



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

December 4, 2023

EA-23-120

Shahe Bagerdjian
Chief Executive Officer
International Isotopes, Inc.
4137 Commerce Circle
Idaho Falls, ID 83401

SUBJECT: INTERNATIONAL ISOTOPES, INC. - NRC INSPECTION
REPORT 030-35486/2023-003

Dear Shahe Bagerdjian:

This letter refers to the limited scope in-office inspection, conducted from August 15 - 21, 2023, of licensed activities performed by International Isotopes, Inc. 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 records and interviews with the radiation safety officer. The enclosed inspection report presents the results of this inspection. A final exit meeting was conducted with you and John Miller, Radiation Safety Officer, on December 4, 2023.

Based on the results of this inspection, two apparent violations were identified and are 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 two apparent violations involve the failure to import special nuclear materials in accordance with NRC requirements for a general license pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 110, and the failure to receive and transfer special nuclear material in accordance with an authorization in a specific license issued by the NRC pursuant to 10 CFR Part 70. The circumstances surrounding the two apparent violations, the significance of the issues, and the need for lasting and effective corrective actions were discussed with you on December 4, 2023.

Before the NRC makes its enforcement decision, we are providing you an opportunity to 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 Neil O'Keefe, Chief, Materials Licensing Branch, at 817-200-1156 or neil.o'keefe@nrc.gov within 10 days of the date of this letter to notify the NRC of your intended response to participate in a PEC. A PEC should be held within 30 days of the date of this letter.

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.

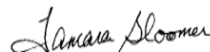
In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation 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 and its enclosure 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>.

If you have any questions concerning this matter, please contact Neil O'Keefe of my staff at 817-200-1156.

Sincerely,



Signed by Bloomer, Tamara
on 12/04/23

Tamara E. Bloomer, Director
Division of Radiological Safety and Security

Docket No. 030-35486
License No. 11-27680-01MD

Enclosure:
Inspection Report 030-35486/2023-003

cc w/Enclosure:
John Miller
Radiation Safety Officer
International Isotopes, Inc.

Rikki Waller
Radiation Control Program Director
Idaho Dept of Health & Welfare
Division of Public Health Bureau of Laboratories
2220 Old Penitentiary Rd Boise, ID 83712-8299

S. Bagerdjian

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Landry Austin
State Liaison Officer
Idaho Department of Environmental Quality
900 North Skyline Drive, Suite B
Idaho Falls, ID 83402

INTERNATIONAL ISOTOPES, INC. - NRC INSPECTION REPORT 030-35486/2023-003 –
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ADAMS ACCESSION NUMBER: ML23299A275

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

OFFICE	RIV:MLB	C:MLB	TL:ACES	RC	OE
NAME	RJTorres	NO'Keefe	JGroom	DCylkowski	DFurst
SIGNATURE	/RA/ E	/RA/ E	/RA/ E	/RA/ E	/RA/ E
DATE	10/23/23	10/24/23	10/23/23	10/31/23	10/31/23
OFFICE	C:ECNB/OIP	OGC	D: DRSS		
NAME	PHabighorst	RAugustus	TBloomer		
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**U.S. NUCLEAR REGULATORY COMMISSION
REGION IV**

Docket No.: 030-35486

License No.: 11-27680-01MD

Inspection Report No.: 030-35486/2023-003

EA No.: EA-23-120

Licensee: International Isotopes, Inc.

Location Inspected: 4137 Commerce Drive
Idaho Falls, ID 83401

Inspection Dates: August 15 through August 21, 2023

Exit Meeting Date: December 4, 2023

Inspectors: Roberto J. Torres
Senior Health Physicist
Materials Licensing Branch
Division of Radiological Safety and Security, Region IV

Andrea Jones
Senior Licensing Officer
Export Controls and Nonproliferation Branch
Office of International Programs

Approved by: Neil O'Keefe
Chief, Materials Licensing Branch
Division of Radiological Safety and Security, Region IV

Peter Habighorst
Chief, Export Controls and Nonproliferation Branch
Office of International Programs

Attachment: Supplemental Inspection Information

Enclosure

EXECUTIVE SUMMARY

International Isotopes, Inc. NRC Inspection Report 030-35486/2023-003

On August 15, 2023, the U.S. Nuclear Regulatory Commission (NRC) began a limited scope in-office inspection of International Isotopes, Inc., a manufacturer and distributor of sealed sources. The inspector continued the inspection through August 21, 2023, and examined activities conducted under the license through review of records and interviews with the radiation safety officer.

Program Overview

The NRC license issued to International Isotopes, Inc., License 11-27680-01MD, authorizes the manufacture and distribution of sealed sources.

Inspection Findings

Two apparent violations were identified and are being considered for escalated enforcement. The two apparent violations involve the failure to import special nuclear materials in accordance with NRC requirements for a general license pursuant to 10 CFR Part 110, and the failure to receive and transfer special nuclear material in accordance with an authorization in a specific license issued by the NRC pursuant to 10 CFR Part 70.

