



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
WASHINGTON, D.C. 20555-0001

February 5, 2018

International Isotopes, Inc.
ATTN: John J. Miller, RSO
4137 Commerce Circle
Idaho Falls, ID 83401

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Miller:

This letter refers to your license renewal application request dated October 24, 2017 (Agencywide Documents Access and Management System [ADAMS] No. ML17304A007) for U.S. Nuclear Regulatory Commission (NRC) Exempt Distribution License Number ~~11-27670-02E~~. 11-27680-02E, Corrected: JEV 11/20/2018

We do not have sufficient information to complete the review of your application. In order to continue our review, please address the issues listed in the enclosure to this letter.

Note that an application for an exempt distribution license, including renewals, should not contain information concerning the possession and use of radioactive material since that is covered in your separate possession license.

We will continue our review upon receipt of this information. If we do not receive your reply within 30 calendar days from the date of this letter, we will consider your application as having been abandoned by you. This action would be without prejudice to the resubmission of another application with the required information.

Please be aware that upon your request, proprietary information submitted to the NRC may be withheld from public disclosure. To do this, you must follow the procedures in 10 CFR 2.390(b) including requesting withholding at the time the information is submitted and complying with the document marking and affidavit requirements set forth in 10 CFR 2.390(b)(1).

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Any correspondence regarding this renewal application should reference control number 601495.

J. Miller

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If you have any questions, please feel free to contact me at (301) 415-5477 or by e-mail at Richard.Struckmeyer@nrc.gov.

Sincerely,

/RA/

Richard K. Struckmeyer
Materials Safety Licensing Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Docket No.: 030-37557

License No. ~~11-27670-02E~~

11-27680-02E, Corrected: JEV 11/20/2018

Enclosure:

Request for Additional Information

J. Miller

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INTERNATIONAL ISOTOPES, INC., REQUEST FOR ADDITIONAL INFORMATION

Date: February 5, 2018

Certified Mail No 7015 3010 0000 7901 7403

ML17304A005 (pkg.)		ML18036A157 (Letter)	
OFC	NMSS/MSST/MSLB	NMSS/MSST/MSLB	NMSS/MSST/MSLB
NAME	RStruckmeyer	DWeaver	RStruckmeyer
DATE	02/5/2018	02/5/2018	02/5/2018

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International Isotopes, Inc., Application dated October 24, 2017
Request for Additional Information

The U.S. Nuclear Regulatory Commission staff has reviewed the International Isotopes, Inc. (INIS) application dated October 24, 2017, and has determined that additional information is needed. In order to continue with our review, please address the issues listed below.

1. On page 1 of your letter, the third bullet indicates that gemstones are cleaned with deionized water prior to irradiation, but on page 2 of Enclosure 2, item B.3 indicates that "surface contamination on the gemstones was easily managed without precleaning prior to irradiation." Later, Item 5.b on page 4 of Enclosure 2, indicates that "INIS prepares gemstones for irradiation, which includes pre-cleaning the stones..." Please clarify whether a pre-cleaning process is used prior to irradiation.
2. On page 4 of Enclosure 2, in response to item B.5.d, the second bullet indicates that gemstones exceeding the criteria identified in C.2.e. may be exported to facility under the release criteria of 74 Bq/g. Due to the fact that this criterion should not be used for release of gemstones in the U.S., does INIS have a means to prevent the reintroduction of such gemstones into the U.S market?
3. On page 8 of Enclosure 2, the response to item C.2.g states: "INIS has not analyzed gemstones received directly from a particle accelerator facility, but has analyzed gemstones that have been irradiated in a particle accelerator only. These gemstones have been indistinguishable from background and gamma spectroscopy does not identify radioisotopes." Please provide additional information to clarify whether the stated result could be due to an insufficiently sensitive analytical method.
4. On page 9 of Enclosure 2, item C.3.c requests information as to why the use of concentrations lower than those specified in response to Item C.2.e is not feasible..." The following response was provided for this item: "Actual doses from gemstones will normally result from external exposures. However, the exempt concentration limits were based on the potential for intakes. Utilizing the exempt concentration values from §30.70 Schedule A is conservative." Although this appears to be an accurate statement, it does not appear to provide the information requested. Please provide additional information to clarify your response.
5. On page 10 of Enclosure 2, item D.3.a ("Selection of samples") states: "Beta counting will be performed if the sum of the ratios of the gamma emitting isotopes identified exceeds 0.3. Quick sorting is only conducted if gamma spectroscopy or beta counting anomalies are identified." Please provide additional information to clarify the meaning of these statements.
 - Why is beta counting not performed unless the sum exceeds 0.3?
 - What anomalies would trigger the need for quick sorting?
6. On page 11 of Enclosure 2, item D.3.c ("Counting efficiency") states, for the quick-sort process: "Probe however is used in the counts per second mode and an efficiency correction is not utilized." Please provide the rationale for not using an efficiency correction.

