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

June 22, 2020

EA-20-073

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

SUBJECT: INTERNATIONAL ISOTOPES, INC. - NRC INSPECTION REPORT 030-35486/2020-001

Dear Mr. Laflin:

This letter refers to the announced routine inspection conducted on February 25-28, 2020, at your facility in Idaho Falls, Idaho, with in-office review through May 20, 2020. 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's (NRC's) 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 at the conclusion of the onsite portion of the inspection on February 28, 2020. A final exit briefing was conducted telephonically with you and your radiation safety officer on June 3, 2020.

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 Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violations involved: 1) International Isotopes, Inc's. (licensee's) failure to have appropriate administrative procedures that assured the completion of safety evaluations as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 33.13(c)(3); and, 2) the approval of procedures by the licensee's radiation safety committee that changed the conditions of the NRC license, and that decreased the effectiveness of the radiation safety program, both of which are prohibited by Condition 23(b) of NRC License 11-27680-01MD. The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with you during the telephonic exit meeting on June 3, 2020.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) request a predecisional enforcement conference (PEC) or, (2) 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. If you decide to participate in a PEC or pursue ADR, please contact Ms. Patricia Silva at 817-200-1455 within

10 days of the date of this letter. 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 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 an 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 on the NRC website at: http://www.nrc.gov/docs/ML0612/ML061240509.pdf.

In lieu of a PEC, 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 third party (the "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 this issue through ADR.

In addition, please be advised that the number and characterization of 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 and from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site 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 Ms. Patricia A. Silva of my staff at 817-200-1455.

Sincerely,

Mary C. Muessle

Digitally signed by Mary C. Muessle
Date: 2020.06.22 08:56:12 -05'00'

Mary C. Muessle, Director
Division of Nuclear Materials Safety

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

Enclosure:
NRC Inspection Report 030-35486/2020-001

cc w/enc.:
Mark Dietrich
Radiation Control Program Director
Idaho Department of Environmental Quality
1410 North Hilton Drive
Boise, ID 83706

Mikel Elsen, Director
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NRC INSPECTION REPORT 030-35486/2020-001 - DATED June 22, 2020

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ADAMS ACCESSION NUMBER: ML20170A868

☒SUNSI Review: JLT ADAMS: ☐ Non-Publicly Available ☒ **Non-Sensitive**
Keyword: ☒ **Yes** ☐ No ☒ **Publicly Available** ☐ Sensitive

OFFICE	R4: SHP	R1: SHP	R3: HP	C:MIB	TL:ACES	RC
NAME	JThompson	BUllrich	RCraffey	PSilva	JGroom	DCylkowski
SIGNATURE	**/RA/ E**	**/RA/ E**	**/RA/ E**	**/RA/ E**	**/RA/ E**	**/RA/ E**
DATE	5/13/2020	5/20/2020	5/20/2020	6/2/2020	6/8/2020	6/11/2020
OFFICE	NMSS	OE	D: DNMS			
NAME	RSun	JPeralta	MMuessle			
SIGNATURE	**/RA/ E**	**/RA/ E**	Mary C. Muessle Digitally signed by Mary C. Muessle Date: 2020.06.22 08:56:54 -05'00'			
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U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket:	030-35486
License:	11-27680-01MD
Report:	2020-001
EA No.:	EA-20-073
Licensee:	International Isotopes, Inc.
Locations Inspected:	4137 Commerce Circle Idaho Falls, Idaho
Inspection Date:	February 25-28, 2020 with in-office review through May 20, 2020
Inspectors:	James Thompson, Senior Health Physicist Division of Nuclear Materials Safety Region IV Betsy Ullrich, Senior Health Physicist Division of Nuclear Materials Safety Region I Ryan Craffey, Health Physicist Division of Nuclear Materials Safety Region III
Approved By:	Patricia Silva, Chief Materials Inspection Branch Division of Nuclear Materials Safety, Region IV
Attachment:	Supplemental Inspection Information

Enclosure

EXECUTIVE SUMMARY

NRC Inspection Report 030-35486/2020-001

Program Overview

International Isotopes, Inc., is authorized under U.S. Nuclear Regulatory Commission's (NRC's) Materials License 11-27680-01MD to possess and use both sealed and unsealed byproduct materials for storage, processing, packaging, research, development, manufacturing, and distribution. International Isotopes, Inc., (licensee) is also authorized to load and unload sealed radioactive sources into and out of certain devices in Federal jurisdiction.

