



International Isotopes Inc.

June 12, 2018

US Nuclear Regulatory Commission
Attn. Ms. Debra Weaver, Licensing Assistant
Materials Safety and Licensing Branch
Office of Nuclear Materials Safety and Safeguards
Two White Flint North
11545 Rockville Pike
Rockville, MD 20852-2738

Subject: Request to Amend NRC License 11-27680-02E

Dear Ms. Weaver,

International Isotopes Inc. (INIS) is requesting to amend US Nuclear Regulatory License 11-27680-02E to authorize the transfer sealed radioactive sources containing byproduct material for commercial distribution to persons exempt from licensing pursuant to §30.18. The manufacturer of sealed radioactive sources will be conducted under NRC license 11-27680-01MD.

Enclosed with this request is:

- Enclosure 1: Blocks 5 and 6 of NRC Form 313
- Enclosure 2: Supporting Documentation and Information
- Enclosure 3: INIS Form F-477, Exempt Source Brochure
- Completed NRC Form 313

Please contact me at 208.524.5300 or via email at jjmiller@intisoid.com if you have any questions or comments regarding this request.

Sincerely,

John J. Miller, CHP
Radiation Safety Officer
JJM-2018-28

5 RADIOACTIVE MATERIAL

5.a. Element and mass number

Ba-133	Cs-137	Na-22
Co-57	Eu-152	
Co-60	Ge-68	

5.b. Chemical and/or Physical Form

Sealed radioactive sources, where the byproduct material is encapsulated in epoxy, electroplated onto metallic surface, or deposited onto solid surface and covered with an aluminized mylar film.

5.c. Maximum amount which will be possessed at any one time

Not Applicable. Possession and handling of byproduct material for the manufactured of sealed radioactive sources for exempt distribution governed by NRC 11-27680-01MD.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

For transfer of sealed radioactive sources containing byproduct material for commercial distribution to persons exempt from licensing pursuant to §30.18.

Blocks 7 – 11 of Form 313 are not applicable to NRC License 11-27680-02E.

- §32.18 (b) The byproduct material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being.
- §32.18 (c) The byproduct material is contained in sealed radioactive sources, where the byproduct material is encapsulated in epoxy, electroplated onto metallic surface, or deposited onto solid surface and covered with an aluminized mylar film.
- §32.18 (d) A copy of the prototype label is provided below:

Model #: (optional) Exempt Quantity

Isotope: ____ Activity: ____

Reference date: (optional)

Serial number: (optional)

**CAUTION
RADIOACTIVE
MATERIAL**

Benchmark

Manufactured and distributed by
International Isotopes Idaho, Inc.,
Idaho Falls, ID

Notes: Label shown is not to scale

Size and shape of label can vary with source geometry

Orientation of text may vary with size and shape of label.

At a minimum the label will contain the radioisotope, the activity, the radioactive tri-foil symbol, and the text "Radioactive Material". Optional data will be included as size permits and is limited by the legibility of the font size.

- §32.18 (d) A copy Form F-477, Exempt Source Brochure with recommended safety instructions is provided with this application as Enclosure 3. Note that this brochure may be revised under INIS's document control procedure but any revision will contain, at a minimum, the information required by §32.19(d).
- §32.19 (a) INIS will establish procedures and modify our order entry database to ensure that no more than 10 exempt quantities set forth in §30.71, Schedule B could be sold or transferred in any single transaction. When multiple isotopes are involved in a single transaction, the sum of the fractions not to exceed unity rule will be applied.
- Exempt distribution sources will be manufactured under NRC license 11-27680-01MD. INIS has established procedures that governs the manufacturer and assay of radioactive sources. The activity of each exempt source will be determined by direct measurement of radioactivity or by gravimetric or volumetric measurements from an aliquot of a radionuclide solution.
- INIS has been an active participant in the radioactivity measurements assurance program

conducted by the National Institute of Standards and Technology since July 2002.

