



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

November 8, 2023

EA-23-103

Catherine Heyneman
Radiation Safety Officer
Advanced Isotopes of Idaho
P.O. Box 2105
Pocatello, ID 83206

SUBJECT: ADVANCED ISOTOPE OF IDAHO - NRC INSPECTION
REPORT 030-37048/2023-001

Dear Catherine Heyneman:

This letter refers to the limited scope inspection, conducted from March 2, through November 7, 2023, of licensed activities performed at your facility in Idaho Falls, Idaho. The inspection examined activities conducted under your license as they relate to safety and compliance with the U.S. Nuclear Regulatory Commission (NRC) rules and regulations, and with the conditions of your license. Within these areas, the inspection consisted of an examination of selected procedures, representative records, and interviews with personnel. The enclosed inspection report presents the results of this inspection. A final exit meeting was conducted with you on November 7, 2023.

Based on the results of this inspection, one apparent violation was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The apparent violation involves the redistribution of a sealed source to a licensee that exceeded the maximum activity listed on the recipient's license. The circumstances surrounding this apparent violation, the significance of the issue, and the need for lasting and effective corrective action were discussed with you on November 7, 2023.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond in writing to the apparent violations addressed in the inspection report within 30 days of the date of this letter; or (2) request a predecisional enforcement conference (PEC). If a PEC is held, it will be open for public observation and the NRC may issue a press release to announce the time and date of the conference. Please contact Dr. Lizette Roldán-Otero at 817-200-1455 or Lizette.Roldan-Otero@nrc.gov within 10 days of the date of this letter to notify the NRC of your choice to either provide a written response or participate in a PEC. A PEC should be held within 30 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a "Response to an Apparent Violation in NRC Inspection Report 030-37048/2023-001; EA-23-103" and should include: (1) the reason for the apparent violation or, if contested, the basis for disputing the

apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be (or has been) achieved. Your response may reference or include previously docketed correspondence if the correspondence adequately addresses the required response. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction.

Your written response, should you choose to provide one, should be emailed to R4Enforcement@nrc.gov and Lizette.Roldan-Otero@nrc.gov within 30 days of the date of this letter, and hard copies may be sent to: U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, and to Director, Division of Radiological Safety & Security, Region IV, 1600 East Lamar Boulevard, Arlington, TX 76011. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned.

In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing your response (Agencywide Documents Access and Management System (ADAMS) Accession No. ML061240509).

In addition, please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's ADAMS, accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction.

If you have any questions concerning this matter, please contact Dr. Lizette Roldán-Otero of my staff at 817-200-1455.

Sincerely,



Miller, Geoffrey signing on behalf
of Bloomer, Tamara
on 11/08/23

Tamara Bloomer, Director
Division of Radiological Safety & Security

Docket No. 030-37048
License No. 11-29216-01MD

Enclosure:
Inspection Report 030-37048/2023-001

ADVANCED ISOTOPES OF IDAHO - NRC INSPECTION REPORT 030-37048/2023-001 –
 DATED NOVEMBER 8, 2023

DISTRIBUTION:

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VDricks, ORA	AMoreno, CA	MBurgess, NMSS
JGroom, ORA	LWilkins, CA	LRoldan-Otero, DRSS
ARoberts, ORA	JJosey, OEDO	LHowell, DRSS
DCylkowski, ORA	LWardrobe, DRSS	

ADAMS ACCESSION NUMBER: ML23306A249

SUNSI Review: ADAMS: Non-Publicly Available Non-Sensitive Keyword:
 By: JGK Yes No Publicly Available Sensitive NRC-002

OFFICE	RIV:MIB	C:MIB	TL:ACES	RC	OE
NAME	LWardrobe	LRoldan-Otero	JGroom	DCylkowski	DBradley
SIGNATURE	/RA/ E	/RA/ E	/RA/ E	/RA/ E	/RA/ E
DATE	11/06/23	11/05/23	11/06/23	11/06/23	11/08/23
OFFICE	D: DRSS				
NAME	TBloomer				
SIGNATURE	/GMiller for/				
DATE	11/8/2023				

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**U.S. NUCLEAR REGULATORY COMMISSION
REGION IV**

Docket No.: 030-37048

License No.: 11-29216-01MD

Inspection Report No.: 030-37048/2023-001

EA No.: EA-23-103

Licensee: Advanced Isotopes of Idaho

Location Inspected: 4968 Rainbow Lane
Chubbock, ID 83202

Inspection Dates: March 2 through November 7, 2023.

