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

April 29, 2025

EAF-RIV-2025-0022

Shahe Bagerdjian, President
International Isotopes, Inc.
4137 Commerce Circle
Idaho Falls, ID 83401

SUBJECT: INTERNATIONAL ISOTOPES, INC. - NRC INSPECTION REPORT 030-35486/2023-002

Dear Shahe Bagerdjian:

This letter refers to the inspection that was conducted on February 23, 2023, and October 24-25, 2023, at your facility in Idaho Falls, Idaho with continued in-office review through April 23,2025. The purpose of the inspection was to examine activities conducted under your license as they relate to public health and safety and to confirm compliance with the U.S. Nuclear Regulatory Commission (NRC) rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of an examination of selected procedures and representative records, observation of facilities and activities, independent radiation measurements, and interviews with personnel. The enclosed inspection report presents the results of this inspection. The inspectors discussed the preliminary inspection findings with you and John Miller, Radiation Safety Officer, at the conclusion of the onsite portion of the inspection on October 25, 2023. A final exit briefing was conducted via videoconference with you and John Miller, CHP, Radiation Safety Officer, on April 23, 2025.

Based on the results of the inspection, seven 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 apparent violations involve the failure to: (1) establish administrative controls and provisions relating to organization and management, procedures, record keeping, material control, and accounting and management review that are necessary to assure safe operations; (2) make or cause to be made, surveys of areas that may be necessary for the licensee to comply with the regulations in 10 CFR Part 20, and are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels; (3) conduct operations so that: the total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem in a year, and the dose in any unrestricted area from external sources does not exceed 0.002 rem in any one hour; (4) submit a written report within 30 days of learning of the occurrence of doses in excess of the limits for an individual member of the public; (5) control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage; (6) conduct a physical inventory every 6 months to account for all sealed sources and/or devices received

and possessed under the license; and (7) secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

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 videoconference exit meeting on April 23, 2025.

Before the NRC makes its enforcement decision, we are providing you with the option to: (1) request a predecisional enforcement conference (PEC); or (2) request alternative dispute resolution. 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 within 10 days of the date of this letter to notify the NRC of your intended response to either 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 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 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 employs 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 ADR 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.

Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued for the apparent violations at this time. 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 on our deliberations in 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.

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 04/29/25

Tamara Bloomer, Director
Division of Radiological Safety & Security

Enclosure:
NRC Inspection Report 030-35486/2023-002

cc:
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

INTERNATIONAL ISOTOPES, INC. - NRC INSPECTION REPORT 030-35486/2023-002 – DATED APRIL 29, 2025

DISTRIBUTION:

RidsOeMailCenter Resource
RidsSecyMailCenter Resource
RidsEdoMailCenter Resource
RidsOiMailCenter Resource
R4-DRSS-MIB
JMonninger, ORA
TBloomer, DRSS
NO'Keefe, DRSS
JGroom, NRR
MBurgess, NMSS
VDricks, ORA
BAlferink, ORA
TSmith, ORA
MSimon, OGC
KPinetti, OGC
RidsNmssOd Resource
RidsOcaMailCenter Resource
EDO_Managers
RidsRgn1MailCenter Resource
R4-ORA-ACES
RAlexander, ORA
MMadison, DRMA
ARoberts, ORA
JCook, DRSS
RErickson, DRSS
AMoreno, CA
LWilkins, CA
AAlenArias, OEDO
DCylkowski, ORA
RidsOgcMailCenter Resource
RidsOigMailCenter Resource
RidsOcfoMailCenter Resource
RidsRgn3MailCenter Resource
R4Enforcement.resource
DPelton, OE
JCai, OE
JPeralta, OE
DBradley, OE
SWoods, OE
AMiller, NMSS
LRoldanOtero, DRSS
JKatanic, DRSS
CAlldredge, DRSS

International Isotopes, Inc. NRC Inspection Report 030-35486/2023-002

ADAMS ACCESSION NUMBER: **ML25094A089**

☒ SUNSI Review By: JFK	ADAMS: ☒ Yes ☐ No	☐ Sensitive ☒ Non-Sensitive	☐ Non-Publicly Available ☒ Publicly Available	Keyword NRC-002

OFFICE	SHP: MIB	HP: MLB	BC:MIB	TL:ACES	RC
NAME	JFKatanic	CAlldredge	LRoldanOtero	BAlferink	DCylkowski
SIGNATURE	/RA/	/RA/ E	/RA/ E	/RA/ E	/RA/ E
DATE	04/07/25	04/08/25	04/08/25	04/04/25	04/07/25
OFFICE	OE	OGC	NMSS	D:DRSS	
NAME	DBradley	MSimon	AMiller	TBloomer	
SIGNATURE	/RA/ E	/NLO/ E	/RA/ E	*/RA/*	
DATE	04/22/25	04/28/25	04/17/25	04/29/25	

OFFICIAL RECORD COPY

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket No.:	030-35486
License No.:	11-27680-01MD
Inspection Report No.:	030-35486/2023-002
EA No.:	EAF-RIV-2025-0022
Licensee:	International Isotopes, Inc.
Locations Inspected:	4077 Commerce Circle and 4137 Commerce Circle Idaho Falls, Idaho 83401
Inspection Dates:	February 23, 2023, and October 24-25, 2023, with in-office review through April 23, 2025
Exit Meeting Date:	April 23, 2025
Inspectors:	Janine F. Katanic, PhD, CHP Senior Health Physicist Materials Inspection Branch Division of Radiological Safety & Security, Region IV Casey Alldredge Health Physicist Materials Licensing Branch Division of Radiological Safety & Security, Region IV
Approved by:	Lizette Roldán-Otero, PhD Chief, Materials Inspection Branch Division of Radiological Safety & Security, Region IV
Attachment:	Supplemental Inspection Information

Enclosure

EXECUTIVE SUMMARY

International Isotopes, Inc. (INIS or Licensee)
NRC Inspection Report 030-35486/2023-002

On February 23, 2023, and October 24-25, 2023, the NRC performed a limited-scope inspection at the licensee's facility in Idaho Falls, Idaho with continued in-office review through April 23, 2025. International Isotopes, Inc. is authorized under NRC Materials License No. 11-27680-01MD to possess and use byproduct, source, and special nuclear materials for various licensed activities. Under its Type A Broad Scope license, they manufacture and distribute cobalt-60 sealed sources and other radionuclide sealed sources; distribute prepared radiopharmaceuticals and radiochemicals, including iodine-131; and are authorized for research and development activities.

