

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Urology of Indiana, LLC
8902 N. Meridian Street, Suite 104
Indianapolis, Indiana 46260

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)

030-38845

4. LICENSE NUMBER(S)

13-35249-01

5. DATE(S) OF INSPECTION

May 26, 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:

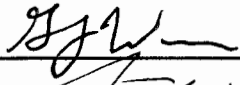
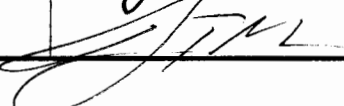
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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	Geoffrey M. Warren		5/26/16
BRANCH CHIEF	Aaron T. McCraw		6/3/16

(07-2012)
10 CFR 2.201**Docket File Information****SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

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8902 N. Meridian Street, Suite 104
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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)

030-38845

4. LICENSE NUMBER(S)

13-35249-01

5. DATE(S) OF INSPECTION

May 26, 2016

6. INSPECTION PROCEDURES USED

87131

7. INSPECTION FOCUS AREAS

03.01 - 03.09

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02200

2. PRIORITY

3

3. LICENSEE CONTACT

Leia Fanelli, Medical Physicist

4. TELEPHONE NUMBER

(317) 853-4500

☒ Main Office Inspection

Next Inspection Date: May 2019

☐ Field Office Inspection☐ Temporary Job Site Inspection**PROGRAM SCOPE**

This was the initial inspection of this license. The licensee was a urology company located in Indianapolis, Indiana, with authorization to use radium-223 under 10 CFR 35.300. The licensee rented space for this activity at a facility run by Integrated Cancer Care. Licensed activities were conducted only at the location indicated on the license. The clinic was staffed with one physicist who performed licensed activities. The physicist typically administered two to five therapeutic procedures using radium-223 chloride, one day each month. The licensee received unit doses as needed from a licensed nuclear pharmacy. All waste was held for decay-in-storage (DIS). The first procedures were performed under this license in February 2016.

Performance Observations: The inspector toured the licensee's facility and determined it was consistent with the map provided to the NRC. No licensed activities were performed during the inspection. The physicist demonstrated morning checks, package receipt and return surveys and wipes, dose preparation, administration, and disposal, and daily area surveys and wipes, and described waste tracking and emergency procedures. The inspector noted no concerns with these activities. The inspector reviewed written directives for radium-223 chloride therapies and identified no concerns. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Dosimetry records indicated no exposures of regulatory concern. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

No violations were identified during this inspection.