hot lab in the hospital's general radiology department performed around seven diagnostic administrations (excluding cardiac stress tests) daily, around five therapeutic administrations of I-131 capsules yearly, and has performed Ra-223 Xofigo treatments in the past, though not lately. Two other full-time technologists performed around seven cardiac stress tests daily at a second hot lab in the hospital's cardiac imaging department. At the Graeenville facility, two full-time technologists performed up to six cardiac stress tests per day on Thursdays and Fridays only. Although authorized to administer Y-90 SIR-Spheres, the licensee has not performed any such administrations to date, and had no plans to do so in the future.

PERFORMANCE OBSERVATIONS: The inspector toured the main hospital in Wyoming as well as the facility in Greenville to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector conducted independent and confirmatory surveys of these facilities, and observed the preparation and and administration of several cardiac stress tests and a HIDA scan, as well as the receipt of packages and decay-in-storage waste handling. The staff also demonstrated the implementation of licensee procedures for therapeutic administrations requiring a written directive, as well as area surveys and spill response. The inspector reviewed a selection of licensee records, including written directives for therapeutic administrations, routine nuclear medicine records, incident reports, Radiation Safety Committee (RSC) meeting minutes and quarterly consultant audits.

The inspector noted a licensee-identified violation of 10 CFR 35.63(d) for the administration of February 25, 2014 of a dosage of Tc-99m that differed from the prescribed dosage by approximately 67 percent. An authorized user ordered a pediatric bone scan, but the patient was given an adult dose of about 25 mCi instead of the intended weight-adjusted dose of 15 mCi. The inspector determined the root cause to be an oversight by licensee personnel. As corrective action, the licensee retrained the individual involved, performed a medical event evaluation (it did not meet the criteria), and discussed the event at the next RSC. The inspector determined that the violation was self-identified, non-repetitive, non-willful and adequate corrective action had been taken, and therefore met the criteria for the NRC to consider this a non-cited violation.