The scope of the inspection was focused on INIS licensed activities that directly impacted on a non-licensee NRC applicant in an adjoining physical space. The purpose of the inspection was to examine these activities conducted under the INIS license as they relate to public health and safety, and to confirm compliance with NRC rules and regulations, and with the conditions of the license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observation of licensed activities and facilities, independent radiation measurements, and interviews with personnel.

Based on the inspection, seven apparent violations were identified regarding the licensee's failure to: (1) establish administrative controls and provisions relating to organization and management, procedures, record keeping, material control, and accounting and management review that are necessary to assure safe operations; (2) make or cause to be made, surveys of areas that may be necessary for the licensee to comply with the regulations in 10 CFR Part 20, and are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels; (3) conduct operations so that: the total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem in a year, and the dose in any unrestricted area from external sources does not exceed 0.002 rem in any one hour; (4) submit a written report within 30 days of learning of the occurrence of doses in excess of the limits for an individual member of the public; (5) control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage; (6) conduct a physical inventory every 6 months to account for all sealed sources and/or devices received and possessed under the license; and (7) secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

As corrective actions, in September 2023, February 24, and again in December 2024, the licensee installed radiation shielding in the INIS facility in order to mitigate radiation levels in the adjoining physical space that was occupied by the non-licensee NRC applicant. To this date the mitigation does not completely address radiation levels in the adjoining space.

REPORT DETAILS

1 Program Overview (Inspection Procedure (IP) 87125)

International Isotopes, Inc. (INIS or licensee) is authorized under NRC Materials License No. 11-27680-01MD to possess and use byproduct, source, and special nuclear materials for various licensed activities. They are a large manufacturing and distribution Type A Broad Scope licensee that manufactures and distributes cobalt-60 sealed sources for medical and industrial applications, as well as numerous models and types of sealed sources of various radioisotopes for calibration and reference standards. They also distribute prepared radiopharmaceuticals and radiochemicals, including iodine-131, and are authorized for research and development activities. The licensee conducts its licensed activities at its facility in Idaho Falls, Idaho.

Type A licenses of broad scope are typically the largest NRC licensed materials programs and encompass a broad range of uses of an equally broad range of licensed materials. In order to satisfy the requirements in 10 CFR 33.13(c)(3), these types of licensees establish a Radiation Safety Committee (RSC), appoint a qualified Radiation Safety Officer (RSO), and establish criteria to review and approve all uses of licensed material and users under the license.

At INIS, licensed activities are overseen by an RSC, which the licensee refers to as its As Low As is Reasonably Achievable (ALARA) Committee. The stated responsibility of the INIS ALARA Committee is to ensure the company's health and safety philosophy, and policy is effectively implemented.

The licensee is authorized to possess category 1 quantities of radioactive material and is subject to the requirements of 10 CFR Part 37. However, specific quantities of licensed materials authorized by the license or possessed by the licensee are considered sensitive security-related information and will not be provided herein.

2 Inspection Scope (IP 87125)

On February 23, 2023, and October 24-25, 2023, the NRC performed limited-scope inspection activities of INIS. The scope of the inspection was focused on INIS licensed activities that directly impacted a non-licensee NRC applicant in an adjoining physical space. The purpose of the inspection was to examine these activities conducted under the NRC license as they relate to public health and safety, and to confirm compliance with NRC rules, and regulations and with the conditions the license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observation of licensed activities and facilities, independent radiation measurements, and interviews with personnel.

3 Background (IP 87125)

The INIS facility in Idaho Falls, Idaho, is a leased facility. In April 2019, INIS began building what they referred to as the "West Expansion," "West Building," "Progenics Wing," or "Progenics Building" onto their leased building. Hereafter it will be referred to as the West Building. The West Building was constructed along the west side of the existing INIS building and was attached to a portion of the exterior of the existing INIS building. The portion of the INIS facility that directly interfaced with the West Building

buildout was an area where INIS handled category 1 quantities of cobalt-60, disassembled and manufactured cobalt-60 sealed sources, and handled iodine-131. In those areas where the West Building interfaced with the existing INIS building, no additional shielding was put in place during construction.

The intent of the approximately 6000 square foot buildout of the West Building was to establish a dedicated area for a company named Progenics Pharmaceuticals, Inc., to have facilities to perform activities under a manufacturing contract with INIS under the INIS NRC license. Progenics would work under the INIS license to produce a certain radioactive drug for distribution under the INIS license. The intent was that two individuals, who were both INIS employees, would work in the West Building under the manufacturing contract with Progenics. The West Building was equipped with various necessary equipment to include a biosafety cabinet, HEPA filtration system, laminar flow hood, ductless fume hood, refrigerators, freezer, hot cell with telemanipulators, a quality control laboratory, and cleanroom facilities. The West Building was constructed as a one level working area. The portion of the West Building with the laboratory area has a mezzanine above for heating, ventilation, and air conditioning systems and other equipment.

Construction of the West Building was completed in June 2020. At that time, four test runs with iodine-131 licensed materials were performed in the new West Building by the INIS staff that were working under the Progenics contract. Progenics was acquired by Lantheus, with their merger being complete in June 2020. In October 2020, Lantheus ended its manufacturing contract with INIS. After that time, the West Building sat vacant with the exception of a set-aside portion that was used for storage by INIS and accessed occasionally by INIS employees.

Subsequently, PharmaLogic Holdings Corp. became interested in acquiring the West Building physical assets and subleasing the building from INIS. PharmaLogic Holdings Corp. is a contract development and manufacturing organization with specialization in radiopharmaceuticals for diagnostic and therapeutic use. Subsidiaries of PharmaLogic Holdings Corp. operate NRC and Agreement State licensed radiopharmacies under individual licenses in several states.

In February 2022, PharmaLogic Idaho, LLC (PharmaLogic), a non-licensee subsidiary of PharmaLogic Holdings Corp., purchased most of the physical assets and equipment contained within the West Building. Concurrently, a sublease agreement was entered into between INIS and PharmaLogic. Under the sublease agreement, PharmaLogic would sublease the West Building from INIS and PharmaLogic would apply for its own NRC license to operate the facility to perform activities related to the manufacturing and distribution of radioactive drugs.