On February 25-28, 2020, the NRC performed a routine, announced inspection of International Isotopes, Inc., at its facility in Idaho Falls, Idaho. The scope of the inspection was to perform a review of the licensee's radiation safety and security programs, as well as to review an event (Event Notification 54042) that occurred on May 2, 2019. The event involved the accidental breach of a cesium-137 sealed source by International Isotopes, Inc., employees at the University of Washington's Harborview Campus in Seattle, Washington, which caused radioactive contamination to spread throughout the work area and throughout much of the building. (Section 1)

Event Analysis

The NRC inspectors determined that one root cause of the Seattle contamination event was the licensee's failure to implement corrective actions identified through the corrective action program for a contamination event that occurred at its facility five months prior to the Seattle contamination event. The NRC inspectors determined the second root cause involved the licensee's radiation safety committee makeup and implementation. International Isotopes, Inc., has a small number of staff performing work with large quantities of material, and the employees that are members of the radiation safety committee are the same employees that manage the company, create procedures, approve these procedures, and train on these procedures. There is a lack of independence of the radiation safety committee from other aspects of the work that is performed. (Section 4)

Inspection Findings

Two apparent violations were identified as a result of this inspection. One violation was of 10 CFR 33.13, which requires that safety evaluations be performed of proposed uses of byproduct material, which take into consideration such matters as the adequacy of equipment, training and experience of the user, and the operating or handling procedures. The second apparent violation was of NRC License Condition 23(b), which requires that any changes made by the licensee to their safety program cannot change existing license conditions and cannot decrease the effectiveness of the radiation safety program. (Section 5)

Corrective Actions

Immediately after the Seattle contamination event, the licensee suspended all field service activities under its NRC license; on April 20, 2020, the licensee submitted a request to remove these field service activities from their license. The licensee took additional corrective actions that are described in the report. (Section 5)

REPORT DETAILS

1 Program Overview (87126 and 87125)

International Isotopes, Inc., (INIS or licensee) was authorized under U.S. Nuclear Regulatory Commission (NRC) Materials License 11-27680-01MD to possess and use both 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, as well as at temporary job sites in areas of NRC jurisdiction.

1.1. Inspection Scope

On February 25-28, 2020, the NRC inspectors performed a routine, announced inspection of INIS at its facility in Idaho Falls, Idaho, with in-office reviews through May 20, 2020. The scope of the inspection was to perform a review of the licensee's radiation safety and security programs. The scope of the inspection also included the review of an event (Event Notification 54042) that occurred on May 2, 2019, which involved the accidental breach of a cesium-137 sealed source by INIS employees at the University of Washington's Harborview Campus in Seattle, Washington which caused radioactive contamination to spread throughout the work area and throughout much of the building.

Within these areas, the inspectors examined activities conducted under the INIS license as they relate to public health and safety, to confirm compliance with the NRC's rules, regulations, and with the conditions of the INIS license. The inspection consisted of a selected examination of procedures and representative records, observations of activities at the facility, independent radiation measurements, and interviews with INIS personnel.

1.2 Observations and Findings

Licensed activities at INIS include but are not limited to: 1) cobalt-60 recovery, recycling, manufacturing, and distribution; 2) iodine-131 bulk manipulation and distribution; 3) cobalt-57 flood source manufacturing and distribution; and, 4) mobile hot cell services performed at temporary job sites in both NRC and Agreement State jurisdiction.

- Cobalt-60 Program

  The licensee's cobalt-60 program involves the manufacturing and distribution of sealed sources, the processing of new sources, and assistance in the U.S. Department of Energy's Offsite Source Recovery Program and the Conference of Radiation Control Program Director's Source Collection and Threat Reduction Program.

