



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

July 03, 2025

Michael Ray Hart, PharmD
Radiation Safety Officer
Advanced Isotopes of Montana
P.O. Box 1261
Manhattan, MT 59741

SUBJECT: ADVANCED ISOTOPES OF MONTANA – ACKNOWLEDGEMENT OF REPLY
TO NRC INSPECTION REPORT 030-39297/2024-001; AND NOTICE OF
VIOLATION

Dear Dr. Hart:

On May 20, 2025, the U.S. Nuclear Regulatory Commission (NRC) cited Advanced Isotopes of Montana, for two violations of NRC requirements involving the failure to: (1) have appropriate policies and procedures to address your license commitments regarding the use of germanium-68/gallium-68 (Ge-68/Ga-68) generators to prepare Ga-68 radiopharmaceuticals; and (2) ensure that hazmat employees were tested by an appropriate means on the training subjects covered in the U.S. Department of Transportation regulations. NRC Inspection Report 030-39297/2024-001 with enclosed Notice of Violation (Notice) required you to reply in writing in 30 days (NRC Agencywide Documents Access and Management System [ADAMS] Accession No. ML25139A082). In a letter dated June 16, 2025, you provided your reply to the Notice (ADAMS Accession No. ML25175A081).

After reviewing the information provided in your reply to the Notice, we have concluded that your completed and proposed corrective actions appear to adequately address the regulatory non-compliances described in the Notice. We will review your implementation of these corrective actions during a future inspection to determine whether full compliance has been restored and whether compliance will be maintained.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

A handwritten signature in black ink, reading "Lizette Roldán-Otero", is placed over a light gray rectangular background.

Signed by Roldan-Otero, Lizette
on 07/03/25

Lizette Roldán-Otero, Ph.D., Chief
Materials Inspection Branch
Division of Radiological Safety and Security

Docket No. 030-39297
License No. 11-35661-01MD

ADVANCED ISOTOPES OF MONTANA – ACKNOWLEDGEMENT OF REPLY TO NRC
INSPECTION REPORT 030-39297/2024-001; AND NOTICE OF VIOLATION – DATED
JULY 03, 2025

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DOCUMENT NAME: ADVANCED ISOTOPES OF MONTANA – ACKNOWLEDGEMENT OF REPLY TO NRC
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ADAMS ACCESSION NUMBER: **ML25183A382**

☒ SUNSI Review: ADAMS: ☐ Non-Publicly Available and Sensitive
By: JFK ☒ Yes ☐ No ☒ Publicly Available and Non-Sensitive

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