On November 30, 2022, PharmaLogic submitted a license application dated October 18, 2022, to the NRC. The application was for a new license to perform licensed activities at 4077 Commerce Circle, Idaho Falls, Idaho. It appeared to the inspector that this address was the West Building of the INIS facility, although that street address was not associated with the INIS NRC license. Consistent with NRC policies and procedures, arrangements were made for NRC inspectors to perform a pre-licensing site visit (PLSV), including an assessment of the suitability of PharmaLogic's proposed facility for the requested purposes specified in the application.

4 Observations and Findings (IP 87125)

4.1 Inspection Observations Related to NRC's February 23, 2023, Inspection Activities

The PLSV of PharmaLogic was performed on February 23, 2023. Based on observations made during the PLSV, the inspectors commenced a limited-scope inspection of INIS on February 23, 2023.

During a tour of PharmaLogic's proposed facility, which was the subleased West Building of the INIS facility, the inspectors observed that Room 102 in the West Building was posted as "Caution - Radiation Area." Because PharmaLogic was not licensed to possess, use, or store licensed materials, the inspectors inquired regarding the posting. PharmaLogic stated that the "Caution - Radiation Area" posting had been in place when they commenced their sublease, and therefore it was posted by INIS.

Room 102 was observed to be a push-to-open door without a handle or lock set. The door was equipped with a magnetic door strike, but it was not activated, and the door was therefore unsecured and was able to be pushed open. The inspector conducted radiation surveys in Room 102, the adjacent rooms, and in other areas of the West Building. The surveys indicated elevated radiation levels in Room 102, significantly higher than background radiation levels that one would expect for an unlicensed facility. The inspector was familiar with the INIS facility and recognized that the INIS cobalt-60 sealed source disassembly and manufacturing area, as well as the INIS general cobalt 60 handling activities, take place in the area immediately behind Room 102. The licensed activities performed by INIS in this area vary significantly depending on INIS customer orders and other business needs. Some activities are longer duration from minutes to hours, and others are shorter and in the order of seconds. Some activities may use a few thousand curies of cobalt-60 while others use tens of thousands. Most activities take place within hot cells. Significant radiation levels are associated with these activities. At the time of the PLSV, there were no licensed cobalt-60 activities ongoing in that portion of the INIS facility.

PharmaLogic personnel expressed to the inspectors that they wanted to better understand the radiation levels from INIS activities that were impacting the West Building. Although an applicant and not a licensee, and thus not required to comply with 10 CFR Part 20 requirements, PharmaLogic had commenced performing weekly radiation surveys to establish a baseline throughout the West Building. PharmaLogic also implemented a personnel dosimetry program starting in November 2022. They had also installed area dosimeters within the West Building and were in the process of installing continuous area radiation monitors.

The inspectors discussed the elevated radiation levels in the West Building with INIS. INIS noted that they were performing monthly radiation surveys in the West Building. They had been surveying the entire West Building, but starting in 2023, had dropped this down to just surveying Room 102.

The then-INIS President and the INIS RSO asserted that PharmaLogic personnel were being occupationally exposed to radiation from INIS activities and were therefore subject to the NRC's occupational dose limits in 10 CFR 20.1201 as opposed to the NRC's dose limits for members of the public in 10 CFR 20.1301. The inspectors discussed with INIS that the PharmaLogic facility was not licensed, and the PharmaLogic personnel were not

engaged in licensed activities, did not have assigned duties involving exposure to radiation or radioactive material, and were not occupationally exposed or monitored employees of INIS, and therefore the public dose limits applied.

The inspectors reviewed INIS radiation survey records. The inspectors observed that the results of the INIS monthly surveys could not be directly correlated to INIS licensed activities. For example, the surveys might have been performed when INIS had cobalt-60 handling activities taking place involving various quantities of cobalt-60, or the surveys might have been performed when no such activities were taking place. For one particular area in Room 102, measurements taken by INIS at or near the surface of the wall ranged in value from 1.1 to 4.7 millirem per hour, but it is unknown what activities, if any, were taking place in the INIS facility at the time the INIS measurements were taken, or how long the exposure occurred, or whether PharmaLogic personnel were present in those areas.

The inspectors observed that INIS had two area dosimeters posted in Room 102 of the West Building, along the adjoining wall with INIS. The inspectors reviewed available dosimetry reports. For the time period of January 2022 – January 2023, the area dosimeter along the north portion of the wall accumulated 662 millirem and the other area dosimeter on the south portion of the wall accumulated 19,306 mrem (19.3 rem). Although these dosimeters were in place continuously, and PharmaLogic personnel were not present continuously, the area dosimeter readings are a strong indicator of the potential radiation levels from INIS licensed activities that were impacting the West Building.

The inspectors determined that during September 2019, while the West Building was still being constructed and had been partially finished with some framing and other features in place, INIS performed a series of radiation surveys using varying amounts of cobalt-60 in the INIS area. A series of radiation surveys were taken at various locations and heights during construction of the West Building, including with “all radioactive material put away,” with a few thousand curies of cobalt-60, and with tens of thousands of curies of cobalt-60. The cobalt-60 was placed at different heights and locations within the INIS cobalt-60 processing and handling area. Photos taken during the surveys indicated that the licensee had the construction area closest to the INIS cobalt-60 processing and handling area roped off and posted as “See Radiological Controls.” Radiation levels documented in the construction area ranged in the order of a few millirem per hour to 35 millirem per hour, depending on the source activity and configuration.

The licensee provided information regarding the quantities of cobalt-60 that are typically used in the INIS processing area. The INIS RSO explained that there was a maximum amount of activity of cobalt-60 that they could put in their processing hot cell. However, this activity, which was in the tens of thousands of curies range, was not specified in any INIS procedure or administrative control. The INIS RSO also explained that the amount they typically use in the processing hot cell is limited by the maximum activity of the sealed source they are authorized to manufacture under their license.