- §32.19 (b) INIS will establish a packaging and shipment procedure to ensure that each exempt quantity set forth in §30.71, Schedule B shall be separately and individually packaged and that no more than 10 such packaged exempt quantities are contained in any outer package for transfer to persons exempt pursuant to §30.18. The dose rate on-contact with any external surface of the outer package will be verified to be less than 0.5 millirem per hours. Packages will be shipped as either an excepted package, UN2910, pursuant to Title 49 CFR §173.421, or as an exempt consignment, pursuant to Title 49 CFR §173.436, as determined by the total activity contained in the outer package.
- §32.19 (c) The label identified in the response to §32.18 (d) will be applied to each exempt quantity source, i.e. immediate container. Radioactive material labels WILL NOT be applied to the outer shipping package.
- §32.19 (d) The requirements to (1) state that the contents are exempt from NRC or Agreement State licensing requirements; (2) bear the words “Radioactive Material—Not for Human Use—Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commercial Distribution is Prohibited—Exempt Quantities Should Not be Combined”; and (3) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material are included in the brochure provided for §32.18 (d).
- §32.20 (a) INIS currently maintains electronic and hard copy records of all source transactions that include the type of source, the activity, and the name and address of the person the source was transferred to. Hard copy records of sources distributed under §301.8 will be kept separate from sources transferred to persons possessing a specific license issued by the US NRC or an Agreement State.
- §32.20 (b) INIS will file a summary report in accordance with §32.20 (b) through §32.20 (e). Note
– (e) that the report filed summarizing the transfers of exempt quantity radioactive sources will be filled separate from the report that is currently filed for the exempt distribution of irradiated gemstones under NRC license 11-27680-02E.
- §32.20 (f) INIS will maintain the record of a transfer for at least one year after the transfer is included in a summary report to the Commission



International Isotopes Inc.

Safe Handling, Use, Storage, and Disposal Recommendations for Sealed Radioactive Sources Distributed to Unlicensed Persons

1. GENERAL

- Radioactive Material – Not for Human Use – Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commercial Distribution is Prohibited – Exempt Quantities Should Not be Combined.
- Pursuant to §32.19(d), sealed radioactive sources distributed under NRC license 11-27680-02E are exempt from NRC or Agreement State Licensing Requirements.

2. HANDLING

- Basic radiation principles of time, distance, and shielding should be practiced so as to minimize radiation exposure (i.e., minimizing the time spent around radioactive material, as well as maximizing the distance and the shielding between persons and the radioactive material)
- Activities such as eating, drinking, smoking, or the application of cosmetics should be prohibited in areas of use.
- DO NOT disassemble the sealed radioactive source to remove the radioactive material.

3. USE

- Use of the sealed radioactive source should be restricted to authorized and responsible persons in authorized and designated areas.
- The sealed radioactive source is intended for use as a radiation reference standard for radiation detection instrumentation.

4. STORAGE

- Sealed radioactive source should be securely stored when not in use.
- A metal lockbox, cabinet or safe is recommended.

5. DISPOSAL

- Sealed radioactive sources in exempt quantities possessed by Unlicensed Persons can be disposed of as regular waste without regard to their radioactive content.
- It is recommended to remove or obliterate any “radioactive material” marking on the source just prior to disposal.
- Persons possessing a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State must dispose of sealed radioactive sources in exempt quantities as required by the conditions of their specific license and applicable regulations.

(10-2017)
10 CFR 30, 32,
33, 34, 35, 36,
37, 39, and 40



APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 06/30/2019

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Information Services Branch (T-2 F43), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE CURRENT VOLUMES OF THE NUREG-1556 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>. SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

MATERIALS SAFETY LICENSING BRANCH
DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

IF YOU ARE LOCATED IN:

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

A. NEW LICENSE

B. AMENDMENT TO LICENSE NUMBER 11-27680-02E

C. RENEWAL OF LICENSE NUMBER

2. NAME AND MAILING ADDRESS OF APPLICANT (Include zip code)

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

3. ADDRESS WHERE LICENSED MATERIALS WILL BE USED OR POSSESSED

4137 Commerce Circle
Idaho Falls, ID 83401

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

John J. Miller

BUSINESS TELEPHONE NUMBER
208 524 5300

BUSINESS CELLULAR TELEPHONE NUMBER
208 589-1580

BUSINESS E-MAIL ADDRESS
jjmiller@intisoid.com

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*) (See 10 CFR 170 and Section 170.31)

*Amendments/Renewals that increase the scope of the existing license to a new or higher fee category will require a fee.

FEE CATEGORY

AMOUNT ENCLOSED \$

PER THE DEBT COLLECTION IMPROVEMENT ACT OF 1996 (PUBLIC LAW 104-134), YOU ARE REQUIRED TO PROVIDE YOUR TAXPAYER IDENTIFICATION NUMBER. PROVIDE THIS INFORMATION BY COMPLETING NRC FORM 531: <https://www.nrc.gov/reading-rm/doc-collections/forms/nrc531info.html>.

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE

John J. Miller, CHP / Radiation Safety Officer

SIGNATURE

DATE

6/12/18

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	