



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

October 5, 2023

EA-23-070

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

SUBJECT: INTERNATIONAL ISOTOPES, INC. - NRC INSPECTION  
REPORT 030-35486/2023-001

Dear Shahe Bagerdjian:

This letter refers to the limited scope inspection, conducted from March 2, 2023, through October 2, 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's (NRC's) 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 and John Miller, Radiation Safety Officer, on October 2, 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 failure to manufacture and distribute a sealed source in accordance with the Sealed Source and Device registry for that sealed source model number and byproduct material combination. 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 October 2, 2023.

Before the NRC makes its enforcement decision, we are providing you an opportunity to:

- (1) respond in writing to the apparent violation addressed in the inspection report within 30 days of the date of this letter;
- (2) request a predecisional enforcement conference (PEC); or
- (3) request alternative dispute resolution (ADR) mediation. 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, Chief, Materials Inspection Branch, at 817-200-1455 or [Lizette.Roldan-Otero@nrc.gov](mailto:Lizette.Roldan-Otero@nrc.gov) within 10 days of the date of this letter to notify the NRC of your intended response to either provide a written response, participate in a PEC, or pursue ADR. A PEC should be held within 30 days and an ADR session within 45 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 030-35486/2023-001; EA-23-070” 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](mailto:R4Enforcement@nrc.gov) and [Lizette.Roldan-Otero@nrc.gov](mailto: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 lieu of a written response or PEC, you may request ADR with the NRC in an attempt to resolve these issues. Alternative dispute resolution is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral mediator works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues.

Additional information concerning the NRC’s program can be obtained at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>. The Institute on Conflict Resolution at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact the Institute on Conflict Resolution at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of these issues through ADR. Alternative dispute resolution sessions are not conducted with public observation though the outcome of the ADR agreement is made public.

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 violation. The guidance in NRC Information Notice 96-28, “Suggested Guidance

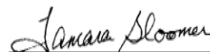
Relating to Development and Implementation of Corrective Action,” may be helpful in preparing your response (Agencywide Documents Access and Management System (ADAMS) Accession No. ML061240509).

In addition, please be advised that the number and characterization of the apparent violation 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,



Signed by Bloomer, Tamara  
on 10/05/23

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

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

Enclosure:  
Inspection Report 030-35486/2023-001

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

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 030-35486/2023-001 –  
 DATED OCTOBER 5, 2023

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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: ML23262B447

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	09/20/23	09/25/23	09/20/23	09/26/23	09/27/23
OFFICE	OGC	D: DRSS			
NAME	RAugustus	TBloomer			
SIGNATURE	/NLO/ E	/RA/			
DATE	09/27/23	10/5/2023			

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

Docket No.: 030-35486

License No.: 11-27680-01MD

Inspection Report No.: 030-35486/2023-001

EA No.: EA-23-070

Licensee: International Isotopes, Inc.

Location Inspected: 4137 Commerce Drive  
Idaho Falls, ID 83401

Inspection Dates: March 2, 2023, through October 2, 2023

Exit Meeting Date: October 2, 2023

Inspector: 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**

### **International Isotopes, Inc. NRC Inspection Report 030-35486/2023-001**

On March 2, 2023, the U.S. Nuclear Regulatory Commission (NRC) began a limited scope inspection of International Isotopes, Inc., a manufacturer and distributor of sealed sources. The inspector continued the inspection through October 2, 2023, and examined activities conducted under the license through review of procedures and records, and interviews with licensee personnel.

#### **Program Overview**

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

#### **Inspection Findings**

One apparent violation was identified and is being considered for escalated enforcement. The apparent violation involves the manufacturing and distribution of a calibration source in excess of the maximum possession limits per the sealed source and device (SS&D) registry.

#### **Corrective Actions**

The licensee committed to revising the manufacturing procedures to include the activity limits for the sealed source model number and byproduct material combination, in accordance with the applicable SS&D registry, in order for the technicians to verify activity limits prior to distribution of the sealed sources.

## REPORT DETAILS

### 1 Program Overview (Inspection Procedure (IP) 87128)

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 (SS&D) registry for the sealed sources and license conditions listed on the license.

### 2 Inspection Overview (IP 87128)

On March 2, 2023, the U.S. Nuclear Regulatory Commission (NRC) began a limited scope inspection of International Isotopes, Inc. with continued review through October 2, 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 licensee personnel and examination of procedures and representative records.

### 3 Observations and Findings (IP 87128)

#### 3.1 Observations

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

#### 3.2 Findings

International Isotopes, Inc. manufactures and distributes cobalt-57 (Co-57) medical reference sealed source intended for use as a reference standard to check the response of dose calibrators used to measure research, diagnostic, and therapeutic radiopharmaceuticals. The SS&D registry associated with the Co-57 sealed source states that the maximum activity allowed is 15 millicurie (mCi).

During the inspection, it was identified that International Isotopes, Inc. manufactured and distributed a sealed source that exceeded the maximum activity specified for the sealed source model number and byproduct material combination (NR-1235-S-102-S, BM06-V5-5715). The source that was manufactured and distributed contained 17.07 mCi of Co-57 and the maximum activity allowed according to the registration certificate was 15 mCi.

#### 3.3 Apparent Violation of 10 CFR 32.210(f)

Title 10 CFR 32.210(f) requires, in part, that the person submitting the request for evaluation and registration of safety information about a sealed source or device containing a sealed source shall manufacture and distribute the product in accordance with the provisions of the registration certificate.

License Condition 9.D of NRC Materials License 11-27680-01MD, Amendment No. 39 states, in part, that in accordance with 10 CFR 32.74, the licensee is authorized to manufacture and distribute sealed sources to persons authorized to receive the licensed material in accordance with the terms and conditions of specific licenses issued by the

U.S. Nuclear Regulatory Commission or under equivalent licenses of any Agreement State, and to persons licensed in accordance with 10 CFR 35 or under equivalent licenses of any Agreement State.

Contrary to the above, on March 18, 2021, the licensee failed to manufacture and distribute a sealed source that was in accordance with the provisions of the registration certificate. Specifically, the licensee manufactured and distributed a sealed source that exceeded the maximum activity specified for the sealed source model number and byproduct material combination (NR-1235-S-102-S, BM06-V5-5715, Co-57). The source that was manufactured and distributed contained 17.07 mCi of Co-57 and the maximum activity allowed according to the registration certificate was 15 mCi.

The failure to manufacture and distribute the sealed source product in accordance with the provisions of the registration certificate was identified as an apparent violation of 10 CFR 32.210(f). (030-35486/2023-001-01)

#### **4 Corrective Actions**

The licensee stated they would revise the sealed source manufacturing procedures to include the maximum activity limits for each combination of sealed source model number and byproduct material combination listed on the SS&D registry, and check that the sealed source constructed does not exceed the maximum activity listed on the SS&D registry and if it does, that the sealed source will be held until it decays below the maximum activity listed on the SS&D registry.

#### **5 Exit Meeting Summary**

On October 2, 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 apparent violation 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

030-35486/2023-001-01	AV	Failure to manufacture and distribute a sealed source in accordance with the applicable SS&D registry. (10 CFR 32.210(f))
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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
ADR	Alternate Dispute Resolution
AV	Apparent Violation
IP	Inspection Procedure
NRC	U.S. Nuclear Regulatory Commission
PEC	Predecisional Enforcement Conference
SS&D	Sealed Source and Device