  The inspectors observed the receipt, handling, and unloading of various casks containing cobalt-60 sources, as well as the preparation and shipment of one cask of manufactured sources for an irradiator reload. This cask was adequately labeled, blocked and braced, and the licensee's transport vehicle was adequately placarded. Independent surveys were consistent with the licensee's measurements in preparation for shipping (a maximum of 14 millirem/hour on contact with the cask, a

maximum of 2 mrem/hour on contact with the trailer, less than 1 mrem/hour at 6 feet from the trailer, and background readings in the passenger compartment of the transport vehicle). The INIS personnel involved in all cask handling activities were knowledgeable of the exposure fields present, used appropriate radiation safety controls, and wore appropriate dosimetry throughout.

The inspectors also observed the manufacture of several sealed cobalt-60 sources for instrument calibrators. The handling and welding of these sources was performed in one of the licensee's designated hot cells using remote manipulators and automated welding equipment. The INIS personnel involved in these activities continuously monitored occupied areas around the hot cell for radiation exposure, routinely monitored material passing in and out of the hot cell for contamination, and routinely verified that the hot cell's negative pressure ventilation system was operational. The inspectors also noted that the INIS personnel wore appropriate physical protection equipment and dosimetry throughout the operation and discussed with them other aspects of the manufacturing process not directly observed, including material accountability and waste handling.

The inspectors reviewed a selection of records related to the cobalt-60 program, including standard operating procedures, material accountability documents, hot cell air sampling results, and shipping papers for outgoing casks.

- Iodine-131 Program

  There were two separate manufacturing activities using iodine-131 at the time of the inspection. One was for the production of iodine-131 sodium iodide solution for use in radiopharmacy, well logging, and other customers. The other was used for testing of the facility for the future manufacturing of a radiopharmaceutical labeled with iodine-131 for a customer.

  The licensee serves as an intermediary between the initial production of iodine-131 and the pharmacies and hospitals that are end-users. Iodine-131 is produced at various reactors around the globe and shipped to INIS for quality control, manipulation, and distribution to smaller end-users such as radiopharmacies. The production of iodine-131 labeled sodium iodide at INIS was performed in a dedicated facility in the main building; a hot cell was used for production activities. The inspectors observed INIS employees during the iodine-131 production activities and reviewed the manufacturing process in detail with the technical lead, once manufacturing activities were completed. Additionally, inventory tracking, quality control, contamination surveys, air monitoring and radiation worker doses were discussed with staff present, as well as with the radiation safety officer.

  The production of a radiopharmaceutical labeled with iodine-131 for customers will occur in a new building on the licensee's site, once the building construction is complete. In addition to meeting the NRC's requirements, this facility must also meet the requirements of the U.S. Food and Drug Administration, since it will be used in the production of radiopharmaceuticals. Inspectors observed the existing facility under construction, as well as a completed hot cell in which dry runs were being performed. Effluent air was released through the same stack as the iodine-131 facility in the main building. Inspectors reviewed the "Progenics ALARA Evaluation

and Survey Results for Test Run" documentation for the testing, which occurred with iodine-131 in December 2019.

Records of inventory, effluent monitoring, thyroid bioassay, dosimetry and surveys for the iodine-131 activities were also reviewed. The licensee's activities were as described in the license application.

- Cobalt-57 Flood Source Program

  One of the licensee's primary activities is the manufacturing and distribution of flood sources for medical imaging applications.

  The inspectors observed the manufacturing, packaging, and quality assurance testing of several flood sources. The INIS personnel involved in these activities wore appropriate physical protection equipment and dosimetry throughout the operation, were knowledgeable of relevant licensee procedures, and practiced appropriate ALARA techniques while working with and around licensed material. Independent exposure measurements in the vicinity of the manufacturing operations were approximately 10 milliroentgen/hour at the face of the fume hood when material was in use. Independent face velocity measurements of this fume hood were approximately 150 linear feet per minute. All outgoing flood sources were appropriately labeled for shipment, as confirmed by independent exposure measurements of several packages.

  The inspectors discussed with INIS personnel the handling of flood source rejects and other waste generated by the cobalt-57 program, and reviewed a selection of records, including standard operating procedures and material accountability documents.