The inspectors determined that in December 2019, the licensee’s ALARA Committee formally evaluated areas in the West Building using INIS Form F-527, Rev. A, “ALARA Committee Evaluation.” Three different areas in the “Progenics Wing” (the West Building) were reviewed. The form contained the question “Could adjacent operations

increase general area radiation levels by 2 millirem per hour?" In all three cases, the answer was "Yes." The next item was "if Yes, affect mitigate using:" and offered three options: temporary shielding, permanent shielding, or administrative controls. In all three cases, "administrative controls" were selected. In all three cases it was noted that "cobalt-60 operations may result in elevated dose rates." The areas in the West Building with elevated dose rates were identified as: (1) Room 102; (2) the area to the left and right of the biosafety cabinet in Room 104; and (3) Room 109, the mechanical area behind the TEMA hot cell in Room 108.

To serve as the designated "administrative controls," the ALARA Committee Evaluation Forms noted that Rooms 102 and 109 would be posted as "Coordinate with cobalt-60 operations prior to entry," and that Rooms 102, 104, 106, 109, and 112 would be posted as "Caution- Radiation Area." The INIS ALARA Committee Evaluation Forms had full ALARA Committee review and approval.

PharmaLogic personnel stated that when they subleased the facility in February 2022, only Room 102 was posted as "Caution - Radiation Area," and that there were no postings regarding contacting INIS cobalt-60 operations prior to entry into the various rooms of their subleased space. The inspectors inquired with INIS as to when and why the administrative controls had been removed, other than Room 102 posted as "Caution-Radiation Area." The removal of the other administrative controls appeared to have occurred prior to February 2022. A review of the INIS ALARA Committee minutes did not find any discussion regarding the removal of the administrative controls.

When the administrative controls were put in place in December 2019, the West Building was an INIS-controlled area, which was staffed by INIS employees. Accordingly, INIS could easily implement the administrative controls and avoid working in areas of the West Building subject to administrative controls (referred to here as "designated areas") when cobalt-60 operations were ongoing. However, after INIS subleased the West Building to PharmaLogic in February 2022, the building and the designated areas within it were no longer controlled by INIS and the building was staffed with PharmaLogic personnel. It appears that there was an informal agreement between some INIS staff and some PharmaLogic staff that INIS would inform PharmaLogic when it was necessary to stay out of the designated areas due to INIS activities that would increase dose rates. PharmaLogic staff that were interviewed by the inspectors stated that they could not recollect ever being informed of any actual cobalt-60 operations or the need to avoid or vacate certain rooms in the West Building.

The inspectors inquired as to why the ALARA Committee Evaluation forms were not revisited when the decision was made by INIS to sublease the West Building to PharmaLogic. The inspectors determined that the F-527 forms had only been used by INIS for the three evaluations in December 2019, and that the forms had not been used for any other INIS projects since 2019. Furthermore, the inspectors determined that Form F-527 existed outside of any INIS procedure, policy, or manual, meaning that there were no INIS procedures or policies that referenced the purpose or use of Form F-527. The INIS Radiation Safety Manual also did not reference the purpose and use of the form.

When touring the Room 109 mechanical area in the West Building, the inspectors observed a small lockable safe-like container on the floor with "Caution – Radioactive Materials" labels taped to it. The contents of the box were examined and found to

contain a RadQual Model BM03 europium-152 sealed source that was exempt from licensing, and a RadQual benchmark Model BM06 barium-133 sealed source (Sealed Source and Device Registration Certificate NR-1235-S-102-S), which requires a specific license to possess. Both of these sources were manufactured by INIS at the adjoining INIS facility for distribution under the INIS license.

The barium-133 sealed source is typically used as a reference source for performing quality control of dose calibrators. The barium-133 source observed was 0.294 millicuries, which requires a specific license to possess. The PharmaLogic proposed site RSO stated that during their day-to-day activities, they found the barium 133 source in one of the rooms in the West Building. Because there were various contractors accessing the room during construction and equipment installation activities, they decided to procure a lockable container to secure the source. They controlled the key for the container. The PharmaLogic proposed site RSO did not appear to be familiar with this type of reference source and was unaware that a specific license was required to possess the source.

The inspectors discussed the barium-133 sealed source with INIS. The former INIS President and the RSO were unaware of that PharmaLogic possessed this specific source and researched the history of the source using its serial number. It was determined that the barium-133 source was manufactured by INIS but not entered into its inventory. Instead, the source had been used by INIS in the West Building when the four test runs with iodine-131 were performed in 2020. It appeared that the source was left in one of the West Building rooms since that time and had not been included in the INIS sealed source inventory. The licensee stated that they considered the source to be "in storage" in the West Building. However, the West Building was subsequently subleased to PharmaLogic and was no longer a location that INIS controlled, and the source was not being used for INIS licensed activities. It was confirmed by INIS that the barium-133 sealed source was not part of the asset purchase made by PharmaLogic, and that the source had not been transferred by INIS to PharmaLogic. Because INIS was unaware that the source was still located in the West Building, it was left behind unsecured, where it was recovered and secured by PharmaLogic, a non-licensed entity, after they subleased the building in February 2022. Following the discussion with the inspectors, INIS requested that PharmaLogic return the source to INIS, which occurred shortly thereafter.

Following the NRC inspection, INIS installed a lockset on the door to Room 102 in order to control access to the radiation area created by INIS licensed activities in the PharmaLogic subleased space. Room 102 remained posted as "Caution- Radiation Area" and INIS controlled the key. PharmaLogic staff had to request access to Room 102 if entry was needed.

On March 29, 2023, PharmaLogic withdrew its license application dated October 18, 2022, and noted that they planned to resubmit an application at a later date.

4.2 Inspection Observations Related to NRC's October 24-25, 2023, Inspection Activities

PharmaLogic submitted a new license application dated June 22, 2023, to NRC. The application was for a new license to perform licensed activities at 4077 Commerce Circle, Idaho Falls, Idaho. As with the original application, arrangements were made for NRC inspectors to perform another PLSV. The purpose of the PLSV included an

assessment of the progress made by the applicant in finishing construction activities in the West Building, and to further assess the suitability of the proposed facility for the requested purposes specified in the application.

The former INIS President and Chief Executive Officer retired in September 2023 and the position was filled with an individual from outside INIS.

The PLSV of PharmaLogic was performed on October 24-25, 2023. Concurrently, the inspectors continued their limited-scope inspection of INIS.

