

Predecisional Enforcement Conference

NRC INSPECTION
REPORT 030-35486/2023-003

January 30th, 2024

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Agenda

- ▶ Review of Background Information
- ▶ Extent of Conditions
- ▶ Corrective Actions Overview
- ▶ Review / Feedback on Corrective Actions
- ▶ Regulatory Significance
- ▶ Discuss Part 70 Licensing
- ▶ Open Discussion with NRC

Background

- ▶ International Isotopes Inc. (INIS) and Laboratoire d'Étalons d'Activité (LEA - Subsidiary of Orano Group) entered into an agreement in June 2020 to distribute each other's sealed sources.
- ▶ INIS distributes calibration and reference sources manufactured by LEA that contain radioisotopes or are of specific geometries that INIS does not manufacture, and LEA distributes calibration and reference sources used in nuclear medicine applications that INIS manufactures.

Evaluation of LEA Products

- ▶ In choosing which LEA products to commercialize in the US, INIS evaluated LEA's top selling products in France weighed against the requirements for an SSDR in the US.
- ▶ 37 single radionuclide source models were evaluated.
- ▶ Sources contained Am241, Ba133, Co60, Cs137, Eu152, H3, Kr85, and Sr90.
- ▶ 23 of the sources were below \$30.71 Schedule B quantities.
- ▶ 1 source (Kr85) required registration.
- ▶ INIS focused on the distribution of LEA sources that did not require an SSDR and were covered under our current license.

INIS Authorization

- ▶ LEA sources would be received and distributed under INIS's NRC license 11-27680-01MD Row A

6. Byproduct, source, and/or special nuclear material

A. Any byproduct material with Atomic Numbers 1 through 85, 87 and 91

7. Chemical and/or physical form

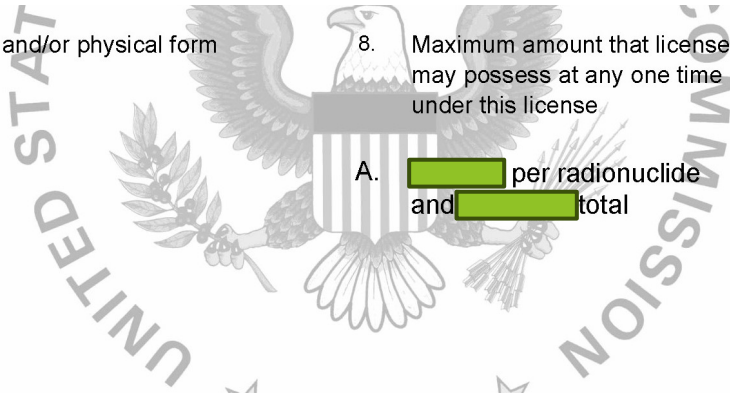
A. Any

8. Maximum amount that licensee may possess at any one time under this license

A. [redacted] per radionuclide and [redacted] total

9. Authorized use

A. For research and development as defined in 10 CFR 30.4, processing and distribution of irradiated gemstones, commercial sample preparation and analysis, and manufacturing and distribution of sealed radioactive sources.



Pu-239 Sources

- ▶ Fluor Idaho (a DOE Contractor) inquires about the availability of Pu-239 sources in December 2021.
- ▶ INIS evaluates Pu-239 source request against the license, believes it to be authorized under Row B.

B. Any byproduct material with Atomic Numbers 88, 90, 92 through 103, with half-lives greater than 120 days

B. Any

B. [redacted] per radionuclide and [redacted] total

sources.

B. For research and development as defined in 10 CFR 30.4, processing and distribution of irradiated gemstones, commercial sample preparation and analysis, and manufacturing and distribution of sealed radioactive sources.

- ▶ INIS evaluates the shipment of the source against the requirements in 10 CFR § 71.88 Air transport of plutonium. Determines the sources would be acceptable for shipment by air.
- ▶ INIS believed § 110.27 General license for imports applied to the shipment.

Self-Identification

- ▶ July 2023 a request for an “exempt” Pu-239 source was received from NASA.
- ▶ INIS does have an exempt distribution license 11-27680-02E, but there are no alpha emitters listed in § 30.71 Schedule B.
- ▶ INIS requested clarification from the customer and was asked about distributing the source under § 70.19.
- ▶ Following a review of § 70.19 and § 70.39, INIS contacted the NRC via email in August 2023 informing them of the situation and asking if the INIS license authorized the transfer.
- ▶ INIS contacted NRC on August 2nd 2023 informing them of the import and transfer. There was no reporting requirement.

NOTE: The NRC letter to INIS dated December 4th, 2023 stated that “During the in-office inspection, *the NRC identified...*” (*emphasis added*), however, we would like to clarify that INIS self-reported this apparent violations and that NRC did not visit the INIS offices; instead INIS had sent to the NRC some documents and the NRC made no further requests and no site visits were made by the NRC to date.