- Mobile Hot Cell Program

  The licensee conducts certain field service operations at temporary job sites established at facilities licensed by the NRC or an Agreement State. The licensee has developed a mobile hot cell that can be used to remove sources from irradiators and gamma stereotactic radiosurgery units and/or transportation containers. The mobile hot cell consists of remote manipulators, radiation hardened video cameras, a video monitor and an interior hoist. This mobile hot cell is transported in a disassembled configuration to temporary job sites, and then reassembled prior to use. There are no windows on this mobile hot cell, so the only way for licensee personnel to visualize operations inside is by a video camera feed.

  In all, INIS used this mobile hot cell on 16 separate occasions over a 6-year period to remove 1,180 sealed radioactive sources from their respective devices. This mobile hot cell was being used when a cesium-137 sealed source was accidentally breached in Seattle, Washington, on May 2, 2019.

- Oversight Activities of the INIS Radiation Safety Committee

  The inspectors reviewed the activities of the INIS ALARA Committee through interviews with committee members and review of minutes, and documents involving incidents, and the development of new processes and procedures.

In accordance with commitments made during the licensing process, the INIS ALARA Committee is comprised of a representative of senior management, the radiation safety officer, a quality assurance manager, an operations supervisor, a representative from engineering, and a representative from the technical staff. The quorum required four of the six persons listed. The company president served as the committee chair.

There were quarterly meetings of the ALARA Committee attended by all available personnel. At these meetings, the committee members were informed of the current radiation exposure results; updates from each work area (field services, nuclear medicine, topaz, cobalt-60, iodine-131, and Progenics); and any other current issues or events related to radiation safety. However, approval of new users, new uses, and other decision-making activities did not usually occur at these quarterly meetings.

In practice, the activities necessary to assure safe operations as described in 10 CFR 33.13(b) and of approving new users as required by 10 CFR 33.17(b) were carried out at smaller meetings. The smaller meetings were held as needed; some were scheduled and others less formal. The representatives at these meetings varied according to the work area involved. For example, if a new activity was considered for the cobalt-60 area, then in addition to the company president and the radiation safety officer (RSO), committee members would be the cobalt-60 quality assurance manager, the cobalt-60 operations supervisor, an engineering representative from the cobalt-60 area, and a technical staff person from the cobalt-60 area.

Documentation of some ALARA Committee meetings could not been found during the inspection. Some new procedures required review and signature by members of the ALARA Committee and were considered documentation of the results of such a meeting; however, not all procedures required review and approval by the ALARA Committee. Some procedures were designated by the president and/or RSO as "ALARA Committee review not required." This was identified as a weakness in the licensee's radiation safety and oversight program, discussed further in Section 4 of this report. Approval of new persons authorized to use, or supervise the use of, licensed materials involved formal documentation and approval by work area management but did not involve review and approval by a quorum from the ALARA Committee.

Additionally, as part of the INIS ALARA Committee oversight function, two categories of event tracking reports are maintained: incidents reports and corrective action reports (CAR). Based on discussions with staff, incidents are those activities that exceed CARs. Inspectors reviewed both report categories from June 2017 through February 2020.

The inspectors reviewed ten CARs; these reports contained a description of the event, identified causes, and corrective actions to be taken. The CAR remained open until all corrective actions were completed. The CARs required review by INIS personnel in the work area including representatives of the ALARA Committee, although none contained direct requirement for ALARA Committee review.

One event occurred on December 26, 2018, when workers in the cobalt work area breached a source while trying to remove it from the source holder in one of the licensee's permanent hot cells. The worker was using a Dremel tool to grind the pins so that the source holder could be opened, and sealed source removed. While this was carried out, a power failure occurred site-wide, causing the air handling equipment to stop, resulting in cobalt-60 airborne contamination to be released from the hot cell.

This event resulted in a CAR to investigate the loss of power and its effect on work activities, and a separate CAR to investigate the contamination event. The CAR for this contamination event represents a critical missed opportunity to have prevented the contamination event that occurred in Seattle, Washington, on May 2, 2019, which is discussed further in Sections 4 and 5 of this report.