During March 2023, after the questions raised during the previous NRC site visit, the licensee ran a test using a cobalt-60 source to simulate a cobalt-60 transfer. The INIS RSO considered that the transfer of cobalt-60 into and out of the INIS hot cells could result in the potential for higher radiation exposure levels in West Building. The cobalt-60 source used during the test was somewhat higher in activity than the maximum cobalt-60 activity source authorized to be manufactured by the licensee. During the test transfer, the highest dose rate observed was 140 millirem per hour on contact with the wall inside of Room 102 in the West Building, and 80 millirem per hour 12 inches from the wall. It was explained that during normal operations, these types of dose rates may exist for a few seconds (5 seconds). The INIS RSO noted that this would not pose a personnel exposure issue.

INIS informed the inspector that Room 102 was going to be used by PharmaLogic as an unoccupied storage room, and therefore the radiation levels in the room were not considerable given the low occupancy of a storage room. However, PharmaLogic stated that when the facility was closer to fully operational, the room would be routinely staffed for approximately 4 hours daily. Furthermore, according to the PharmaLogic corporate RSO, the sublease agreement did not contain any restrictions regarding the occupancy or usage for Room 102.

On April 18, 2023, the licensee's ALARA Committee met to discuss the use of additional shielding on the INIS cobalt-60 hot cells to reduce the radiation exposure rates in Rooms 102 and 104 in the West Building. On August 15, 2023, the licensee's ALARA Committee met again to discuss the proposed additional shielding. The additional shielding, which was designed by INIS, was installed in September 2023.

During the inspection, INIS showed the inspectors the radiation shielding that they had installed in September 2023. The shielding consisted of two rows of concrete blocks and 2.25 inches of iron. The shielding extended part way up the wall behind the production hot cell. Shielding was not installed behind the "clean" cobalt-60 hot cell. The emphasis of the shielding placement was focused on direct shielding between the cobalt-60 source handling activities and a potential receptor directly on the other side of the wall, in Room 102 or 104 of the West Building. Based on radiation surveys performed by INIS and PharmaLogic, the shielding appeared to be effective in reducing general radiation levels in Room 102, although the dose rates were not fully mitigated.

Furthermore, the inspectors observed that the shielding as installed would have no impact on radiation dose from skyshine. The skyshine phenomenon occurs when a ceiling or roof is not adequate for shielding and radiation penetrates the roof, scattering off the atmosphere and irradiating individuals even at some distance from the source of radiation. Based on weekly surveys performed by PharmaLogic, the skyshine

phenomenon was evident, with months of radiation measurements indicating that for Room 102, the radiation levels further from the adjoining wall with INIS (closer to the door and hallway) were regularly 3 to 5 times higher than readings nearer to the wall. For example, one survey in Room 102 indicated 410 microrem per hour close to the adjoining wall, whereas further away from the wall, closer to the door and the hallway, the survey indicated 2.05 millirem per hour.

During the inspection, INIS also took the inspectors on a general tour of the exterior of the INIS facility, which included the INIS warehouse and a quonset hut used by INIS for storage of certain radioactive materials. It was explained by INIS that they had made changes in the warehouse since the prior NRC site visit, by disposing of some licensed materials and moving other licensed materials further from the PharmaLogic facility. Both of these actions were taken to reduce the radiation impact from the INIS licensed operations on the PharmaLogic facility, particularly the office and breakroom area used by PharmaLogic personnel.

As the inspectors approached the quonset hut, no INIS personnel were present in the vicinity of the facility. The quonset hut roll-up door was closed, but the inspectors observed that it was unlocked. The inspectors observed that inside of the quonset hut were several 55-gallon drums and other containers labeled as “Radioactive Materials.” The labels on the drums and containers indicated that they contained cobalt-57, germanium-68, and sodium-22 waste, or contained contaminated items. An unknown object was covered by a clear poly bag, which was labeled, in part, “Caution: fixed contamination, 3000 cpm [counts per minute], possible removeable contamination, reactor and NARM [naturally-occurring and accelerator-produced radioactive material] radionuclides.” The inspectors observed that the gate to the INIS facility was open, and the area in the vicinity of the quonset hut was accessible by non-licensee personnel.

During a tour of the West Building on October 24, 2023, the inspectors noted that the “Caution - Radiation Area” posting from the prior NRC site visit was no longer on the door to Room 102, and the lock set was no longer installed. Access was being controlled via a keycard using the magnetic strike, with both INIS and PharmaLogic personnel having access. The inspectors inquired with INIS regarding the removal of the posting. The INIS RSO stated that Room 102 did not meet the criteria to require posting as a Radiation Area. When the inspectors returned on October 25, 2023, Room 102 had again been posted as “Caution – Radiation Area” and had a sign indicating that access was restricted, and that for access, the INIS RSO or INIS Facilities Manager should be contacted.

Outside of Room 102, in the hallway, was a dedicated hand and foot monitor “frisker” station that had been installed by PharmaLogic in anticipation of future operations. PharmaLogic demonstrated to the inspectors that the instrument would immediately enter into alarm mode when turned on because of the radiation impact from the INIS licensed activities.

The inspectors reviewed the calendar year 2023 year-to-date results of the area dosimeters that INIS posted in Room 102 of the West Building, along the adjoining wall with INIS. For the time period of January 2023 – July 2023, representing two quarters, or approximately half a year, the area dosimeter along the north portion of the Room 102 wall accumulated 694 millirem and the other area dosimeter on the south portion of the

wall accumulated 15,471 mrem (15.5 rem). Although these dosimeters were in place continuously, and PharmaLogic personnel were not present continuously, the dosimeter readings are a strong indicator of the potential radiation levels impacting the West Building.

The inspectors observed that PharmaLogic had made considerable progress in installing equipment and in further finishing the facility, including office space and a break area. PharmaLogic stated that based on their radiation surveys, radiation levels were elevated in their office area when compared with background. The inspector's radiation surveys indicated elevated radiation levels considerably higher than background. The office space was quite a bit further away from the area of the INIS cobalt-60 operations and appeared to be impacted by radioactive waste and other materials being stored by INIS in its detached warehouse and quonset hut. The INIS warehouse and the quonset hut were several feet away from the PharmaLogic office area. The PharmaLogic office space also appeared to be additionally impacted by INIS licensed activities during those days of the week when INIS had large numbers of shipments of licensed materials awaiting pickup from the INIS shipping and receiving area.