- ▶ *(Self-Identification continued on next slide)*

Self-Identification *(cont'd)*

- ▶ Corrective action process initiated on August 18, 2023 following email correspondence with NRC suggesting the import and subsequent transfer to DOE was an apparent violation.
- ▶ We immediately refrained from accepting any requests for Pu-239 until we determined if we were authorized to do so.
- ▶ We subsequently removed references to LEA sources that contained Pu-239, Pu-238, U-233 and U-235. These isotopes were specifically listed in the LEA catalog and included on the RadQual⁽¹⁾ website.

(1) RadQual is now a wholly owned subsidiary of INIS, INIS has been the contract manufacturer for RadQual products since 2001.

Root Cause Analysis

- ▶ Two individuals at INIS were tasked with conducting a root cause analysis:
 - ▶ John Miller - Radiation Safety Officer
 - ▶ Method: 5 Whys - John Miller was tasked with an RCA since he was closest to the facts of the situation and has conducted various RCAs through-out his career.
 - ▶ Dawn Langston - Quality Assurance Manager
 - ▶ Method: 5 Whys - Dawn Langston was completely independent of the apparent violations, yet she is a seasoned QA Manager who routinely conducts RCAs.
- ▶ The RCA contained here (slides 10-14) is a summary of John Miller's and Dawn Langston's RCAs

Root Cause Analysis 5-Whys

1. Under what license did INIS believe it was authorized to import sealed Pu-239 calibration and reference sources?
 - ▶ INIS imported the sealed Pu-239 calibration and reference sources under the general import license provided in 10 CFR 110.27.
2. Why did INIS believe §110.27 applied to the sealed Pu-239 source imported from LEA?
 - ▶ INIS believed that NRC license 11-27680-01MD authorized possession under the relevant NRC regulations.

Root Cause Analysis 5-Whys

3. Why did INIS believe it was authorized to receive and possess sealed Pu-239 calibration and reference sources under NRC license 11-27680-01MD?
 - ▶ INIS believed that Row B of 11-27680-01MD authorized possession because the atomic number of Pu-239, (94) is included in 6.B. a sealed source would be included in “Any” physical and/or chemical form under 7.B., the activity of the sealed sources where orders of magnitude below the maximum authorized activity under 8. B., and distribution of sealed radioactive sources was authorized under 9. B.

Root Cause Analysis 5-Whys

4. Why did INIS not consider Pu-239 as a special nuclear material when 6.B. specifically limits the radionuclides to “Any byproduct material”?
 - ▶ 6.B. identifies atomic numbers, 90 (thorium), and 92 (uranium) and the range from 92 to 103, includes atomic number 94 (plutonium), the RSO misinterpreted the authorized radionuclides under 6.B. because the list of atomic numbers included radionuclides that did not meet the definition of byproduct material under §30.4. The RSO interpreted the inclusion of atomic numbers 90 (thorium), 92 (uranium) and 94 (plutonium within the range of atomic numbers 92-103) that meet the §40.4 and §70.4 definitions of source and/or special nuclear material as including these isotopes within the definition of Byproduct material for NRC license 11-27680-01MD.

Root Cause Analysis 5-Whys

5. Whose job is it to interpret the INIS NRC License?
 - The Radiation Safety Officer has the final say on acceptable isotopes, activity levels, form of isotope, and licenses to conduct activities.
6. Why was the RSO's interpretation of NRC license 11-27680-01MD not challenged?
 - The RSO has the most experience in INIS regarding regulations pertaining to radioactive materials. Whereas INIS employees directly involved with processing requests for radioactive materials are less knowledgeable in these regulations and would default to the interpretation of the RSO.
7. Is there another verifying party in this process?
 - In the case of LEA products, there was not. Perhaps the sales personnel or the CEO should have also verified eligibility to import and transfer SNM.

Root Cause Analysis 5-Whys

Root Cause(s):

Human error interpreting NRC license, coupled with an inadequate evaluation of a new product line by senior management and a lack of secondary controls on order approvals.

Extent of Condition Review

- ▶ We believe this is an isolated situation. Our existing protocols were able to identify the issue during the next order for SNM products.
- ▶ In reviewing our records, the INIS self-identified transactions were the only ones on record for non-byproduct.
- ▶ While we are confident that they were not a systematic failure, we have implemented additional protocols and safeguards (see Corrective Actions; slide 15).

