

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Michigan Institute of Urology, P.C.
130 Town Center
Suite 101
Troy, MI 48084

REPORT NUMBER(S) 2017001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-38895

4. LICENSE NUMBER(S)

21-32348-02

5. DATE(S) OF INSPECTION

January 10, 2017

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:

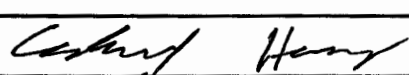
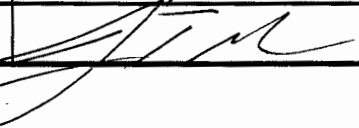
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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	Edward F. Harvey		1/10/17
BRANCH CHIEF	Aaron T. McCraw		1/26/17

Docket File Information

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6. INSPECTION PROCEDURES USED

87131

7. INSPECTION FOCUS AREAS

All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02200

2. PRIORITY

3

3. LICENSEE CONTACT

Bonnie Greenblatt

4. TELEPHONE NUMBER

(248) 740-0670

- ☒ Main Office Inspection Next Inspection Date: January 10, 2020
- ☐ Field Office Inspection _____
- ☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an announced, initial inspection of a private urology clinic authorized to use byproduct materials for therapeutic medical procedures under 10 CFR 35.300. The licensee performed approximately 2-4 radium-223 Xofigo administrations per week for prostate metastases. The licensee employed one part-time nuclear medicine technologist that worked Tuesday mornings only.

The inspector observed nuclear medicine staff demonstrate package receipt and surveying procedures, daily dose calibrator constancy checks, daily surveys, and waste disposal procedures. In addition, the inspector observed three administrations of radium-223. The inspector noted that both the NMT and Authorized User wore appropriate personal protective equipment, assayed the doses, and verified patient identity prior to administering the doses. The nuclear medicine staff also demonstrated adequate knowledge of radiation protection principles and emergency procedures in the event of a spill through interviews with the inspector.

The inspector reviewed a selection of licensee records, including written directives, dose calibrator linearity records, dose calibrator accuracy records, dose calibrator geometry records, source inventories, survey meter calibration records, package receipt logs, and dosimetry with no issues noted. In addition, the inspector performed independent surveys, which revealed no readings that would indicate residual contamination or exposures to members of the public in excess of regulatory limits.

No violations were identified during this inspection.