The inspectors were informed that PharmaLogic considered storing their control dosimeters in the office space, but the radiation levels were deemed too high. As a result, the PharmaLogic proposed site RSO decided to store the control badges at their personal residence. PharmaLogic staff had been informed by the proposed site RSO to not leave their dosimeters in the office, but rather to take the dosimeters home at night, because the radiation levels in the office area were too elevated and would contribute erroneous dose to the dosimeters.

PharmaLogic also stated that based on their personnel dosimetry reports, one of its employees had exceeded 100 mrem during calendar year 2023, specifically as recorded in the available August 2023 year-to-date report. The dosimeter indicated that the individual had received a deep dose equivalent of 107 mrem. The inspectors interviewed the individual, who worked for PharmaLogic as a facilities engineer that installed and serviced heating, ventilation, and air conditioning systems and other mechanical equipment. The individual related that they spent quite a bit of time in the mezzanine mechanical area above the subleased space and rarely entered Room 102. The individual stated that they had never worked with or around radiation before, and that during the dosimeter wear period, neither they nor any family members had undergone any medical procedures involving exposure to radiation or radioactive materials.

When the individual's dose exceeding 100 millirem was identified, PharmaLogic asked the individual to remain at home and not return to the facility. PharmaLogic stated that they had informed INIS of the dose to the individual and that the individual had been asked to remain at home. However, in October 2023, the individual was informed that the PharmaLogic corporate RSO cleared the individual to return to the facility.

The individual's radiation dose was discussed with INIS, and an inquiry made as to why this dose to a member of the public in excess of NRC's dose limits for members of the public in 10 CR 20.1301(a)(1) was not reported to the NRC in accordance with 10 CFR 20.2203(a)(2)(iv). It was reasserted by INIS that they believed that PharmaLogic personnel were occupationally exposed and not members of the public. Accordingly, per INIS, the public dose limits in 10 CR 20.1301(a)(1) were not exceeded and a report was not required in accordance with 10 CFR 20.2203(a)(2)(iv). It was further elaborated by

INIS that the individual was told by PharmaLogic not to return to the facility and was no longer being exposed. The inspectors informed INIS that the individual had recently returned to work based on a determination by the PharmaLogic corporate RSO.

On April 4, 2024, PharmaLogic withdrew its license application dated June 22, 2023.

4.3 Apparent Violations

Based on the inspectors' review of licensed activities, seven apparent violations were identified regarding the licensee's failure to: (1) establish administrative controls and provisions relating to organization and management, procedures, record keeping, material control, and accounting and management review that are necessary to assure safe operations; (2) make or cause to be made, surveys of areas that may be necessary for the licensee to comply with the regulations in 10 CFR Part 20, and are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels; (3) conduct operations so that: the total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem in a year, and the dose in any unrestricted area from external sources does not exceed 0.002 rem in any one hour; (4) submit a written report within 30 days of learning of the occurrence of doses in excess of the limits for an individual member of the public; (5) control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage; (6) conduct a physical inventory every 6 months to account for all sealed sources and/or devices received and possessed under the license; and (7) secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

4.3.1 **Apparent violation of 10 CFR 33.13(c)(3)**

Title 10 CFR 33.13(c)(3) requires, in part, that the licensee establish administrative controls and provisions relating to organization and management, procedures, record keeping, material control, and accounting and management review that are necessary to assure safe operations, including the establishment of administrative procedures to assure: (i) control of procurement and use of byproduct material; (ii) completion of safety evaluations of proposed uses of byproduct material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and (iii) review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 10 CFR 33.13(c)(3)(ii) prior to use of the byproduct material.

Contrary to the above, from February 2022 to October 25, 2023, the licensee failed to establish appropriate administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that were necessary to assure safe operations. The licensee's administrative procedures were inadequate to assure: (i) control of procurement and use of byproduct material; (ii) completion of safety evaluations of proposed uses of byproduct material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and (iii) review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 10 CFR 33.13(c)(3)(ii) prior to use of the byproduct material. Four examples of the licensee's failure were identified, specifically:

1. When the licensee subleased the West Building, the licensee's ALARA Committee failed to re-evaluate the elevated dose rates in the West Building caused by INIS licensed activities. When the facility was subleased, the licensee removed administrative controls that it had in place which included that certain rooms in the West Building be posted as "Caution - Radiation Area" and "Coordinate with cobalt-60 operations prior to entry."
2. When the licensee subleased the West Building, the licensee's ALARA Committee failed to take into consideration that the sublessee was a non-licensed entity and that personnel working in the West Building were not occupationally exposed individuals, and therefore the public dose limits in 10 CFR 20.1301 were applicable.
3. When the licensee subleased the West Building, the licensee failed to consider the impact of its licensed activities on all of the areas of the West Building, including rooms, corridors, mezzanine space, office space, and break areas.
4. When designing and installing shielding to mitigate the radiation levels in the West Building, the licensee failed to conservatively account for potential radiation impacts from all of its licensed activities, including all cobalt-60 handling and storage, handling and storage of other radioactive materials, temporary storage of radioactive materials prepared for shipment, and radioactive materials waste handling and storage areas.

The licensee's failure to establish administrative controls and provisions relating to organization and management, procedures, record keeping, material control, and accounting and management review that are necessary to assure safe operations, was identified as an apparent violation of 10 CFR 33.13(c)(3). (030-35486/2023-002-01)

4.3.2 **Apparent violation of 10 CFR 20.1501(a)**

Title 10 CFR 20.1501(a), requires, in part, that each licensee shall make or cause to be made, surveys of areas that may be necessary for the licensee to comply with the regulations in 10 CFR Part 20, and are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels.

Contrary to the above, from February 2022 to October 25, 2023, the licensee failed to make, or cause to be made, surveys of areas that may be necessary for the licensee to comply with the regulations in 10 CFR Part 20, and were reasonable under the circumstances to evaluate the magnitude and extent of radiation levels. Specifically, the licensee's surveys of the subleased West Building, which was an unrestricted area occupied by a non-licensed entity, were not adequate or reasonable under the circumstances to evaluate the magnitude and extent of radiation levels caused by its licensed activities. The licensee's surveys were inadequate because they failed to fully evaluate the elevated radiation levels throughout the West Building. As a result, the licensee's surveys of the West Building failed to consider the full impact of its licensed activities on all of the areas in the West Building.

