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 St. Pontiac, MI 48341 **Report Number(s)** 2024001	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	5/14 through 6/13/2024

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 20.1906(c) on multiple occasion including October 2023, January 2024, and April 2024, the licensee failed to perform the monitoring required by 10 CFR 20.1906(b) as soon as practical after receipt of the package, but not later than 3 hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours. 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 AND DATE
LICENSEE'S REPRESENTATIVE		
NRC INSPECTOR	Zahid Sulaiman, Health Physicist	Zahid M. Sulaiman Digitally signed by Zahid M. Sulaiman Date: 2024.07.01 12:58:57 -05'00'
BRANCH CHIEF	Rhex Edwards, Chief, MIB	Digitally signed by RHEX EDWARDS Date: 2024.07.01 13:42:23 -05'00'

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Materials Inspection Report (Continued)

As corrective action, the licensee promptly revised the package receipt procedure to comply with NRC requirements and will provide training to ensure timely package surveys.

NRC FORM 592M
(10-04-2022)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

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

4. Report Number(s):	5. Date(s) of Inspection:
2024-001	5/14/2024 with in-office review through 6/13/2024

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Zahid Sulaiman, HP, Mary Casto, HP	02230	2	87131, 87132

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Larry Kestin, RSO Bryce Murray, AMP	lkestin@mhpdoctor.com bmurray@mhpdoctor.com	248-553-0606 ext 1210 208-313-5466

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial ☑ Routine ☐ Announced ☐ Non-Routine ☑ Unannounced	☐ Hybrid ☑ Main Office ☑ Field Office ☐ Temporary Job Site ☐ Remote	05/14/2026 ☑ Normal ☐ Extended ☐ Reduced ☐ No change

16. Location(s) Inspected List:
Pontiac Facility: 70 Fulton St., Pontiac, MI 48341
Troy Facility: 4550 Investment Dr., #B111, Troy, MI 48098.

17. Scope and Observations:
This was an unannounced, routine inspection of the radiation oncology clinic with three authorized locations of use in Pontiac, Troy, and Madison Heights, Michigan. The licensee was authorized to perform therapeutic administrations of radiopharmaceuticals (Lu-177, Lutathera and/or Ra-223, Xofigo) under 10 CFR 35.300 at all three locations and high dose rate remote afterloader (HDR) brachytherapy under 10 CFR 35.600 at Pontiac and Troy, Michigan facilities. The licensee was staffed with a full-time oncologist, a dosimetrist, and an authorized medical physicist (AMP) at each location. At the Pontiac location, the licensee conducted about 20 HDR gynecological, breast, and superficial skin cancer treatments annually, no HDR procedures had been performed since September 2023.
At the Troy facility, the licensee conducted about 90 HDR prostate, gynecological, and superficial skin cancer treatments annually. The licensee was staffed with a full-time nuclear medicine technologist (NMT) who performed about 10-12 Lu-177 therapeutic treatments monthly and 1-2 Ra-223 Xofigo treatments annually. The licensee plans to conduct research studies using Pb-212 and/or Ac-225 for neuro-endocrine tumors under 10 CFR 35.300.

Performance Observation:
This inspection consisted of a tour of the oncology department; hotlab; interviews with select licensee personnel; review of select records; observation of security of the materials; and independent measurements. At the Troy, Michigan, facility, the inspectors observed a HDR treatment planning, approval, and completion of a prostate procedure. The inspectors had the NMT conduct a physical inventory of sealed sources, and all sources were accounted for. The inspectors had the NMT demonstrate the dose calibrator constancy check, package receipt procedures, the end of the day daily and weekly area surveys, and proper handling of radioactive waste and disposal procedures with no issue noted. The NMT described the Lu-177 administration procedures and setup of the designated Lu-177 therapeutic administration suite. The inspectors performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

The inspectors had the AMP demonstrate the HDR unit's: (1) security, (2) daily spot checks, (3) emergency equipment and response procedures, (4) safety procedures and instructions, (5) door interlock system, and (6)

Materials Inspection Record (Continued)

radiation monitoring equipment checks. The inspectors reviewed select Lu-177, Ra-223, and HDR written directives and treatment plans. Through these demonstrations, observations, and other discussions, the inspector found that the licensee personnel were knowledgeable of radiation protection principles, licensee procedures, and regulatory requirements.

The inspectors reviewed the following records: annual radiation protection program audits (last audit 4/30/2024); radiation safety committee minutes; quarterly program audits; package receipts; waste disposal records; DOT Hazmat training; constancy, linearity, and accuracy of the dose calibrator; instrument calibration; sealed source leak tests and inventory; daily area surveys; and weekly wipe tests. The inspector reviewed dosimetry records for 2023 through April 30, 2024, the doses were within the regulatory limits.

The inspectors identified a SLIV violation of 10 CFR 20.1906(c) related to the monitoring of a high-dose-rate (HDR) sealed source package. The licensee failed to conduct the required package survey within 3 hours of receiving the package on multiple occasions (including October 2023, January 2024, and April 2024). Instead of conducting the survey promptly, the staff stored the package in a storage cabinet, awaiting the HDR manufacturer engineer's survey during source exchange. As corrective action, the licensee promptly revised the package receipt procedure to comply with NRC requirements and will provide training to ensure timely package surveys.

Signature and Date - Branch Chief

Digitally signed by RHEX EDWARDS
Date: 2024.07.01 13:41:52 -05'00'