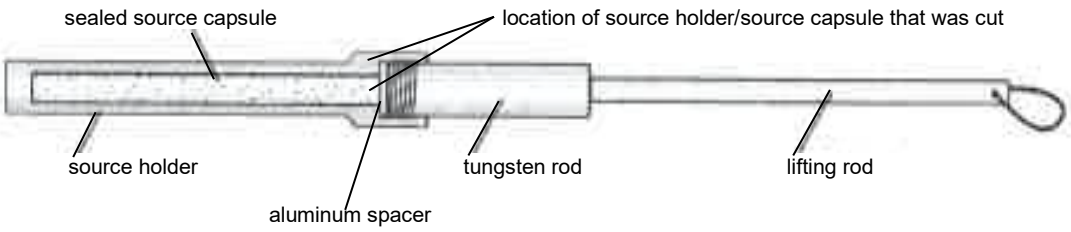
1.3 Conclusions

There were no violations identified with regards to licensed activities involving cobalt-60 manufacturing and distribution, iodine-131 bulk manipulation and distribution activities, or cobalt-57 flood source manufacturing and distribution. Violations were identified with regards to the licensee's mobile hot cell field services and ALARA Committee oversight, however, and are described in Section 5 of this report.

2 International Isotopes, Inc., Involvement in the Seattle Contamination Event

International Isotopes, Inc., was selected as a subcontractor by Triad National Security (contractor for Los Alamos National Laboratory) to remove a JL Shepherd (JLS) Mark 1 self-shielded irradiator containing approximately 2,900 curies of cesium-137 from the University of Washington's Harborview Medical Center in downtown Seattle, Washington. International Isotopes, Inc., planned to remove the irradiator by first removing the sealed source capsule containing the cesium-137 from its source holder (JLS Model 6810) in the field at the University utilizing the INIS mobile hot cell.

On May 2, 2019, INIS personnel began operations on-site at the University to remove the sealed source capsule from the source holder by using a high-speed cut-off saw, with attached grinding wheel, while the source holder was within the mobile hot cell. The original plan was to grind down the ends of a roll pin (a small rod inserted perpendicular through the source holder and the tungsten rod in the area of their threaded interface) sufficiently to allow the tungsten rod to be unthreaded from the source holder, thereby allowing the source holder to be opened and sealed source capsule removed. International Isotopes, Inc., considered it necessary to remove the sealed source capsule from the source holder because the source holder was too long to fit into the NPI transportation cask which they had previously used for shorter source holders, and the external dose rates were too high to use the 10-160B transportation cask.



International Isotopes, Inc., personnel proceeded to make several circumferential cuts into the source holder in an area that they believed to contain the threaded portion of the tungsten rod/source holder interface (INIS was apparently unsure of the critical dimensions of the source holder/source capsule, and where the active portion of the source capsule was located). Some of the circumferential cuts into the source holder penetrated the source capsule at various lengths and depths, which resulted in the release of cesium-137. Since this work was performed within the mobile hot cell, it would be assumed that a radioactive release would have been contained; however, this mobile hot cell was not designed to contain unsealed radioactive material, so the contamination subsequently spread outside of the mobile hot cell and into the room in which the work was ongoing, contaminated the workers within the room, and eventually spread throughout the University's Harborview Medical Center.

The inspectors determined that INIS was not authorized by the NRC to remove the sealed source from its source holder in the field using its mobile hot cell; INIS was only authorized to remove the source holder from the device (irradiator) using the mobile hot cell. It was further determined that INIS approved this procedure for cutting the source holder in the mobile hot cell without the NRC's approval through license amendment, even though this new procedure actually changed a condition in the license, License Condition (LC) 16, and decreased the effectiveness of the radiation safety program, both of which are prohibited by LC 23(b).

3 Timeline of International Isotopes, Inc., Procedural Revisions/Operations (87103)

The following represents a brief overview of the procedures that were created and/or revised by INIS that were germane to the Seattle contamination event, and the timeline associated with these procedures.

- 8/25/2010:
  Letter to NRC with enclosed procedures that discusses how INIS will receive sealed materials at its main office in Idaho Falls, remove sealed sources from their source holders, and open sealed sources to extract radioactive materials in order to produce new sealed sources under their manufacturing and distribution authorization.