The licensee's failure to make or cause to be made, surveys of areas that may be necessary for the licensee to comply with the regulations in 10 CFR Part 20 and were reasonable under the circumstances to evaluate the magnitude and extent of radiation levels, was identified as an apparent violation of 10 CFR 20.1501(a). (030 35486/2023-002-02)

4.3.3 **Apparent violation of 10 CFR 20.1301**

Title 10 CFR 20.1301 requires, in part, that each licensee shall conduct operations so that: (1) the total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem in a year, exclusive of the dose contributions from background radiation, and (2) the dose in any unrestricted area from external sources does not exceed 0.002 rem in any one hour.

Contrary to the above, from February 2022 to October 25, 2023, the licensee failed to conduct operations so that: (1) the total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem in a year, exclusive of the dose contributions from background radiation, and (2) the dose in any unrestricted area from external sources does not exceed 0.002 rem in any one hour. Specifically, an employee of an unlicensed entity working in the West Building, adjacent to the licensee's facility, received a dose exceeding 0.1 rem for calendar year 2023, and radiation surveys performed in the West Building during 2022-2023 indicated that the dose resulting from the licensee's activities could exceed 0.002 rem in any one hour.

The licensee's failure to conduct operations so that: (1) the total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem in a year, and (2) the dose in any unrestricted area from external sources does not exceed 0.002 rem in any one hour, was identified as an apparent violation of 10 CFR 20.1301. (030-35486/2023-002-03)

4.3.4 **Apparent violation of 10 CFR 20.2203(a)(2)(iv)**

Title 10 CFR 20.2203(a)(2)(iv) requires, in part, that each licensee shall submit a written report within 30 days of learning of the occurrence of doses in excess of the limits for an individual member of the public in 10 CFR 20.1301.

Contrary to the above, in October 2023, the licensee failed to submit a written report within 30 days of learning of the occurrence of doses in excess of the limits for an individual member of the public in 10 CFR 20.1301. Specifically, after being informed in approximately September 2023 that an employee of a non-licensed entity working in the West Building, adjacent to the licensee's facility, had received a dose exceeding 0.1 rem for calendar year 2023, the licensee failed to report this information to the NRC within 30 days.

The licensee's failure to submit a written report within 30 days of learning of the occurrence of doses in excess of the limits for an individual member of the public in 10 CFR 20.1301, was identified as an apparent violation of 10 CFR 20.2203(a)(2)(iv). (030-35486/2023-002-04)

4.3.5 **Apparent violation of 10 CFR 20.1802**

Title 10 CFR 20.1802 requires that the licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Contrary to the above, from February 2022 to February 23, 2023, the licensee failed to control and maintain constant surveillance of licensed material that was in a controlled or

unrestricted area and that was not in storage. Specifically, between the specified dates, the licensee left a RadQual Model BM06E-33 sealed source containing approximately 294 microcuries of barium-133 (Sealed Source and Device Registration Certificate NR-1235-S-102-S) in an area that was subleased to a non-licensed entity and was not under control or constant surveillance by the licensee.

The licensee's failure to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage, was identified as an apparent violation of 10 CFR 20.1802. (030-35486/2023-002-05)

4.3.6 **Apparent violation of License Condition 18**

License Condition 18 of NRC License No. 11-27680-01MD, Amendment No. 40, dated May 3, 2021, requires, in part, that each licensee shall conduct a physical inventory every 6 months to account for all sealed sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 3 years from the date of each inventory, and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

Contrary to the above, from February 2022 to February 23, 2023, the licensee failed to conduct a physical inventory every 6 months to account for all sealed sources and/or devices received and possessed under the license. Specifically, during the specified time frame, a period in excess of 6 months, the licensee failed to perform a physical inventory for a RadQual Model BM06E-33 sealed source containing approximately 294 microcuries of barium-133 (Sealed Source and Device Registration Certificate NR 1235-S-102-S).

The licensee's failure to conduct a physical inventory every 6 months to account for all sealed sources and/or devices received and possessed under the license, was identified as an apparent violation of License Condition 18. (030-35486/2023-002-06)

4.3.7 **Apparent violation of 10 CFR 20.1801**

Title 10 CFR 20.1801 requires that the licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Contrary to the above, on October 24, 2023, the licensee failed to secure from unauthorized removal or access licensed materials that were stored in controlled or unrestricted areas. Specifically, the licensee failed to secure from unauthorized removal or access (1) licensed material contained in several 55-gallon drums labeled as "Radioactive Materials" that contained cobalt-57, germanium-68, and sodium-22 waste, and (2) an object in a clear poly bag labeled as having 3000 counts per minute of radioactive contamination. The items were stored in a licensee quonset hut, but the roll-up door to the quonset hut was not locked, and the materials were not under constant control and surveillance by the licensee.

The licensee's failure to secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas, was identified as an apparent violation of 10 CFR 20.1801. (030-35486/2023-002-07)

5 Causal Evaluation (IP 87125)

A formal root cause analysis was not performed by the inspectors as it was beyond the scope of the inspection. The inspectors' general observations were that the deficiencies could largely be attributed to the lack of oversight of the Type A Broad scope license by the INIS ALARA Committee.

As a manufacturing and distribution Type A Broad Scope, the NRC authorizes the licensee to review and approve its own users and uses without having to seek NRC approval. If the licensee does not have appropriate or adequate processes or procedures for its ALARA Committee to review changes in facility usage and to evaluate and mitigate radiation levels, the NRC's confidence in the licensee's ability to continue to have Type A Broad Scope authorization is diminished.

When the West Building was constructed, INIS intended that the facility would be controlled by INIS and that individuals would perform licensed activities in the facility under the INIS license. As a result, the INIS ALARA Committee evaluated the radiation levels in the new facility and decided to not implement engineered controls such as installing temporary or permanent radiation shielding, but rather to rely on administrative controls. The administrative controls consisted of postings on certain doors within the new facility. This decision had full ALARA Committee review and approval.