Corrective Actions

1. Stopped all sales of sealed sources manufactured by LEA that contains radionuclides not meeting the §30.4 definition of byproduct material (August 18, 2023, sent by RSO, 2nd notice to employees sent on December 4th, 2023 by CEO)
2. Remove reference to any of the above-mentioned isotopes from our website & catalogs (December 4th, 2023)
3. Trained all employees which were in the sales/supply chain for LEA/RadQual source sales and proper identification of required licensing. (Implemented new training requirements on December 4th, 2023) (*See attached Exhibit A - Source Limitation Training 2023*)
4. CEO to CEO phone call w/ LEA's Simon Segal on December 7th, 2023 to communicate the situation and INIS corrective actions.
5. Amended our agreement with LEA, official notice to discontinue SNM sales sent to LEA on December 11th, 2023.
6. Require CEO and RSO to personally approve all orders for LEA sources to ensure only byproduct material is included in the sales and comply with license authorizations (December 4th, 2023)
7. Decision to amend NRC License 11-27680-01MD to authorize the receipt and possession of special nuclear material in the form of sealed sources for subsequent distribution to authorized licensees (December 12th, 2023). Still on-going, to be discussed with NRC.
8. Creation and implementation of flow chart to identify products by isotope, form, activity, and licensing requirements for (i) import/export, possession, and transfer/sale (*See Attached Exhibit B - LEA Flow Chart*).

Regulatory Significance

- ▶ Regulatory Significance of INIS's apparent violations:
 - ▶ Limited Number of affected sources (8 total sources to a single end user (U.S. Department of Energy) ranging in activity from 0.003 uCi to 0.04 uCi, totaling 0.138uCi.
 - ▶ *Did the violations result in actual safety or security consequences?*
 - ▶ No, we do not believe any actual safety or security consequences were created.
 - ▶ *Did the violation have potential safety or security consequences?*
 - ▶ No, we do not believe so given the limited scope and low activity of the SNM sources in question.
 - ▶ *Did the violation impacted the ability of the NRC to perform its regulatory oversight function?*
 - ▶ No, we do not believe the situation has impacted the NRC's ability to perform its functions.
 - ▶ *Did the violation involve willfulness?*
 - ▶ No willfulness, simple human performance issue / error.
 - ▶ INIS self reported to the NRC.
- ▶ While we take the situation very serious, we believe no safety consequences from INIS's apparent violations and we ask that the NRC consider these violations as a Severity Level IV.

Thank you for your time.

Please see Exhibit A & B

Exhibit A - Source Limitation Training 2023

Import, Possession, and Transfer Restrictions on Source and Special Nuclear Materials

General License to Import 10 CFR 110.27

Most of our imports of radioactive materials is conducted under the general import license, 10 CFR 110.27 (a)

Except as provided in paragraphs (b) and (c) of this section, a general license is issued to any person to import byproduct, source, or special nuclear material *if* the U.S. consignee is authorized to receive and possess the material under the relevant NRC or Agreement State regulations.

Byproduct Material

- ▶ NRC definition can be found in 10 CFR 20.1003.
- ▶ INIS manufactures RadQual sources using 2 types of byproduct material -
 - ▶ §20.1003 Byproduct material (a) *Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material.* Radioisotopes that are produced in a reactor (Co60, Cs137, Ba133, I131, Eu152, Gd153),
 - ▶ §20.1003 Byproduct material (3)(ii) *Any material that - (A) Has been made radioactive by use of a particle accelerator. (Co57, Ge68, Na22)*

Byproduct Radioisotopes in common LEA Sources

- ▶ **Am-241** Other byproduct radioisotopes used in sources from LEA or other suppliers:
- ▶ Ba-133
- ▶ Co-60
- ▶ Cs-137
- ▶ Eu-152
- ▶ H-3 (Tritium)
- ▶ Kr-85
- ▶ Sr-90
- ▶ C-14
- ▶ Cm-244
- ▶ Cl-36
- ▶ Cs-134
- ▶ Fe-55
- ▶ Pm-247
- ▶ Tl-204

Source Material and Special Nuclear Material

- ▶ Source Material - Uranium or thorium, or any combination thereof, in any physical or chemical form, except for U-233 or uranium enriched in U-235.
- ▶ Special nuclear material - Plutonium (all isotopes of Pu-), uranium 233, uranium enriched in the isotope 233 or in the isotope 235

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Importing radioactive materials

Since our license only includes Byproduct material, we are not authorized to import, possess, or distribute any plutonium, uranium or thorium isotopes.

Two alpha-emitting radioisotopes commonly used in sealed sources, Am-241 and Cm-244 fall under the byproduct category and we can import and possess these LEA products however the maximum activity per radioisotope is limited to 10 uCi, **AND** the customer's license would need to include these isotopes in ANY form or as an unregistered sealed source.

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Radioisotopes contained in LEA sources that are Source or Special Nuclear Material

| Special Nuclear Material Offered | Source Material Offered |
|----------------------------------|-------------------------|
| PU-238 | U-238 |
| Pu-239 | |
| U-233 | |
| U-235 | |

While not offered in the LEA Catalog, Th-232 falls under Source Material and may be requested by a customer as a sealed source.

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Special Cases for Ra-226 and Am-241, and Plutonium

The §31.8 general license for Ra-226 and Am-241 sealed sources does not apply to LEA sources because these sources have not been evaluated against the requirements contained in §32.57.

The §70.19 general license for plutonium sealed sources does not apply to LEA sources because the LEA sources have not been evaluated against the requirements contained in §70.39.

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Exhibit B - LEA Flow Chart

