

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

<p>1. LICENSEE/LOCATION INSPECTED:</p> <p>McLaren Medical Center Bay Region Nuclear Medicine 1900 Columbus Avenue Bay City, MI 48708</p> <p>REPORT NUMBER(S) 2017001</p>	<p>2. NRC/REGIONAL OFFICE</p> <p>Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352</p>	
<p>3. DOCKET NUMBER(S)</p> <p>030-13900</p>	<p>4. LICENSE NUMBER(S)</p> <p>21-18585-01</p>	<p>5. DATE(S) OF INSPECTION</p> <p>March 21, 2017</p>

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):

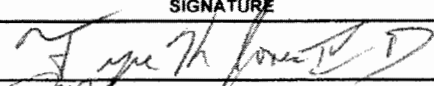

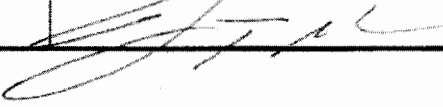
- 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Contrary to Title 10 of the Code of Federal Regulations (CFR) 71.5(a) and 49 CFR 172.702, from 2012 to March 21, 2017, the licensee failed to provide recurrent training at least once every three years for a hazmat employee that satisfied the requirements in Subpart H to 49 CFR 172.704(c)(2). Specifically, one nuclear medicine technologist (NMT) was not provided recurrent hazmat training since August 27, 2012 - a period greater than three years.

The cause of the violation was an isolated oversight on the part of the licensee. As corrective action, the NMT completed the training on March 22, 2017, and is aware of the requirement to have hazmat training every three years.

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	Tyre Kenneth Jones II		4/14/17
NRC INSPECTOR	Luis Nieves Folch		4/3/17
BRANCH CHIEF	Aaron T. McCraw		4/3/17

Nieves Folch, Luis

From: Nieves Folch, Luis
Sent: Monday, April 03, 2017 11:47 AM
To: 'tyrejonesmd@icloud.com'
Subject: NRC 591 Report
Attachments: image2017-04-03-123753.pdf

Dear Mr. Jones,

This email is to send you with a copy of the inspection report done for the inspection conducted from March 21, 2017. The results of the inspections was one severity level IV violations as discuss during the exit meeting over the phone. You are required to sign the report next to the space that says Licensees Representative as acknowledgment and receipt of this report and send it back to me at this email address, after that no further actions are required on your part.

In accordance with Title 10 of the Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Please feel free to contact me if you have any questions, or if there is anything else we at the NRC can do to assist you.

Luis Nieves
Health Physicist
US Nuclear Regulatory Commission
Materials Inspection Branch, Region III
(630) 829-9571

Docket File Information

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6. INSPECTION PROCEDURES USED 87132	7. INSPECTION FOCUS AREAS 03.01-03.08
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02230	2. PRIORITY 2	3. LICENSEE CONTACT Tyre K. Jones, IV, M.D., RSO	4. TELEPHONE NUMBER (989) 667-6675
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Main Office Inspection Next Inspection Date: March 21, 2019

Field Office Inspection Midland Road, Bay City

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced, routine inspection of a local hospital authorized to use byproduct material under 10 CFR 35.100, 200, 300, 400, 600, and Y-90 in Bay City, Michigan. At the time of the inspection, the licensee performed a full spectrum of diagnostic nuclear medicine studies at its main facility and HDR treatments at the Midland Road location. The licensee performed 23 therapeutic administrations of I-131 and Xofigo in 2016, and 15 in 2017. The licensee's radiation oncology department performed 75 gynecological HDR fractions in 2016 and four prostate seed implants in 2016 and 2017. No Y-90 treatments have been performed since they added it to their license. The licensee retained the services of a medical physics consultant to perform quarterly audits.

PERFORMANCE OBSERVATIONS

The inspector toured the nuclear medicine department to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector observed the preparation and administration two cardiac rest studies using Tc-99m. The inspector conducted independent and confirmatory surveys and found no residual contamination or exposures to members of public in excess of regulatory limits. The technologists on staff demonstrated implementation of procedures for package receipt; administration of I-131 therapies, including patient release evaluation; area surveys; and waste handling. The licensee also demonstrated HDR daily checks and brachytherapy treatment planning and verification. Through these demonstrations and other discussions, the licensee's staff demonstrated adequate knowledge of radiation protection principles, licensee procedures, and NRC requirements. The inspector reviewed the licensee's records for the administration of byproduct material requiring a written directive, including several I-131 and Xofigo therapies, as well as a selection of HDR and brachytherapy treatments, performed since the last inspection. The inspector also reviewed a selection of nuclear medicine records, dosimetry, and quarterly audits.

One violation of NRC requirements were identified as a result of this inspection, as included in Part 1.