Enclosure

7. On page 11 of Enclosure 2, item D.3.f. states that the time of counting (in relation to completion of irradiation and transfer to unlicensed persons) “[v]aries with irradiation hours. Stones received from MURR *will be held for decay may held* for 500+ days after the end of irradiation before the counting process begins.” Please clarify this statement.
8. On page 11 of Enclosure 2, item D.3.g. (“Minimum Detectable Activity”) states: Quick Sort – Qualitative analysis MDA is not recorded. Gamma Spectroscopy – < 0.3 nCi/g (1 Bq/g) Beta Counting – P-32 < 0.3 nCi/g (1 Bq/g) S-35 < 1.5 nCi/g (55.5 Bq/g). Please describe how the MDAs for gamma spectroscopy and beta counting were determined.
9. On page 11 of Enclosure 2, item D.3.e, “Counting geometry,” the description is not clear. This item appears to refer to three geometry configurations for the Gamma Spectroscopy HPGe Detector, namely, Petri dish, 500 milliliter beaker, and 1-liter Marinelli beaker.
 - Please confirm this or explain what was intended.
 - Please describe when each of these geometries is used. (This is related to Question 12, below.)
10. On page 15 of Enclosure 2, in response to items E.2.a & E.2.b, the following statement is made: “The worst-case concentration assumed the initial activity concentration of each of the isotopes identified as major isotopes at the end of irradiation was equal, that a 1 year decay period occurs from the end of irradiation to the date the gemstone is released and that the sum of the ratios at the time of release is equal to one.” Please explain why this is the worst-case scenario.
11. With regard to Procedure OP-TPZ-001, Revision F, “Blue Topaz Processing,” step 7.4.4, please explain the rationale for the 1,000 dpm removable contamination level; i.e., why are levels below this value considered to be clean? Also, for step 7.4.26.4, why are contamination levels less than 2250 pCi/100 cm² (5000 dpm/100 cm²) considered clean? (The same information is also found in in Procedure OP-TPZ-002, Revision H, “White Topaz and Diamond Processing,” Steps 7.6.8 and 7.6.2.3.) For each of these steps, how do these values compare to the activity levels of irradiated topaz upon release?
12. With regard to Procedure OP-TPZ-004, Revision G, “Blue Topaz Counting,” step 7.1.3 and Procedure OP-TPZ-008, Revision B, “TSO Stone Counting,” step 7.1.5, the instructions say to [f]ollow WI-TPZ-006 “Counting Topaz on Gamma Spec” to place the stones in their proper sample holder geometries and count them via gamma spectroscopy to determine the activity of the gamma emitting nuclides. Please describe the sample holder geometries and how they are chosen.
13. With regard to Procedure WI-TPZ-001, Revision F, “Topaz Quick Sort Instructions,” steps 2.3.3 and 2.3.4, please explain the rationale for the 1000 cps decision point. Also, for step 2.9, please explain rationale for removing any hot stone reading > 350 cps above the average background.