

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: McLaren Cardiovascular Institute Waterford 5220 Highland Rd. Waterford, MI 48328 REPORT NUMBER(S) 2018001	2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
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3. DOCKET NUMBER(S) 030-39060	4. LICENSE NUMBER(S) 21-35436-01	5. DATE(S) OF INSPECTION March 9, 2018
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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:

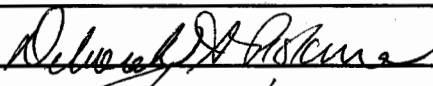
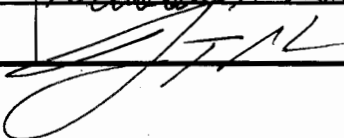
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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	Deborah A. Piskura, Senior Health Physicist		3/9/18
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB		3/13/18

Docket File Information

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6. INSPECTION PROCEDURES USED 87130	7. INSPECTION FOCUS AREAS 03.01 - 03.07
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02201	2. PRIORITY 5	3. LICENSEE CONTACT Adam Schwaderer, M.D., RSO	4. TELEPHONE NUMBER (810) 667-7322
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Main Office Inspection Next Inspection Date: March 9, 2023

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an initial inspection of an out-patient clinic authorized to use byproduct material in 10 CFR 35.100 and 35.200. The clinic initialed its licensed activities on 11/29/2017, with the receipt of calibration and reference sources. The clinic started imaging patient cases on 12/13/2017.

The licensee staffed its nuclear medicine department with one part-time technologist who performed studies on Fridays. The department administered approximately 30-40 patient studies per month, limited to cardiac procedures. The licensee received its material in unit dose form from a licensed radiopharmacy. The clinic retained the services of a consultant who will perform quarterly audits of the radiation safety program (first audit scheduled for the week of 3/26/2018).

This inspection consisted of interviews with licensee personnel, a review of selected records, a tour of the nuclear medicine department, and independent measurements. The inspection included observations of dose calibrator QA checks, security of licensed material, inventories of sealed sources, and use of personnel monitoring.

No violations of NRC requirements were identified during this inspection.