NRC FORM 591M
(04-2022)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Report

1. Licensee/Location Inspected:	2. NRC/Regional Office
American Oncologic Associates of Michigan, P.C. d/b/a MHP Radiation Oncology Institute 70 Fulton Street Pontiac, MI 48341 Report Number(s) 2022-001	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
030-33134	21-26488-01	02/28/22 - 09/30/22

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. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.

A. 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, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied.
(Non-cited violation(s) was/were discussed involving the following requirement(s)

B. The following violation(s) is/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)

Contrary to 10 CFR 20.1501(a)(1), on multiple occasions including February 18 and March 7, 2022, American Oncologic Associates of Michigan failed to make surveys to assure compliance with 10 CFR 20.1906(b)(1), which requires monitoring the external surfaces of labeled packages containing quantities of radioactive material in excess of a Type A quantity for radioactive contamination. Specifically, the licensee used an instrument to make these surveys which could not determine whether removable surface contamination below 22,200 dpm exceeded the limits in 10 CFR 71.81(i). As corrective action, the licensee obtained a new instrument which could make this determination and revised its procedure for receiving packages to incorporate its use.

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 AND DATE
LICENSEE'S REPRESENTATIVE	Teamour (Tim) Nurushev	
NRC INSPECTOR	Ryan Craffey	Digitally signed by Ryan J. Craffey Date: 2022.10.17 13:03:52 -04'00'
BRANCH CHIEF	Michael Kunowski	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2022.10.20 05:39:26 -05'00'

Add Continuation Page

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
American Oncologic Associates of MI	030-33134	21-26488-01

4. Report Number(s):	5. Date(s) of Inspection:
2022-001	02/28/22 and 03/08/22; in-office review through 09/30/22

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Ryan Craffey	02230	2	IP 87130, 87132

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Larry Kestin, MD - RSO Teamour Nurushev - AMP	N/A teamour.nurushev@usa.genesiscare.com	248-338-0300 248-410-8011

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial ☑ Routine ☐ Announced ☐ Non-Routine ☑ Unannounced	☑ Main Office ☑ Field Office ☐ Temporary Job Site ☐ Remote	02/28/2024 ☑ Normal ☐ Extended ☐ Reduced ☐ No change

16. Scope and Observations:

American Oncologic Associates of Michigan, P.C., d/b/a MHP Radiation Oncology Institute (formerly 21st Century Oncology) operated a series of cancer treatment centers across the Detroit metropolitan area, with authorized locations of use in Pontiac, Troy, and Madison Heights, Michigan. At the time of the inspection, the licensee performed therapeutic administrations of radiopharmaceuticals (Lu-177 Lutathera and/or Ra-223 Xofigo) at all three locations, as well as HDR treatments in Pontiac and Troy. At the time of the on-site inspection, the licensee used microSelectron HDR units, but by May 2022 had replaced them with Flexitron units.

On February 28, the inspector visited the Pontiac location. All areas were adequately posted, and all licensed material was adequately secured. The inspector performed independent surveys of the HDR unit and the treatment vault during demonstrations of daily spot checks; readings were well below regulatory limits to the public and the unit and all associated equipment were in good condition and functioned as intended. The licensee's staff were knowledgeable of radiation protection principles as well as HDR procedures, and wore personnel dosimetry as assigned. The inspector reviewed a selection of available records including HDR written directives and treatment documentation, source exchange and HDR full calibration documentation, and HDR safety training records.

On March 8, the inspector visited the Troy location. All areas were adequately posted, and all licensed material was adequately secured. The inspector observed the planning and administration of two HDR prostate treatments including daily spot checks, and the preparation and administration of one Lutathera dose. While discussing the latter, the inspector learned that the AMP who received the dose the day prior had used a dose calibrator to check the package for contamination. The AMP said they regularly did so for packages sent to Troy since there was no well counter there, unlike Pontiac and Madison Heights. However, the dose calibrator's minimum resolution of 0.01 microcuries meant that it could not identify contamination on the wipe that was above the regulatory limit of 7,200 dpm (3.2 nanocuries) per 300 square cm but below at least 22,200 dpm (10 nanocuries). This was noted as a SLIV violation of 10 CFR 20.1501(a)(1) for failure to make surveys to assure compliance with 10 CFR 20.1906(b)(1). The root cause was a lack of understanding of licensee procedures for opening packages, which directed staff to use a thin-window GM survey meter to check for contamination. The presence of well counters at the other locations and a high workload for AMPs were contributing factors. As corrective action, the licensee obtained a well counter for Troy and revised its procedure for receiving packages, retiring the survey meter method in favor of using well counters.

During the period of in-office review through September 30, the inspector reviewed additional records not available during the on-site inspection. These included personnel dosimetry reports, documentation of audit activities, and documentation confirming full compliance with requirements for dose measurements and HDR spot checks.