Corrective Actions

The licensee stopped importing, receiving, and transferring calibration and reference sources containing special nuclear material pending NRC approval of a license amendment request that would authorize those activities.

REPORT DETAILS

1 Program Overview (Inspection Procedure (IP) 87125)

International Isotopes, Inc. is authorized under NRC Materials License 11-27680-01MD to manufacture and distribute sealed sources in accordance with the sealed source and device registry for the sealed sources and license conditions listed on the license.

2 Inspection Overview (IP 87125)

On August 15, 2023, the U.S. Nuclear Regulatory Commission (NRC) began a limited scope in-office inspection of International Isotopes, Inc. with continued review through August 21, 2023. The inspection scope examined licensed activities and compliance with the NRC's regulations and the conditions of the license. The inspection consisted of interviews with the radiation safety officer and examination of records.

3 Observations and Findings (IP 87125)

3.1 Observations

During the inspection, two apparent violations of NRC requirements were identified.

3.2 Findings

International Isotopes, Inc. manufactures and distributes sealed sources containing byproduct material intended for use as a reference standard to check the response of dose calibrators used to measure research, diagnostic, and therapeutic radiopharmaceuticals.

During the in-office inspection, the NRC identified that International Isotopes, Inc., imported sealed sources containing special nuclear material without meeting the requirements for a general license as described in 10 CFR 110.5, "Licensing requirements," 10 CFR 110.20, "General license information," and 10 CFR 110.27, "General license for import."

During the in-office inspection, the NRC identified that International Isotopes, Inc., received and transferred sealed sources containing special nuclear material without an authorization in a specific license issued by the NRC pursuant to 10 CFR 70, "Domestic Licensing of Special Nuclear Material."

3.3 Apparent Violation of 10 CFR 110.5

Title 10 CFR 110.5 states, in part, that no person may import any nuclear material listed in 10 CFR 110.9a unless authorized by a general or specific license issued under 10 CFR Part 110.

Title 10 CFR 110.9a(b) includes special nuclear material.

Title 10 CFR 110.20(a) states, in part, that a person may use an NRC general license as an authority to export or import nuclear equipment or material if the nuclear equipment or material to be exported or imported is covered by the NRC general licenses described in 10 CFR 110.21 through 110.27.

Title 10 CFR 110.27(a) states, in part, that a general license is issued to any person to import special nuclear material if the U.S. consignee is authorized to receive and possess the material under the relevant NRC or Agreement State regulations.

Contrary to the above, between March 2 and September 15, 2022, International Isotopes Inc., imported special nuclear material without authorization by a general license issued under 10 CFR Part 110. Specifically, International Isotopes Inc., imported eight plutonium-239 calibration and reference sources ranging in activity from 0.003 microcuries to 0.040 microcuries.

The failure to import plutonium-239, which is special nuclear material, in accordance with the provisions of a general license was identified as an apparent violation of 10 CFR 110.5. (030-35486/2023-003-01)

3.4 Apparent Violation of 10 CFR 70.3

Title 10 CFR 70.3, states, in part, that no person subject to the regulations in 10 CFR Part 70 shall receive or transfer special nuclear material except as authorized in a license issued by the Commission pursuant to these regulations.

Contrary to the above, between March 2 and September 15, 2022, International Isotopes Inc., received and transferred special nuclear material without an authorization in a license issued by the Commission pursuant to 10 CFR Part 70. Specifically, International Isotopes Inc., without authorization under its NRC License Number 11 27680-01MD, received eight plutonium-239 calibration and reference sources ranging in activity from 0.003 microcuries to 0.040 microcuries and then transferred those same eight sources to a government agency.

The failure to receive and transfer plutonium-239, which is special nuclear material, in accordance with the provisions of a specific license was identified as an apparent violation of 10 CFR 70.3. (030-35486/2023-003-02)

4 Corrective Actions

The licensee stopped importing, receiving, and transferring calibration and reference sources containing special nuclear material pending NRC approval of a license amendment request that would authorize those activities.

5 Exit Meeting Summary

On December 4, 2023, a telephonic exit meeting was conducted with Shahe Bagerdjian, President and CEO, and John Miller, Radiation Safety Officer of International Isotopes, Inc. The licensee acknowledged the two apparent violations and did not dispute the details presented during the exit meeting.

Supplemental Inspection Information

PARTIAL LIST OF PERSONS CONTACTED

John Miller, Radiation Safety Officer
Shahe Bagerdjian, President, and CEO

INSPECTION PROCEDURES USED

IP 87125 – Materials Processor/Manufacturer Programs

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-35486/2023-003-01	AV	Failure to import special nuclear material in accordance with the provisions of a general license (10 CFR 110.5)
030-35486/2023-003-02	AV	Failure to receive and transfer special nuclear material in accordance with the provisions of a specific license (10 CFR 70.3)

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