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 Medical Center - Hobart 1500 S. Lake Park Ave. Hobart IN and 300 W 61st Ave. Hobart, IN REPORT NUMBER(S) 2018001	Region III 2443 Warrenville Rd., Suite 210 Lisle, IL 60532 Select a location (Use keyboard arrows to select). . .

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030 - 31379	13-03459-03	11/29/18

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	Robert G. Gattone, Jr.	Robert G. Gattone, Jr.	11/29/18
BRANCH CHIEF	Anthony T. McCraw		12/14/18

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
St. Mary Medical Center - Hobart 1500 S Lake Park Ave., Hobart, IN and 300 W 61st. Ave., Hobart, IN REPORT NUMBER(S) 2018001	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
030-31379	13-03459-03	11/29/18

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87132	02.01, 02.02, 02.04, 02.05, 02.06, 02.07, 02.09

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02240	2	Santosh K. Kar, M.S., RSO	(815) 370-6538

☑ Main Office Inspection Next Inspection Date: 11/29/2020

☐ Field Office Inspection 300 W 61st. Ave., Hobart, IN

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced, routine inspection. At the time of the inspection, seven full-time nuclear medicine technologists performed approximately 10 to 12 diagnostic administrations per day, and approximately two therapeutic administrations of I-131 capsules per month. The licensee retained the services of a medical physics consultant to review the content and implementation of the program quarterly, and maintained a Radiation Safety Committee, which also met quarterly.

Performance Observations

The inspector: (1) observed that licensed material was secured as required; (2) observed a nuclear medicine technologist (NMT) properly administer iodine-123 to a patient for a thyroid uptake test and a thyroid scan; (3) observed an NMT wearing whole body and extremity dosimeter badges while handling licensed material; (4) noted that there were no Y-90 SIR-Spheres administrations during the inspection; (5) noted that the licensee used technetium-99m macroaggregated albumin to conduct a liver to lung shunting test prior to administering Y-90 SIR-Spheres; (6) reviewed applicable records and interviewed applicable staff regarding Y-90 SIR-Spheres administrations; (7) noted that the licensee conducted ambient exposure rate surveys of patients post Y-90 SIR-Spheres administration; (8) noted that the licensee conducted proper ambient exposure rate surveys of applicable materials to determine the amount of Y-90 SIR-Spheres that was administered to the patient; (9) noted that there was no 10 CFR 35.300 use during the inspection but the inspector reviewed applicable records of 35.300 use; (10) followed up on the licensee's contact with the NRC Region III Office on August 18, 2016, concerning a potential medical event at the hospital involving a patient getting 35 mCi Tc-99m MDP instead of the intended non-nuclear bone densitometry test and the inspector noted that the patient actually received 25.5 mCi Tc-99m MDP and the inspector used the proper Tc-99m-MDP package insert to determine that there was no medical event because the patient did not receive 5 rem to the whole body nor 50 rem to an organ or tissue; (11) noted that the licensee conducted a root cause analysis for preventing the aforementioned 25.5 mCi Tc-99m MDP incident, and implemented actions to prevent similar occurrences; and (12) reviewed dosimeter badge records for 2015-2018 to date, and the annual highest whole body and extremities doses were 321 millirem, and 2690 mrem, respectively.

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