- 6/28/2013:
  Procedure OP-SRC-024 created: "Utilizing INIS Mobile Hot Cell, Revision A," submitted with letter dated 6/28/2013 requesting an amendment to the NRC license to use the Mobile Hot Cell (MHC), listed now as LC 27, Item I, Agencywide Documents Access and Management System (ADAMS) Accession ML13184A190. The procedure lists as compatible GammaCell (GC)-10, GC-40, GC-100, GC-200, and GC-220 self-shielded irradiators for source unloading. Revisions to OP-SRC-O24 were approved by the radiation safety committee under LC 23. This procedure describes how to set up the MHC and what irradiators were considered compatible with it at the time. It does not describe removing a sealed source from its source holder in the MHC.

- 5/6/2014:
  Procedure OP-SRC-026 created: "JL Shepherd Model 109 Irradiator Source Unloading." This procedure is the first MHC procedure that is not tied to the license, which means that the NRC staff was not given the opportunity to review it, so it was

required to have been reviewed and approved by the INIS Radiation Safety (ALARA) Committee (RSC). Additionally, this procedure does not describe removing a sealed source from its source holder in the MHC.

- 5/4/2017:
  Procedure OP-SRC-040 created: "JL Shepherd Model Mark 1 and 143 Series Irradiator Source Unloading." This procedure is the second MHC procedure that is not tied to the license, again meaning that the NRC was not given the opportunity to review it. Additionally, this procedure first introduced the additional step of removing a sealed source from its source holder in the MHC.

- 5/16/2017:
  The removal of the sealed source from its source holder in the MHC was performed successfully in Cleveland, Ohio (first use of OP-SRC-040). This irradiator was a JLS Mark 1 and was the same type of irradiator involved in the Seattle contamination event. The sealed source was removed from the source holder with the use of a chop saw fitted with a grinding disc, over-encapsulated, then loaded into an NPI transportation cask.

- 12/26/2018:
  An event occurred at INIS main facility in Idaho Falls, Idaho in which a JLS sealed source was accidentally breached when personnel were attempting to remove it from its source holder. This was the same type of source that was involved in the Seattle contamination event. During this evolution, INIS employees were using a Dremel tool to cut the source holder when they accidentally cut into the sealed source causing contamination.

- 2/4/2019:
  As a corrective action for the above sealed source breach, work instruction WI-SRC-032, "Source Recovery from Holder" was developed to describe how to safely remove sealed sources from their source holder when cutting or other destructive method is required. This procedure was applicable to the fixed hot cell at the main facility, as well as MHC. This procedure also required negative pressure ventilation be used during removal of the source holder through destructive methods.

- 5/2/2019:
  A sealed source was breached in Seattle, Washington during MHC work with the same model sealed source that was breached in the 12/26/2018 event at the INIS main facility in Idaho Falls, Idaho.

4 Causal Evaluation of the Seattle Contamination Event (87103)

The licensee had not performed a causal analysis as of the date of the inspection; however, the NRC inspectors performed a causal analysis and arrived at two possible root causes of the Seattle contamination event. Additionally, there were multiple contributing causes identified as a result of this analysis.

4.1 Contributing Causes

One of the most critical factors contributing to the Seattle contamination event was the decision by INIS to remove the sealed source from its source holder in the field using the mobile hot cell. According to the INIS radiation safety officer, this decision was based, in part, on the fact that the two transportation casks that they had previously used for work of this nature were not suitable for this particular source design/model. The Neutron Products cask (NPI) was not suitable because the source holder was too long to fit inside of it. Alternatively, the Energy Solutions 10-160B transportation cask could have been used, except for the fact that the activity of this particular shipment (approximately 2,800 curies) would have exceeded the maximum activity (2,040 curies) allowed for this transportation cask as described in the NRC Certificate of Compliance No. 9204.

Instead of requesting a one-time exemption (special permit) for the use of the 10-160B cask for this particular evolution, INIS personnel decided to remove the sealed source from its source holder, and transport the sealed source in the NPI cask, because they did not believe that the request for the special permit would be approved. This decision was also influenced by a lack of trust in the manufacturer's claim that the sources were certified special form material, an important prerequisite for transportation with either cask. The manufacturer offered to provide documentation of said certification, though at a cost. This additional cost further justified the perceived benefits of re-encapsulation of the sealed source after its removal from the source holder.

