



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

May 26, 2022

EA-20-073
EA-22-028

Steve Laflin, President
International Isotopes, Inc.
4137 Commerce Circle
Idaho Falls, Idaho 83401

SUBJECT: NRC INSPECTION REPORT 030-35486/2022-001 AND NOTICE OF VIOLATION

Dear Mr. Laflin:

This letter refers to the announced routine inspection conducted on January 27-28, 2022, at your facility in Idaho Falls, Idaho, with continued in-office review through April 14, 2022. The purpose of the inspection was to examine 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 a selected examination of procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel. The enclosed report presents the results of the inspection. The preliminary inspection findings were discussed with you and your radiation safety officer (RSO) at the conclusion of the onsite portion of the inspection. A final exit briefing was conducted telephonically with you and your RSO on May 5, 2022.

Based on the results of this inspection, an apparent violation was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current NRC Enforcement Policy is included on the NRC website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The apparent violation involved a failure to meet requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 37 and is characterized in the non-public portion of the inspection report (Enclosure 2). The circumstances surrounding the apparent violation, the significance of the issue, and the need for lasting and effective corrective action were discussed with you during the telephonic exit meeting on May 5, 2022.

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, the NRC may issue

Enclosures 1 and 2 contain Sensitive Unclassified Non-Safeguards Information (SUNSI). When separated from Enclosures 1 and 2, this letter and Enclosure 3 are decontrolled.

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a press release to announce the time and date of the conference; however, the PEC will be closed to public observation since Security-Related Information will be discussed. Please contact Dr. Lizette Roldán-Otero, Chief, Materials Inspection Branch, at 817-200-1455 or by email at 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 of the date of this letter and an ADR session within 45 days of the date of this letter.

If you choose to provide a written response to the apparent violation, it should be clearly marked as a “Response to an Apparent Violation in NRC Inspection Report 030-35486/2022-001; EA-22-028” 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 achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. Your response should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy mailed to the Director, Division of Radiation Safety and Security, Region IV, 1600 East Lamar Boulevard, Arlington, Texas, 76011, and emailed to R4Enforcement@nrc.gov, within 30 days of the date of this letter. 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. You can find the Information Notice using the NRC’s Agencywide Documents Access and Management System (ADAMS) Accession No. [ML061240509](#).

In lieu of a PEC or written response, you may request ADR with the NRC in an attempt to resolve this issue. 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.

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Additional information concerning the NRC's ADR program can be obtained at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html> as well as NRC brochure NUREG/BR-0317, "Enforcement Alternative Dispute Resolution Program" Revision 2, ADAMS Accession No. [ML18122A101](#). 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 this issue through ADR.

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 addition, the NRC determined, in accordance with the NRC Enforcement Policy, that three Severity Level IV violations of NRC requirements occurred. The Severity Level IV violations are cited in the non-public Enclosure 1, "Notice of Violation" (Notice) because they were identified by the NRC during the inspection. The violations involved failures to meet requirements in 10 CFR Part 37. The circumstances surrounding these violations are described in the enclosed non-public inspection report (Enclosure 2).

You are required to respond to the Notice and should follow the instructions specified in the Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In addition, the two Severity Level II violations documented in the NRC letter dated October 20, 2020 (ADAMS Accession No. [ML20294A080](#)) that involved failures to: (1) perform safety evaluations of proposed uses of byproduct material required by 10 CFR 33.13(c)(3); and (2) obtain prior NRC approval for changes to procedures that changed existing license conditions were adequately addressed by the corrective actions taken and the violations are now considered closed.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this cover letter and Enclosure 3 will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>.

However, the non-public Notice and inspection report (Enclosures 1 and 2) contain Security-Related Information withheld under 10 CFR 2.390(d)(1) and their disclosure to unauthorized individuals could present a security vulnerability. Therefore, the material in Enclosures 1 and 2 will not be made available electronically for public inspection. Additionally, if Security-Related Information is necessary to provide an acceptable response to Enclosure 1, please mark your entire response Security-Related Information in accordance with 10 CFR 2.390(d)(1) and follow the instructions for withholding in 10 CFR 2.390(b)(1).

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Should you have any questions regarding this letter or the enclosed Notice and inspection report, please contact Dr. Lizette Roldán-Otero of my staff at 817-200-1455.

