

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

McLaren - Flint
401 South Ballenger Highway
Flint, MI 48532

REPORT NUMBER(S) 2016-001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-02048

4. LICENSE NUMBER(S)

21-04171-04

5. DATE(S) OF INSPECTION

APRIL 26 & 27, 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:


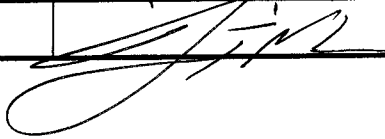
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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		4/27/16
BRANCH CHIEF	Aaron McCraw		5/2/16

Docket File Information

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1. LICENSEE/LOCATION INSPECTED: McLaren - Flint 401 South Ballenger Highway Flint, MI 48532 REPORT NUMBER(S) 2016-001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S) 030-02048	4. LICENSE NUMBER(S) 21-04171-04	5. DATE(S) OF INSPECTION April 26-27, 2016	
6. INSPECTION PROCEDURES USED 87131, 87132	7. INSPECTION FOCUS AREAS All		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02230	2. PRIORITY 2	3. LICENSEE CONTACT Christopher Conlin, MD - RSO	4. TELEPHONE NUMBER (810) 342-3830
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- ☒ Main Office Inspection Next Inspection Date: 04/26/2018
- ☒ Field Office Inspection 4100 Beecher Rd. & 501 S. Ballenger Hwy.
- ☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced routine inspection of a tertiary teaching hospital authorized to use byproduct material for medical purposes at three adjacent facilities in Flint, Michigan. At the time of the inspection, the main hospital's nuclear medicine department performed 5-10 diagnostic administrations per day and occasional I-131 whole-body scans requiring a written directive. The licensee's outpatient imaging center also maintained a nuclear medicine lab, which performed three to four diagnostic administrations each weekday except Thursdays. The licensee's cancer center performed HDR treatments primarily for skin cancers (2-3 fractions daily), I-131 capsule administrations primarily for thyroid carcinomas (1-2 per month), Ra-223 Xofigo administrations (12 courses since July 2013), as well as occasional Y-90 Zevalin administrations and permanent implant brachytherapy treatments. The licensee's RSO was a physician who practiced at the main hospital and the imaging center. The licensee retained the services of a medical physics consultant to audit various aspects of the radiation safety program, and maintained an RSC, which met quarterly.

PERFORMANCE OBSERVATIONS: The inspector toured all three facilities in Flint to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector conducted independent and confirmatory surveys of these facilities, and found no residual contamination or exposures to members of the public in excess of regulatory limits. The inspector observed the administration of one HDR fraction for a skin cancer treatment, several cardiac stress tests at the main hospital and one HIDA scan at the imaging center. The inspector also observed the conduct of HDR spot checks and the receipt of packages containing byproduct material. The licensee's staff demonstrate or discussed implementation of procedures for area surveys, spill response, radioactive waste handling, admission of I-131 in-patients, and monthly/annual HDR equipment checks. Through these observations and discussions the inspector found the licensee's staff to be knowledgeable of radiation protection principles, standard operating procedures, and regulatory requirements.

The inspector reviewed a selection of relevant records, including written directives, treatment plans and verifications for all therapeutic modalities, documentation of various HDR equipment checks and source exchanges, routine nuclear medicine records, personnel training documentation and dosimetry reports, consultant audits and RSC meeting minutes.

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