International Isotopes Inc.

February 23, 2018

US Nuclear Regulatory Commission
Attn. Mr. Richard Struckmeyer
Materials Safety and Licensing Branch
Office of Nuclear Materials Safety and Safeguards
Two White Flint North
11545 Rockville Pike
Rockville, MD 20852-2738

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

Subject: Response to Request for Additional Information – ~~11-2760-02E~~
Docket No.: 030-37557

Dear Mr. Struckmeyer,

International Isotopes Inc. (INIS) is providing the requested additional information to support the renewal of NRC License 11-27680-02E.

RAI 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.

Response: Pre-cleaning of gemstones prior to irradiation is only conducted on gemstones that are visibly dirty.

RAI 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?

Response: The 74 Bq/g criteria is for release of gemstones outside of the U.S. The date that gemstones initially distributed under the 74 Bq/g criteria will decay to a level that will fall below the §30.70 Schedule A – Exempt Concentration criteria is also provided to the customer. The customer will then determine if the gemstones will be exported back into the United States. INIS relies on the integrity of the foreign customer and the U.S. importer to import gemstones only after they have decayed below the exempt concentration criteria. INIS will provide the importer a certificate of release for these gemstones when they meet the U.S. release criteria

and when requested by the importer. INIS has no physical control over the gemstones once they are shipped from the facility.

RAI 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.

Response: We have observed over the course of our operations that irradiated gemstones slightly above or below the exempt concentration criteria are indistinguishable from background when analyzed with a hand-held GM pancake or NaI(Tl) probe. We have also observed that the high purity germanium (HPGe) gamma spectroscopy results for the majority of irradiated gemstones analyzed under a testing service order (TSO) fail to identify gamma emitting radionuclides. In the case of irradiated topaz, it is not known if these results are due to a significant period of decay or the type of irradiation.

In the case of irradiated diamonds, the type of irradiation the gemstone had under gone is visibly apparent. Diamonds that have been neutron irradiated are evident by the resulting jet-black color whereas the color of diamonds irradiated in a particle accelerator are varying shades of yellow and green. Distinguishing between a diamond irradiated in a reactor and one that has been irradiated in a particle accelerator is achieved through a visible observation. We have also found that diamonds that have been irradiated in a reactor exhibit a gamma spectrum very similar to that seen in reactor irradiated topaz. To date, we have never identified gamma emitting radionuclides in diamonds irradiated in a particle accelerator.

Analyzing irradiated gemstones by scanning with hand-held GM pancake probes or NaI(Tl) detectors does not have the necessary sensitivity to determine if the gemstones meet the exempt distribution criteria. While we utilize a hand-held NaI(Tl) detector to scan irradiated gemstones to identify outliers, we do not attempt to quantify this analysis.

Quantification of gamma emitting radionuclides is performed using the HPGe gamma spectroscopy system, which has a sensitivity sufficient enough to detect activity concentrations at fractions of exempt concentration, with minimum detectable activity concentrations less than 2% of the exempt concentration. The tables below provide examples of TSO results and MDAs as a fraction of the exempt concentration

Nuclide	Exempt Conc. (Bq/g)	TSO-6193A Conc. (Bq/g)	TSO-6193A % Exempt	TSO-7003 Conc. (Bq/g)	TSO-7003 % Exempt	TSO-7006 Conc. (Bq/g)	TSO-7006 % Exempt	TSO-7033A Conc. (Bq/g)	TSO-7033A % Exempt
Na-22	1.4E+01	1.25E-02	0.09%			1.27E-01	0.93%	1.63E-02	0.12%
Sc-46	1.5E+01	1.07E-01	0.72%	2.30E-02	0.16%	4.73E-01	3.20%	6.56E-02	0.44%
Mn-54	3.7E+01	6.12E-01	1.65%	2.19E-01	0.59%	3.35E+00	9.06%	3.36E-01	0.91%
Zn-65	3.7E+01								
Cs-134	3.3E+00	2.52E-02	0.76%	1.38E-02	0.41%	1.30E-01	3.89%		
Ta-182	1.5E+01	4.60E-01	3.11%	9.61E-02	0.65%	1.63E+00	11.00%	2.23E-01	1.51%

Nuclide	Typical MDA (Bq/g)	MDA % Exempt Conc.
Na-22	1.00E-02	0.07%
Sc-46	2.04E-02	0.14%
Mn-54	3.23E-02	0.09%
Zn-65	4.11E-02	0.11%
Cs-134	3.70E-02	1.11%
Ta-182	5.38E-02	0.36%

RAI 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.