Sincerely,

/RA/

Mary C. Muessle, Director
Division of Radiological Safety and Security

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

Non-Public Enclosures:

1. Notice of Violation
2. Security – NRC Inspection Report
030-35486/2022-001 with Attachment

Public Enclosure:

3. Health and Safety – NRC Inspection
Report 030-35486/2022-001 with Attachment

cc w/enc.:

Mr. Mark Dietrich
Emergency Response Coordinator
Idaho Department of Environmental Quality
1410 N Hilton Street
Boise, Idaho 83706

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SUBJECT: NRC INSPECTION REPORT 030-35486/2022-001 AND NOTICE OF VIOLATION – DATED MAY 26, 2022

DISTRIBUTION:

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LRoldanOtero, DRSS
R4-DRSS-MIB

Cvr Ltr w/Enclosure 3 only (Public): ADAMS ACCESSION NUMBER: ML22146A362

SUNSI Review: JCD ADAMS: Non-Publicly Available Non-Sensitive
 Yes No Publicly Available Sensitive

Keyword: RGN 4-001

Cvr Ltr & Enclosures (Non-Public): ADAMS ACCESSION NUMBER: ML22138A204

SUNSI Review: JCD ADAMS: Non-Publicly Available Non-Sensitive
 Yes No Publicly Available Sensitive

Keyword: RGN 4-001

OFFICE	C:MIB	ACES	RC	OE	D:DRSS
NAME	LRoldanOtero	JGroom	DCylkowski	CRiveraDiaz	MMuessle
SIGNATURE	/RA/ E	/RA/	/RA/ E	/RA/ E	/RA/ E
DATE	05/06/22	05/10/22	05/10/22	05/18/22	05/26/22

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

Docket No.: 030-35486

License No.: 11-27680-01MD

Inspection Report No.: 030-35486/2022-001 (Health and Safety)

EA No: EA-22-028

Licensee: International Isotopes, Inc.

Location Inspected: 4137 Commerce Circle, Idaho Falls, Idaho

Inspection Dates: January 27-28, 2022

Exit Meeting Date: May 5, 2022

Inspectors: Jason Dykert
Health Physicist

Dr. Janine Katanic, CHP
Senior Health Physicist

Approved By: Dr. Lizette Roldán-Otero, Chief
Materials Inspection Branch
Division of Radiological Safety and Security, Region IV

Attachment: Supplemental Inspection Information

EXECUTIVE SUMMARY

**International Isotopes, Inc.
NRC Inspection Report 030-35486/2022-001 (Health and Safety)**

Program Overview

International Isotopes, Inc., (INIS) was authorized under U.S. Nuclear Regulatory Commission (NRC) Materials License 11-27680-01MD to possess sealed and unsealed byproduct materials for storage, processing, packaging, research, development, manufacturing, and distribution. Licensed activities were authorized to be performed at the licensee's facility located in Idaho Falls, Idaho, and at temporary job sites in areas of NRC jurisdiction.

Inspection Findings

No violations were identified regarding NRC health and safety requirements. Previous health and safety violations from NRC Inspection Report 030-35486/2020-001, that involved failures to: (1) perform safety evaluations of proposed uses of byproduct material required by Title 10 of the *Code of Federal Regulations* (10 CFR) 33.13(c)(3); and (2) obtain prior NRC approval for changes to procedures that changed existing license conditions, were closed during this inspection.

REPORT DETAILS

1 Program Overview (Inspection Procedures (IP) 87125 and 87126)

International Isotopes, Inc. (INIS), holds a Type A broad scope manufacturing and distribution license, U.S. NRC Materials License number 11-27680-01MD.

2 Inspection Overview (IPs 87125 and 87126)

2.1 Inspection Scope

The announced inspection on January 27 and 28, 2022, consisted of a selected examination of procedures and representative records, observations of activities at the facility, independent radiation measurements, and interviews with INIS personnel regarding licensed activities as they relate to public health and safety, and security.

2.1 Background

The INIS broad scope license is authorized under 10 CFR Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material," and is a Type A category broad scope license with a medical specialty authorization that permits medical isotope manufacturing and distribution.

Under the license, INIS has established administrative controls and provisions related to the organization and management, procedures, recordkeeping, material control, and accounting and management review necessary to ensure safe operations. A Radiation Safety Committee (RSC) has been established, and a qualified radiation safety officer (RSO) was appointed and named on the license to oversee operations involving radioisotopes. Administrative procedures have been developed to ensure proper control of procurement and use of byproduct material. The uses of materials receive safety evaluations and consider the adequacy of facilities and equipment, training and experience of the users, and require the development of operating and handling procedures.

The medical uses are reviewed, approved, and recorded by the RSC through the safety evaluations, and products may only be manufactured or developed under the direct supervision of individuals approved by the licensee's RSC.

