

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

American Oncologic Associates of Michigan, P.C.
d/b/a 21st Century Oncology of Michigan
70 Fulton Street
Pontiac, MI 48341

REPORT NUMBER(S) 2015-001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-33134

4. LICENSE NUMBER(S)

21-26488-01

5. DATE(S) OF INSPECTION

FEBRUARY 26TH, 2015

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:

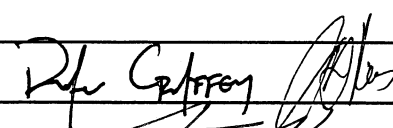
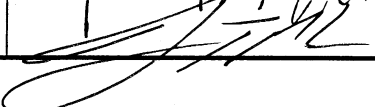
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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 / Luis Nieves		2/26/15
BRANCH CHIEF	Aaron McCraw		3/12/15

Docket File Information

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3. DOCKET NUMBER(S) 030-33134	4. LICENSE NUMBER(S) 21-26488-01	5. DATE(S) OF INSPECTION February 26, 2015
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 Jeffrey D. Forman, MD - RSO	4. TELEPHONE NUMBER (248) 338-0300
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☒ Main Office Inspection Next Inspection Date: February 2017

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine inspection of a standalone cancer treatment center on the campus of St. Joseph Mercy Oakland (030-02104) in Pontiac, Michigan, with authorization to perform high dose rate remote afterloading brachytherapy and therapeutic administrations of Sm-153 and Ra-223. At the time of the inspection, the licensee performed gynecological HDR procedures, averaging one fraction per week. The licensee had administered one course of Ra-223 Xofigo to date, but had not administered any Sm-153 since before the previous inspection. The licensee's staff also performed brachytherapy services under the St. Joseph Mercy Oakland license. The company's corporate office in Florida performed annual reviews of the content and implementation of the licensee's radiation safety program.

PERFORMANCE OBSERVATIONS

The inspectors toured the Pontiac facility to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector conducted independent surveys of the licensee's facility and found no readings which would indicate residual contamination or exposure to members of the public in excess of regulatory limits. Although no treatments were scheduled while the inspectors were on-site, the licensee's staff were still able to demonstrate implementation of procedures for HDR daily checks, source exchanges, brachytherapy treatment planning, administration and verification, and Ra-223 administration including package receipt and area surveys. Through these demonstrations and other discussions, the licensee's staff demonstrated adequate knowledge of radiation protection principles, licensee procedures and regulatory requirements.

The inspectors reviewed a selection of licensee records for the administration of byproduct material requiring a written directive, including several HDR brachytherapy treatments and the only Ra-223 Xofigo treatment to date. The inspectors also reviewed records relating to the last HDR source exchange, and a selection of dosimetry and audit records.

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