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
Munson Medical Center 1105 Sixth Street Traverse City, MI 49684 REPORT NUMBER(S) 16-001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Rd, Suite 210 Lisle, IL 60532

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-02074	21-08317-01	March 29, 30, 2016

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 Sulaiman	3/30/16
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB		4/8/16

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(07-2012)
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U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02230	2	Dennis J. Aurand M.S., RSO	(231) 935-7100

☑ Main Office Inspection Next Inspection Date: 03/30/2018

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine inspection of a large medical institution (390+ bed hospital) authorized under NRC license to use byproduct materials for medical uses permitted by 10 CFR 35.100, 35.200, 35.300, 35.400, 35.600, and 35.1000. The nuclear medicine department was staffed with five full-time nuclear medicine technologists (NMT) and two PRNs who performed approximately 200 diagnostic nuclear medicine procedures monthly. The licensee received unit doses, bulk Tc-99m, and I-131 in capsule form from a licensed radiopharmacy. Doses were primarily Tc-99m for cardiac, bone scan, thyroid, MUGA, lung scan using Xe-133, gastric emptying, and other studies. The nuclear medicine department performed approximately 60 I-131 hyperthyroid and thyroid ablation treatments annually. The department performed approximately 10 Ra-223 Xofigo treatments per year. The licensee conducted the first Y-90 TheraSphere treatment on January 21, 2015, since then, a total of 12 patients were treated by the time of inspection. The licensee submitted an amendment request on Jan 20, 2016, to add Traverse Heart and Vascular, license# 21-26531-01 as one of the additional use sites for Munson Medical Center with concurrent termination of Traverse Heart and Vascular license.

The radiation oncology department was staffed with four oncologists, and three authorized medical physicists (AMP). The licensee conducted approximately 30-40 I-125/Pd-103 permanent prostate implants annually. The licensee conducted approximately 80 high dose-rate brachytherapy (HDR) patient treatments per year. The majority of treatments conducted were for gynecological and prostate cancers. The licensee moved the HDR unit from the old cancer center building to the Linac room at the main hospital. The licensee is remodeling the Linac room for HDR treatments only. The HDR source was removed from the unit and stored in the long-term storage, ready to be shipped back to the manufacturer. The licensee expected to receive the HDR source by April 5, 2016. The licensee performed 10-12 cases of IVBT coronary in-stent restenosis per year using Sr-90.

Performance Observations:

The inspector observed administrations of Tc-99m diagnostic dose for bone scan and cardiac stress to a patient, and an administration of I-131 hyperthyroid treatment in a capsule form. The inspection consisted of interviews with select licensee personnel; review of select records; tours of the nuclear medicine department and cancer center facility; and independent measurements. 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 dose calibrator constancy check, package receiving and check-in procedures, the end of the day daily and weekly area surveys, and proper handling of radioactive waste

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(Continued)

and disposal procedures. The inspector reviewed radiation safety committee minutes, program audits conducted by an outside consultant every quarter, and leak test report, with no findings. The inspector reviewed Y-90 TheraSphere treatment written directives, authorized user (AU) and AMP manufacturer training completion certificate, and the treatment plans, with no issues noted. The inspector had the AMP demonstrate the HDR unit's: (1) security of licensed material; (2) daily spot checks with dummy source only; (3) emergency equipment and procedures; (4) safety procedures and instructions; (5) door interlock system; and (6) radiation monitoring equipment. The inspector reviewed 9 IVBT, 12 manual brachytherapy and 5 HDR treatment written directives and treatment plans, with no issues noted. The inspector reviewed dosimetry records for 2014 and 2015, indicating the maximum annual dose to be 311 mrem - DDE, and 2480 mrem - SDE, and performed independent radiation measurements of the hot lab, imaging, and stress room areas that were consistent with the licensee's survey results and within regulatory limits.

No violations of NRC requirements were identified during this inspection.