Another important contributing factor to the Seattle contamination event was that the internal configuration of the source holder INIS personnel attempted to recover in Seattle was slightly different from that of the source holder recovered in Cleveland. The source holder recovered in Cleveland had around one inch of internal threading on the tungsten rod, whereas the source holder recovered in Seattle had only half an inch of internal threading on its tungsten rod. This resulted in considerably less margin between the roll pin and the source itself to cut the source tube safely. The INIS personnel were not aware of this difference before cutting into the source tube, as it was not externally apparent.

Another contributing factor to the Seattle contamination event was the failure of INIS personnel to identify radioactive contamination as a potential hazard during the development of the procedure that was ultimately used during the removal of the sealed source from its source holder on May 2, 2019. This procedure, OP-SRC-040, "JL Shepherd Model Mark 1 and 143 Series Irradiator Source Unloading," Revision A, instructed staff to cut the irradiator's source holder within a mobile hot cell using a power tool to remove the sealed sources, but the licensee failed to identify the potential engineering controls required if a source were to be breached during removal. The only potential hazards identified in the procedure were high radiation levels due to unshielded sealed sources, industrial hazards such as rigging and forklift operations, and unintentional powering of the irradiator unit.

4.2 Root Causes

The inspector identified root cause was the licensee's failure to implement corrective actions identified through the Corrective Action Report (CAR) program. Specifically, INIS personnel failed to institute corrective actions from lessons learned regarding a contamination event that occurred at their main facility on December 26, 2018. During

this event, INIS employees were attempting to remove a sealed source from its source holder (of almost identical configuration as the one that was breached in the Seattle event) when they inadvertently cut into the sealed source. This caused contamination of the permanent hot cell, as well as slight contamination of the surrounding workspace due to the negative-pressure ventilation system being temporarily inoperable, either because of obstructed air filters or a loss of facility power and transfer to backup that occurred shortly before the source was breached.

International Isotopes, Inc., put this event into the CAR program to investigate the loss of power and its effect on work activities, and a separate CAR to investigate the contamination event. These CARs resulted in the creation of a Work Instruction (WI-SRC-032, "Source Recovery from Holder") that required "adequate cell ventilation" be available "to mitigate the spread of contamination in the event of a breached source". This Work Instruction, and INIS' failure to implement this Work Instruction at temporary job sites, represents a critical missed opportunity to have mitigated the magnitude of the spread of contamination that occurred in Seattle, Washington on May 2, 2019.

The second inspector identified root cause involved the licensee's Radiation Safety (ALARA) Committee makeup and implementation. International Isotopes, Inc., has a small number of staff performing work with large quantities of material in diverse and somewhat unrelated product lines. The various product line activities are performed by smaller specialized sub-groups, and the ALARA Committee is composed of a minimum of two representatives from the applicable sub-group, along with the President and RSO.

The employees that are members of the ALARA Committee are the same employees that manage the company, create procedures and processes, approve these procedures and processes, and train on these procedures and processes. There is a lack of independence of the ALARA Committee from every other aspect of the work that is performed; for example, the RSO is also responsible for performing some of the work activities that he is supposed to oversee, and the people that are writing new procedures or revising existing procedures are the same people that are members of the ALARA Committee and approve these procedures. This lack of separation precluded an independent and objective review of the procedures that is necessary for adequate radiation safety oversight of large quantities of licensed materials by a small number of users. This resulted in the evolution of work that caused the contamination event in Seattle on May 2, 2019.

5 Inspection Findings and Corrective Actions (87126 & 87125)

5.1 Apparent Violation of 10 CFR 33.13(c)(3)(ii)

Title 10 CFR 33.13(c)(3)(ii) requires, in part, that the licensee establish appropriate administrative procedures to assure completion of safety evaluations of proposed uses of byproduct material which take into consideration such matters as the adequacy of equipment, training and experience of the user, and the operating or handling procedures.

From May 4, 2017, to May 2, 2019, the licensee failed to establish appropriate administrative procedures to assure completion of safety evaluations of proposed uses of byproduct material which took into consideration such matters as the adequacy of

equipment, training and experience of the users, and the operating or handling procedures.