Response: We believe the use of the concentrations values identified in §30.70 Schedule A, or in the case of multiple nuclides that the sum of the ratios is less than one is the appropriate release criteria to be applied for irradiated gemstones and that concentrations lower than the §30.70 Schedule A values are not justified or feasible.

As reported in NRC Information Notice 2009-12, the first-year effective dose equivalent (EDE) received as the result of wearing irradiated topaz is estimated at 0.03 mrem. We consider a 0.03 mrem EDE as a negligible dose and that any

costs associated with longer storage periods and delays in introducing the gemstones into the market to further reduce this dose is not justified.

Under our current process, neutron irradiated gemstones require between 1.5 and > 5 years of decay after irradiation to meet the §30.70 Schedule A - Exempt concentrations, sum of ratio less than unity criteria. This is a significant length of time for our customer to hold gemstones in inventory before they can be released into the consumer market. It is also important to note that INIS does not release gemstones directly to the consumer. Instead the gemstones are released to wholesalers and jewelers who then introduce the gemstones into the market, so there is additional decay time before the gemstone is being purchased by the consumer.

RAI 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?

Response: Process history indicates that Ta-182, Cs-134, Mn-54 and Sc-46 are the predominate radioisotopes present in irradiated gemstones. While these ratios may differ with the type and origin of the stone, Ta-182 is usually the most predominate in topaz and Cs-134 is the most predominate in beryl. Following long periods of decay the longer-lived isotopes of Mn-54 and Cs-134 may be the only isotopes identified via gamma spectroscopy. Because P-32 and S-35 are only minor isotopes and their half-lives are shorter than that of Ta-182, Cs-134 and Mn-54 it is highly unlikely that P-32 or S-35 would be present in concentrations approaching the concentrations of any of the identified gamma emitting isotopes. In fact, concentrations of P-32 or S-35 identified in irradiated gemstones has never been the limiting factor determining the release dates for the gemstones. We believe that using the 0.3 threshold is conservative because it is highly unlikely that P-32 and S-35 would be present in concentrations that would account to 70% of the activity that would result in the sum of the ratios to exceed unity.

Quick sorting is the initial step in the analysis of irradiated gemstones that we receive directly from the University of Missouri (MURR). In this case the activity concentration of the gemstones is such that the radiation levels observed during the quicksort are noticeably higher than background. The purpose of the quicksort is to identify and remove what we refer to as "hot stones" and, in the case of irradiated topaz, to visually identify and remove beryl stones.

The concentration of the gemstones received as a TSO is usually well below the exempt concentrations at the time of receipt and the radiation levels that would be observed during the quicksort may not be distinguished from background. Anomalies that would trigger the need for the quick sort would be;

1) Gamma spectroscopy results that show the concentration is well above the exempt concentration criteria. A quick sort in this instance would allow us to determine if the elevated results were due to a "hot stone or stones" that could then be removed from the pack.

2) A pack consisting of a mixture of stone type, i.e. beryl and topaz. Quick sorting would be necessary to separate the gemstones because we would expect the beryl gemstones to contain more Cs-134 than the topaz gemstones and we would not want to dilute the concentration of Cs-134 with the mass of the topaz when it would be contained primarily in the beryl. Note that separating the gemstones by stone type would be performed based on the appearance of the gemstone and not by the response of the detector.

RAI 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

Response: The quick sort process is a qualitative screening mechanism that is used to identify gemstones that are more radioactive than the other gemstones associated with the pack. The quick sort results are not used to quantify the activity of the stone, so the use of an efficiency correction is not necessary.

RAI 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.

Response: After irradiation gemstones are stored for decay before they are analyzed. The length of decay time is based on the length of time the gemstones had been irradiated. The criteria that is currently used to determine the Earliest Count Date is:

Earliest Count Date = End of Irradiation Date + (2 days x irradiation hours).

A gemstone that has been irradiated for 100 hours will be held for at last 200 days after the end of irradiation date before the counting process begins.

RAI 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.

Response: The MDA equations that are used are provided below. The gamma spectroscopy MDA calculation is built into the Canberra APEX Software. The Beta MDA equation is calculated within the excel spreadsheet, Form F-46.

$$Beta\ MDA = \frac{3 + 3.29\sqrt{\mathrm{RbTs}(1 + \frac{\mathrm{Ts}}{\mathrm{Tb}})}}{\text{eff. x Ts}}$$

$$Gamma\ MDA = \frac{2.71 + 3.29\sqrt{\mathrm{RbTs}(1 + \frac{\mathrm{Ts}}{\mathrm{Tb}})}}{\text{eff. x Ts}}$$

RAI 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.)

