

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Mount Clemens Regional Medical Center
d/b/a McLaren Macomb
1000 Harrington Blvd.
Mount Clemens, MI 48043

REPORT NUMBER(S) 2018001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-02040

4. LICENSE NUMBER(S)

21-04080-01

5. DATE(S) OF INSPECTION

March 8, 2018

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:

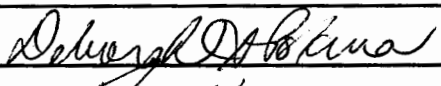
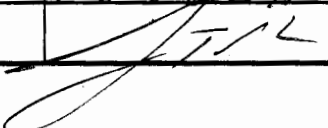
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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		3/8/18
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB		3/14/18

Docket File Information

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6. INSPECTION PROCEDURES USED

87130, 87131, & 87132

7. INSPECTION FOCUS AREAS

03.01 - 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02230

2. PRIORITY

2

3. LICENSEE CONTACT

Arthur Frazier, M.D., RSO

4. TELEPHONE NUMBER

(586) 493-7510

- ☒ Main Office Inspection Next Inspection Date: March 8, 2020
- ☒ Field Office Inspection Ted B Wahby Cancer Center, Mt. Clemens, MI
- ☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was routine inspection of a large hospital authorized to use licensed material permitted by 10 CFR 35.100, 35.200, 35.300, 35.400 (limited to permanent prostate implants) and Ir-192 in an HDR unit. Nuclear medicine studies were performed daily. The nuclear medicine department was staffed with four FT and 2 PT technologists who performed approximately 325-350 diagnostic procedures per month. The licensee received unit doses and bulk Tc-99m for kit preparation; the department administered a full spectrum of diagnostic studies. The hospital maintained an active therapeutic radiopharmaceutical program including I-131 and Ra-223 treatments.

Radiation therapy activities were performed at the main hospital and the Clarkston center. The radiation oncology department was staffed with 3 AMPs, and 4 authorized physician users. The licensee administered approximately 200-250 patient treatments annually utilizing its HDR. These treatments included a variety of cancer cases. All HDR patient treatments were administered by the attending radiation oncologist and the AMP. Service, maintenance, and source exchanges were performed by the HDR device manufacturer. The department also administered I-125 permanent prostate implants (10-15 cases/year). The licensee filed an amendment request (pending) to add Y-90 microspheres.

This inspection consisted of interviews with selected licensee personnel; a review of selected records; tours of the nuclear medicine and radiation oncology departments; and independent measurements. The inspector observed the licensee staff receive and survey packages, perform dose calibrator QA checks, and administer several diagnostic dosages. The inspector reviewed the patients' written directives and the treatment plans for several I-125 implants and HDR treatments. The inspection included observations of HDR safety checks, security of byproduct material, use of personnel monitoring, and postings.

No violations of NRC requirements were identified during this inspection.