NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Michigan Institute of Urology 130 Town Center Drive, Suite 101 Troy, MI 48084 REPORT NUMBER(S) 2019001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-38895	21-32348-02	September 24, 2019

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 violations(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	Ryan Craffey	9/24/19
BRANCH CHIEF	Robert Ruiz, Acting Chief Geoffrey Warren for RR		10/16/19

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Michigan Institute of Urology 130 Town Center Drive, Suite 101 Troy, MI 48084 REPORT NUMBER(S) 2019001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-38895	21-32348-02	September 24, 2019

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131	All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02200	3	Colin Stoneberg - RSO	(888) 456-5255

☑ Main Office Inspection Next Inspection Date: 09/24/2022

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced routine inspection of a private medical practice authorized to use byproduct material for therapeutic medical purposes at its facility in Troy, Michigan. At the time of the inspection, one part-time nuclear medicine technologist performed around thirty administrations of Ra-223 dichloride per year using unit doses shipped from a licensed radiopharmacy. The licensee typically scheduled these administrations for Tuesday afternoons starting around 3:30 pm, though sometimes scheduled them for Wednesday afternoons instead. The licensee retained the services of a medical physics consultant, who performed quarterly audits of the program and served as RSO.

PERFORMANCE OBSERVATIONS: The inspector toured the facility in Troy to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector performed independent surveys of the facility, and found no evidence of residual contamination or exposures to members of the public in excess of regulatory limits. The inspector observed the preparation and administration of two doses of Ra-223 dichloride, noting the use of adequate ALARA practices throughout. The inspector interviewed the technologist and primary AU and found them to be knowledgeable of radiation protection principles and regulatory requirements for the safe use of radioactive material. The inspector also reviewed a selection of records, including written directives and treatment verification documentation, consultant audits, instrument calibration and quality control records, sealed source inventory and leak test results, area and package survey records, annual radiation safety and hazmat training materials, and personnel dosimetry reports, which indicated that occupational exposures from these licensed activities were well below regulatory limits.

The inspector noted that in several instances, the licensee's administrative staff had incorrectly prepared treatment verification documentation which suggested that millicurie quantities of Ra-223 had been administered. The inspector confirmed that all written directives completed since the last inspection correctly identified that microcurie quantities of Ra-223 were to be administered, and that the totality of the licensee's documentation for each administration still provided high confidence that all treatments had been performed in accordance with the written directive. The inspector discussed these minor discrepancies with the licensee's administrative staff, who then promptly reviewed and revised all treatment form templates to ensure that the correct units were typed in all spaces where a value for activity was to be written. No violations of regulatory requirements were identified as a result of this inspection.