The INIS Radiation Safety Manual, PD-RSP-001, Rev. N, dated April 28, 2021, Section II.C.2.e. states that any time a work document or project, that had initially received full ALARA Committee review, and which is modified or revised, shall be reviewed by the ALARA Chairperson, as a minimum, to determine whether full committee review of the modified work process is required.

When INIS decided to sublease the facility to a non-licensed entity, the INIS ALARA Committee did not re-evaluate its determination that only administrative controls would be necessary to mitigate the radiation levels in the facility from INIS licensed activities. Furthermore, all of the administrative controls with the exception of one "Caution – Radiation Area" posting on Room 102 were removed. The West Building transitioned from a facility that INIS controlled and used, and that was staffed by INIS personnel, to a facility that was in the control of a non-licensed entity and staffed by non-INIS personnel who met the 10 CFR 20.1003 definition of *members of the public*.

When the licensee took actions to install shielding in its facility to mitigate the radiation levels in the West Building, the actions were not comprehensive. The installed shielding was not adequate, and the scope and extent of the shielding did not fully consider all potential sources of radiation impacting the West Building.

6 Corrective Actions and Status (IP 87125)

In September 2024, INIS installed radiation shielding behind the INIS cobalt-60 production hot cell, in order to mitigate radiation levels in the West Building.

In July 2024, INIS submitted a license amendment request to authorize PharmaLogic to work as a contractor under the INIS NRC license. This amendment request was approved by NRC and issued on November 14, 2024, as Amendment No. 41 to NRC License No. 11-27680-01MD. With this approval, the PharmaLogic personnel would be

occupationally exposed and monitored under the INIS license. This was meant to be a short-term solution to allow PharmaLogic to continue to develop procedures and processes necessary to obtain its own NRC license.

In December 2024, the licensee had additional shielding installed in the INIS facility in order to mitigate radiation levels in the West Building. This new shielding was installed to higher up the wall and covered the areas behind the production hot cell, clean hot cell, and other adjacent areas.

On January 6, 2025, PharmaLogic submitted a license application to NRC dated December 19, 2024. The application was for a new license to perform licensed activities at 4077 Commerce Circle, Idaho Falls, Idaho. This license application is currently under review by NRC.

Based on the information provided by PharmaLogic, despite the multiple shielding attempts by INIS described above, several areas with elevated radiation levels continued to exist within the West Building. PharmaLogic worked with the licensee to identify the additional sources of radiation in the INIS facility so that they could be shielded. Additional shielding was implemented by INIS in February 2025, but areas of elevated radiation levels persist and are being evaluated for further shielding by INIS.

7 Conclusions (IP 87125)

Based on the inspection, seven apparent violations were identified regarding the licensee's failure to: (1) establish administrative controls and provisions relating to organization and management, procedures, record keeping, material control, and accounting and management review that are necessary to assure safe operations; (2) make or cause to be made, surveys of areas that may be necessary for the licensee to comply with the regulations in 10 CFR Part 20, and are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels; (3) conduct operations so that: the total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem in a year, and the dose in any unrestricted area from external sources does not exceed 0.002 rem in any one hour; (4) submit a written report within 30 days of learning of the occurrence of doses in excess of the limits for an individual member of the public; (5) control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage; (6) conduct a physical inventory every 6 months to account for all sealed sources and/or devices received and possessed under the license; and (7) secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

8 Exit Meeting Summary

On April 23, 2025, a final videoconference exit meeting was conducted with Shahe Bagerdjian, President; and John Miller, CHP, RSO, to discuss the inspection findings. The NRC representatives discussed the content of the inspection report, described the NRC's enforcement process, and described the options for the licensee to: (1) request a predecisional enforcement conference; or (2) request alternative dispute resolution. The licensee did not identify any proprietary information.

Supplemental Inspection Information

PARTIAL LIST OF PERSONS CONTACTED

INIS:
Shahe Bagerdjian, President and Chief Executive Officer
Steve Laflin, former President and Chief Executive Officer
John Miller, CHP, RSO

PharmaLogic:
Frank Plastini, PharmaLogic Holdings Corp., Corporate RSO
James Nunn, PharmaLogic Holdings Corp., former Corporate RSO
Jonathan Popovich, PharmaLogic Holdings Corp., Associate Director of Theranostics
Nicholas Christiansen, PharmaLogic Idaho, former proposed RSO
Gary Smith, PharmaLogic Idaho, Manager of Manufacturing Operations

INSPECTION PROCEDURES USED

IP 87125 Materials Processor/Manufacturer Programs

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-35486/2023-002-01	AV	Failure to establish administrative controls and provisions relating to organization and management, procedures, record keeping, material control, and accounting and management review that are necessary to assure safe operations. (10 CFR 33.13(c)(3))
030-35486/2023-002-02	AV	Failure to make or cause to be made, surveys of areas that may be necessary for the licensee to comply with the regulations in 10 CFR Part 20, and are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels. (10 CFR 20.1501(a))
030-35486/2023-002-03	AV	Failure to conduct operations so that: (1) the total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem in a year, and (2) the dose in any unrestricted area from external sources does not exceed 0.002 rem in any one hour. (10 CFR 20.1301)
030-35486/2023-002-04	AV	Failure to submit a written report within 30 days of learning of the occurrence of doses in excess of the limits for an individual member of the public. (10 CFR 20.2203(a)(2)(iv))
030-35486/2023-002-05	AV	Failure to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. (10 CFR 20.1802)

030-35486/2023-002-06	AV	Failure to conduct a physical inventory every 6 months to account for all sealed sources and/or devices received and possessed under the license. (License Condition 18)
030-35486/2023-002-07	AV	Failure to secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. (10 CFR 20.1801)

Closed

None

Discussed

None

LIST OF ACRONYMS AND ABBREVIATIONS USED

10 CFR	Title 10 of the *Code of Federal Regulations*
ADAMS	Agencywide Documents Access and Management System
ADR	Alternative Dispute Resolution
ALARA	As Low As is Reasonably Achievable
AV	Apparent Violation
CPM	counts per minute
IP	Inspection Procedure
INIS	International Isotopes, Inc.
NARM	Naturally-Occurring and Accelerator-Produced Radioactive Material
NRC	U.S. Nuclear Regulatory Commission
PEC	Predecisional Enforcement Conference
PLSV	pre-licensing site visit
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer