

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) 2017001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Rd, Suite 210 Lisle, IL 60532
3. DOCKET NUMBER(S) 030-33134	4. LICENSE NUMBER(S) 21-26488-01	5. DATE(S) OF INSPECTION May 22, 2017, with final exit on June 1, 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)

1. Title 10 of the Code of Federal Regulations (CFR) Section 35.40(a) requires that written directives must be dated and signed by an authorized user before the administration of any therapeutic dosage of unsealed by product material.

Contrary to the above, on March 31, 2017 and April 7, 2017, two Ra-223 Xofigo written directives (one on each of the aforementioned dates) were not dated and signed by an authorized user (AU) before the administration of Ra-223.

Continued on next page

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	Kimberly Mona	<i>Kimberly Mona</i>	6-15-17
NRC INSPECTOR	Zahid Sulaiman, Health Physicist	<i>Zahid Sulaiman</i>	6/13/17
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB	<i>[Signature]</i>	6/13/17

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(Continued)

2. Title 10 CFR 35.40(b)(2) states, in part, that the written directives for an administration of a therapeutic dosage of unsealed byproduct material must contain the radioactive drug, dosage, and route of administration.

Contrary to the above, on May 6, 2016, March 10, 2017 and April 7, 2017, three Ra-223 Xofigo written directives (one on each of the aforementioned dates) did not contain the route of administration, and on December 9, 2015, one written directive did not contain the dosage.

The root cause was an oversight by the licensee staff to fully complete the written directives. As corrective actions, the licensee modified the current electronic written directive form and separated the written directive section from rest of the medical physics procedures section of the form. The licensee will also train the users on the new workflow with verification of the mandatory signature by the AU and the medical physicist prior to the procedure.

Sulaiman, Zahid

From: Mona, Kimberly K. <Kimberly.Mona@21co.com>
Sent: Thursday, June 15, 2017 2:59 PM
To: Nurushev, Teamour S.; Sulaiman, Zahid
Cc: Mona, Kimberly K.
Subject: [External_Sender] RE: NRC Safety and Compliance Inspection Report - NRC Form 591M - American Oncologic Associates
Attachments: NRC 591M - American Oncologic Associates of Michigan - May 2017- Signed-signed.pdf

Here is the signed letter.

Kim

Kim Mona RN MSN AOCNS
Vice President of Operations
21st Century Oncology
Michigan and Indiana Regions
Phone 313-300-1736
Email Kimberly.mona@21co.com

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Thank you

From: Nurushev, Teamour S.
Sent: Thursday, June 15, 2017 2:01 PM
To: Mona, Kimberly K.
Subject: RE: NRC Safety and Compliance Inspection Report - NRC Form 591M - American Oncologic Associates

Hi Kim,
Have you had a chance to sign the letter?
Thanks,
Tim.

From: Nurushev, Teamour S.
Sent: Tuesday, June 13, 2017 10:30 PM
To: Kestin, Larry L.; Mona, Kimberly K.
Subject: FW: NRC Safety and Compliance Inspection Report - NRC Form 591M - American Oncologic Associates

Hi Guys,
Here is the written inspection report.
Kim, would you mind signing it and getting back to me or directly to the inspector?
Thank you,
Tim.

From: Sulaiman, Zahid [<mailto:Zahid.Sulaiman@nrc.gov>]
Sent: Tuesday, June 13, 2017 3:08 PM
To: Nurushev, Teamour S.
Cc: Sulaiman, Zahid
Subject: NRC Safety and Compliance Inspection Report - NRC Form 591M - American Oncologic Associates

Hi Tim,

Attached is the NRC Safety and Compliance Inspection report - form 591M Part 1 & 2, from the routine inspection that was conducted on May 22, 2017. Please have the management sign the report and return the signed copy to me through email or fax. If you have any question, please feel free to contact me at 630-829-9752.

Thanks

Zahid

Zahid Sulaiman

Health Physicist

US Nuclear Regulatory Commission - Region III

Division of Nuclear Materials Safety

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Lisle, IL 60532

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