Exit Meeting Date: November 7, 2023

Inspectors: Leonardo Wardrobe
Health Physicist
Materials Inspection Branch

Approved by: Lizette Roldán-Otero, PhD
Chief, Materials Inspection Branch
Division of Radiological Safety & Security

Attachment: Supplemental Inspection Information

Enclosure

EXECUTIVE SUMMARY

Advanced Isotopes of Idaho NRC Inspection Report 030-37048/2023-001

On March 2, 2023, the U.S. Nuclear Regulatory Commission (NRC) began a limited scope inspection of Advanced Isotopes of Idaho (licensee), a distributor of radiopharmaceuticals and re-distributor of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74. The inspector continued the inspection through November 7, 2023, and examined activities conducted under the license through review of procedures and records, and via interviews with licensee personnel.

Program Overview

The NRC license issued to Advanced Isotopes of Idaho, NRC Materials License 11-29216-01MD, authorizes the distribution of radiopharmaceuticals and redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74.

Inspection Findings

One apparent violation was identified during the course of the inspection. Contrary to License Condition 9I of NRC Materials license 11-29216-01MD, the licensee redistributed a sealed source to a licensee and the recipient licensee was not authorized to receive/possess the sealed source.

Corrective Actions

The licensee committed to revising their package receipt procedures to include checking the activity listed on the sealed source certificate and checking against the activity limits on the license of the end user.

REPORT DETAILS

1 Program Overview (Inspection Procedure (IP) 87139)

Advanced Isotopes of Idaho (licensee) is a radiopharmacy, based in Chubbock, ID, authorized under NRC Materials License 11-29216-01MD to distribute radiopharmaceuticals and to redistribute sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74. The licensee provides unit doses of radiopharmaceuticals to nine local hospitals and medical clinics authorized to perform medical administrations using by-product material in accordance with 10 CFR Part 35. The licensee also provides, on occasion, by-product materials to other NRC non-10 CFR Part 35 licensees.

2 Inspection Overview (IP 87139)

2.1 Inspection Scope

On March 2, 2023, the U.S. Nuclear Regulatory Commission (NRC) began a limited scope inspection of the licensee with continued review through November 7, 2023. The inspection scope examined licensed activities and compliance with the NRC regulations and the conditions of the license. The inspection consisted of interviews with licensee personnel and examination of procedures and representative records.

2.2 Background

The licensee is authorized to redistribute sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74. During the inspection of a client of the licensee, it was identified that the licensee shipped a cobalt-57 sealed source with an activity greater than permissible under the Sealed Source & Device Registry (SS&DR) (NR 1235-S-102S). This caused the client of the licensee to be in violation because they exceed the maximum activity per source in accordance their NRC license. Both the SS&DR and clients license limits the activity to 15 millicuries of cobalt-57. The source certificate for the source listed the assayed activity as 17.07 millicuries of cobalt-57. The source was purchased through and redistributed from Advanced Isotopes of Idaho.

3 Observations and Findings (IP 87139)

During the inspection, one apparent violation of NRC requirements was identified.

3.1 Apparent Violation of License Condition 9I of NRC Materials License 11-29216-01MD

License Condition 9I of NRC Materials license 11-29216-01MD, Amendment 12, states, in part, that the licensee is authorized to redistribute sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74 to authorized recipients.

Contrary to the above, on March 19, 2021, the licensee redistributed a sealed source initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74 to an unauthorized recipient. Specifically, the licensee distributed a sealed source that contained 17.07 millicuries of cobalt-57 to a licensee with a license possession limit of a maximum of 15 millicuries of cobalt-57 per source.

The licensee's redistribution of sealed source to a recipient not authorized to receive the licensed material was identified as an apparent violation of License Condition 9I of NRC Materials license 11-29216-01MD. (030-37048/2023-001-01)

4 Corrective Actions

The licensee committed to revising its package receipt procedures to include checking the activity listed on the sealed source certificate and checking against the activity limits on the license of the end user.

5 Exit Meeting Summary

On November 7, 2023, a telephonic exit meeting was conducted with Catherine Heyneman, Radiation Safety Officer of Advanced Isotopes of Idaho. The licensee acknowledged the apparent violation and did not dispute the details presented during the exit meeting.

Supplemental Inspection Information

PARTIAL LIST OF PERSONS CONTACTED

Catherine Heyneman, Radiation Safety Officer

INSPECTION PROCEDURES USED

IP 87127 – Radiopharmacy Programs

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-37048/2023-001-01	AV	Advanced Isotopes redistributed a sealed source to another licensee that exceeded its maximum possession limit
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Closed

None

Discussed

None

LIST OF ACRONYMS USED

10 CFR	Title 10 of the <i>Code of Federal Regulations</i>
ADAMS	Agencywide Documents Access and Management System
AV	Apparent Violation
IP	Inspection Procedure
NRC	U.S. Nuclear Regulatory Commission
PEC	Predecisional Enforcement Conference
RSO	Radiation Safety Officer
SS&DR	Sealed Source and Device Registry