

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

McLaren Northern Michigan
416 Connable Avenue
Petoskey, MI 49770

REPORT NUMBER(S) 2015-001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-11715

4. LICENSE NUMBER(S)

21-16732-01

5. DATE(S) OF INSPECTION

August 26th, 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:

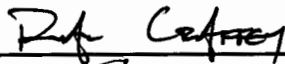

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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	Ryan Craffey		8/26/15
BRANCH CHIEF	Aaron McCraw		8/28/15

Docket File Information

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3. DOCKET NUMBER(S) 030-11715	4. LICENSE NUMBER(S) 21-16732-01	5. DATE(S) OF INSPECTION August 26, 2015
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6. INSPECTION PROCEDURES USED 87131, 87132	7. INSPECTION FOCUS AREAS All
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02230	2. PRIORITY 2	3. LICENSEE CONTACT Daniel Dryden, MS - RSO	4. TELEPHONE NUMBER (231) 487-4264
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Main Office Inspection Next Inspection Date: 08/26/2017

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced routine inspection of a community hospital authorized to perform diagnostic and therapeutic administrations of radiopharmaceuticals, manual brachytherapy, and fractionated HDR treatments at its facility in Petoskey, Michigan. The licensee was also authorized to perform diagnostic and therapeutic administrations at a hospital it recently purchased in Cheboygan, Michigan. At the time of the inspection, the licensee had temporarily ceased licensed activities there, but was planning to resume them in Fall 2015. At the nuclear medicine department in Petoskey, the licensee performed around ten diagnostic administrations per day, and approximately two therapeutic administrations of I-131 per month. The licensee had also administered three courses of Xofigo since beginning them in July 2014. At the oncology department in Petoskey, the licensee performed around a dozen prostate seed implants per year, but only two so far in 2015. The licensee had not yet installed an HDR unit since receiving authorization to do so in July 2015. However, the licensee did anticipate installation to begin in mid-September 2015, and for treatments to begin shortly thereafter.

PERFORMANCE OBSERVATIONS: The inspector toured the nuclear medicine department, radiation oncology hot lab, and future HDR vault to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector conducted independent surveys of these areas, and found no exposures to members of the public distinguishable from background. The inspector observed the preparation and administration of a gastric emptying study and cardiac stress test, as well as the receipt of packages containing licensed material. The inspector verified the licensee's inventory of temporary implant brachytherapy seeds, and observed demonstrations by licensee staff of the implementation of various procedures, including treatment planning and verification for permanent implant brachytherapy. The inspector discussed the licensee's preparations for future use of HDR with the RSO, and reviewed a selection of written directives and treatment plans for prostate seeds, I-131 and Xofigo, in addition to routine nuclear medicine records, RSC meeting minutes, consultant audits, training and dosimetry.

The license was previously cited for violations relating to the administration of a therapeutic dose which was greater than 20% of the prescribed dose. The inspector reviewed the licensee's corrective actions, which appeared to be adequate, and found the violations to be non-recurring. Therefore, the NRC considers both of these violations to be closed. No other violations of NRC requirements were identified as a result of this inspection.