Specifically, the licensee developed procedure, OP-SRC-040, "JL Shepherd Model Mark 1 and 143 Series Irradiator Source Unloading," Revision A, without performing an adequate safety evaluation to analyze the adequacy of equipment, the training and experience of users, and operating procedures to mitigate the risk of contamination release. The procedure instructed staff to cut the irradiator's source holder within a mobile hot cell using a power tool to remove the sealed sources, but the licensee's administrative procedures failed to identify the potential safety and engineering controls required if a source were to be breached during removal, as occurred during the contamination event on May 2, 2019 in Seattle, Washington.
(AV 030-35486/2020-001-01, the failure to perform the safety evaluations of proposed uses of byproduct material required by 10 CFR 33.13(c)(3)(ii)).

5.2 Apparent Violation of NRC License 11-27680-01MD

NRC License 11-27680-01MD, Amendment 31 Condition 24(b) and Amendments 32-35 Condition 23(b) state, in part, that the licensee is authorized to make program changes and changes to procedures without prior Commission approval, as long as the revised program is in accordance with regulatory requirements, will not change the license conditions, and will not decrease the effectiveness of the radiation safety program.

NRC License 11-27680-01MD, Amendments 31-35 Condition 16 states that sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee except as specifically authorized by this license.

Licensee procedure, OP-SRC-040, "JL Shepherd Model Mark 1 and 143 Series Irradiator Source Unloading," Revision A, provides steps to unload sources from Mark 1 series irradiators utilizing a licensee mobile not cell. To remove the source from the source tube, Step 7.4.3 requires, in part, to carefully cut the aluminum tube just below the pin if the pin cannot be removed.

From May 4, 2017, to May 2, 2019, the licensee failed to obtain prior Commission approval for changes to procedures that changed license conditions and decreased the effectiveness of the radiation safety program. Specifically, licensee procedure OP-SRC-040 instructed users to perform an activity not authorized by NRC License 11-27680-01MD and not in accordance with License Condition 16 (the license only authorized the use of the mobile hot cell for the removal of the source holder from the irradiator). Further, the instructions to cut the source holder increased the probability of contamination release without corresponding engineering or process controls to mitigate the potential consequences, thereby increasing the risk of performing licensed activities and decreasing the effectiveness of the radiation safety program as implemented at temporary job sites. These changes to the procedure decreased the effectiveness of the radiation safety program which resulted in the contamination event on May 2, 2019, in Seattle, Washington. (AV 030-35486/2020-001-02, the failure to obtain prior NRC approval for changes to the licensee's procedures that changed existing NRC license conditions, as per License Condition 23)

5.3 International Isotopes, Inc., Corrective Actions Taken

Immediately following the contamination event in Seattle, INIS indefinitely suspended all field work operations, to include not only self-shielded irradiator servicing/removal, but also field work for resourcing teletherapy and gamma knife devices worldwide. Subsequently, on April 20, 2020, INIS submitted a license amendment request to formally remove the authorization for all field service activities from the license.

Additionally, INIS revised internal procedure OP-QMS-012, “Failure Mode and Effects Analysis,” to better inform the risk analyses when developing or revising future procedures. INIS also revised the radiation safety manual to better define the roles and responsibilities of the ALARA Committee members.

6 Exit Meeting

The inspectors presented the preliminary inspection findings at the conclusion of the onsite inspection on February 28, 2020, with Mr. Steve Laflin, President and Chief Executive Officer, and Mr. John Miller, Certified Health Physicist, Radiation Safety Officer. On June 3, 2020, 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
BJ Camphouse, Operations Supervisor
Shawn Anderson, Cobalt-60 Products Manager
Kurt Smith, I-131 Hot Lab Technical lead
Shelby Carlson, I-131 distribution records
Josh Burtenshaw – Support Technician
Tony Jones – Support Technician

INSPECTION PROCEDURES USED

87125	Materials Processor/Manufacturer Programs
87126	Industrial/Academic/Research Programs
87103	Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

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

Closed

None

Discussed

None

LIST OF ACRONYMS AND ABBREVIATIONS USED

ADAMS	Agencywide Documents Access and Management System
ALARA	As Low as Reasonably Achievable
CFR	*Code of Federal Regulations*
INIS	International Isotopes, Inc.,
NRC	U.S. Nuclear Regulatory Commission
CAR	Corrective Action Reports