Medical Flood and Check Source Program

One of the licensee's primary activities is the manufacturing and distribution of flood and check sources for medical imaging applications. At the time of inspection, various types of check sources including isotopes of europium-152, cobalt-57 and cobalt-60, cesium-137, sodium-22, germanium-68/ gallium-68, and barium-133 were being produced for medical equipment calibration standards.

The inspectors observed the manufacturing area, bulk storage of materials, quality control and testing laboratory, and radiation controls in place. The INIS personnel discussed handling and processing materials and demonstrated proper survey techniques, frisking protective equipment and dosimetry use. Records of bulk receipt, air monitoring, waste

generation and handling, inventory and use tracking, and personnel dosimetry were reviewed.

3 Violations Closed from Inspection Report 030-35486/2020-001

During a previous inspection, as described in Inspection Report 030-35486/2020-001, (NRC's Agencywide Documents Access and Management System (ADAMS) Accession No. [ML20170A868](#)) the licensee's radiation safety program and Event Notification 54042 were reviewed and evaluated. Event 54042 occurred on May 2, 2019, and involved the accidental breach of a cesium-137 sealed source by International Isotopes, Inc. employees while working at the University of Washington's Harborview Campus in Seattle, Washington.

Two violations were identified during the previous inspection, as described in the NRC letter dated October 20, 2020, ADAMS Accession No. [ML20294A080](#), and involved failures to perform safety evaluations of proposed uses of byproduct material required by 10 CFR 33.13(c)(3), and also failure to obtain prior NRC approval for changes to procedures that changed existing license conditions.

In response to the 2019 event and 2020 inspection report, the licensee stopped all field service work, and then removed that type of authorization for mobile hot cell work from the license. The inspectors reviewed the licensee's corrective actions detailed in the written response to the previous report. All of the corrective actions were completed and as described in the licensee's written correspondence. (ADAMS Accession Nos. [ML20209A543](#) and [ML20330A143](#))

The inspectors reviewed selected Radiation Work Permits (RWP) revisions and new procedures created in 2020 and 2021, and noted that the As Low As Reasonably Achievable (ALARA) Committee engaged in reviews of procedures that could have decreased the effectiveness of the radiation protection program. The licensee's high-risk activities associated with cobalt-60 handling and source manufacturing had been reviewed and assessed for risk in a failure mode and effect analysis process. The licensee utilized the analysis to formalize safety evaluations for high radiological risk and all other activities involving cobalt-60 manufacturing and distribution.

Following the NRC's 2020 inspection, the licensee reduced high-risk activities performed under active RWPs from 24 in 2020 to 16 in 2022. An independent third party reviewed and audited the licensee's radiation protection program. The inspectors reviewed the independent audits, ALARA committee meeting minutes and selected procedure change reviews, and noted that the licensee had assessed procedures for changes that would decrease the effectiveness of the radiation protection program. These corrective actions appear to have been effective in preventing recurrence of a similar event, and the 2020 violations, 030-35486/2020-001-01 and 030-35486/2020-001-02, from Inspection Report 030-35486/2020-001 and EA-20-073 are considered closed.

4. Exit Meeting Summary

The inspectors presented the preliminary inspection findings at the conclusion of the onsite inspection on January 28, 2022, with Mr. Steve Laflin, President and Chief Executive Officer, and Mr. John Miller, Certified Health Physicist, Radiation Safety Officer.

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On May 5, 2022, a final telephonic exit meeting was conducted with Mr. Laflin and Mr. Miller. The licensee acknowledged the findings and did not dispute any of the details presented during the exit call.

Supplemental Inspection Information

LIST OF PERSONS CONTACTED

Steve Laflin, President and Chief Executive Officer
John Miller, Certified Health Physicist, Radiation Safety Officer
Dawn Langston, Quality Assurance Manager
Shawn Anderson, Cobalt-60 Products Manager
Kirk Stommel, Cobalt-60 Technician
Josh Burtenshaw, Cobalt-60 Technician
Trevor Dixon, Production Technician

INSPECTION PROCEDURES USED

87125 – Materials Processor/Manufacturer Programs
87126 – Industrial/Academic/Research Programs

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

None

Closed

030-35486/2020-001-01	VIO	Failure to perform the safety evaluations of proposed uses of byproduct material required by 10 CFR 33.13(c)(3).to
030-35486/2020-001-02	VIO	Failure to obtain prior NRC approval for changes to the licensee’s procedures that changed existing NRC license conditions, as per License Condition 23.

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
ALARA	As Low as Reasonably Achievable
INIS	International Isotopes, Inc.,
NRC	U.S. Nuclear Regulatory Commission
PEC	Pre-decisional Enforcement Conference
RMS	Remote Monitoring System
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
RWP	Radiation Work Permit
VIO	Violation

Attachment