Response: We currently have 5 counting geometries for gamma spectroscopy, two of which are not used at this time but could be used again in the future if the need arises.

- Petri dish,
- 1-Liter Marinelli Beaker (high density),
- 1-Liter Marinelli Beaker (low density),
- 500 milliliter Marinelli Beaker (high density) not currently used,
- 500 milliliter Marinelli Beaker (low density) not currently used.

The geometries are used as follows:

- Petri Dish – small batches of gemstones (< 50 g), geometry linked to multi-nuclide filter standard.
- 1-Liter Marinelli Beaker (high density) – batches of loose gemstones (≈ 2500 g), geometry linked to multi-nuclide high density 1-Liter Marinelli Beaker standard.
- 1-Liter Marinelli Beaker (low density) – batches of wrapped TSO

gemstones (<1000 g), geometry linked to multi-nuclide low density 1-Liter Marinelli Beaker standard.

- 500 milliliter Marinelli Beaker (high density) – would be used for batches of loose gemstones (≈ 1200 g), geometry linked to multi-nuclide high density 500 milliliter Marinelli Beaker standard, not used at this time.
- 500 milliliter Marinelli Beaker (low density) – would be used for batches of wrapped TSO gemstones (< 500 g), geometry linked to multi-nuclide low density 500 milliliter Marinelli Beaker standard, not used at this time.

RAI 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

Response: This was considered a worst-case scenario using realistic assumptions.

We set a decay period of just one year from the end of irradiation to the time the gemstone meets the §30.70 exempt concentration. This reduced the amount of decay for the Sc-46, (half-life = 83.8 d) which emits 1121 keV and 889 keV photons per decay which are notable contributors to the dose.

We assumed that only the major gamma emitting radioisotopes and the two beta only emitting isotopes, P-32 and S-35 were produced in the gemstone during the irradiation.

We assumed that the concentrations of these isotopes were equal at the end of the irradiation. This assumption was used to simplify the equation.

We also assumed that the concentration of the isotopes remained constant during the 1-year exposure period and the calculated dose was based on the dose rate at time T= 0. We know that this is not the case and that the assumption added a significant level of conservatism to the results.

We have since performed additional calculations.

Using the same assumptions as before but ignoring P-32 and S-35, which in the case of P-32, decays to negligible levels after 1-year of decay and in the case of S-35, contributes a negligible dose from the low energy beta emission the same model produces a 1 year on-contact dose of 136.1 mrem and a 1 year 4.0 cm dose of 0.81 mrem.

A table summarizing the activity and results is provided below:

	Activity (Ci)	On-Contact mr/hr	4.0 cm mr/hr	1 Y OC mrem	1 Y 4.0 cm mrem
Cs-134	6.38E-11	1.55E-02	9.21E-05	136.13	0.81
Mn-54	3.97E-11				
Na-22	6.84E-11				
Sc-46	4.37E-12				
Ta-182	9.80E-12				
Zn-65	3.16E-11				

Alternately one could argue that the worst-case dose would result from a single radionuclide at a concentration equal to its §30.70 concentration at the time of release. Ignoring the presence of P-32 and S-35 for the reasons noted above, the resulting worst-case dose received over the period of one year was, 375 mrem, on contact and 2.2 mrem at 4.0 cm. Again, the dose rates at time T=0 were used to calculate the on-contact and 4.0 cm doses.

This highest dose would be observed if only Mn-54 was present at its §30.70 concentration. Results of major gamma emitting isotopes are provided in the table below.

	Activity (Ci)	On-Contact mr/hr	4.0 cm mr/hr	1 Y OC mrem	1 Y 4.0 cm mrem
Cs-134	9.00E-11	6.82E-03	4.05E-05	59.73	0.35
Mn-54	1.00E-09	4.28E-02	2.51E-04	374.75	2.20
Na-22	3.70E-10	3.78E-02	2.24E-04	330.69	1.96
Sc-46	4.00E-10	3.72E-02	2.21E-04	325.78	1.93
Ta-182	4.00E-10	2.16E-02	1.28E-04	189.13	1.12
Zn-65	1.00E-09	3.10E-02	1.80E-04	271.74	1.57

RAI 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 cm^2 (5000 dpm/100 cm^2) 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?

Response: The < 1,000 dpm/100 cm^2 removable contamination level criterion for the topaz irradiation canister (Step 7.4.8 of OP-TPZ-002) is obtained from the acceptable

surface contamination levels for beta-gamma emitters from Table P.5 of NUREG 1556 Volume 12. This criterion was established to minimize the spread of contamination during the handling and packaging of topaz irradiation canisters for shipment to the MURR and subsequent handling of the canisters at MURR.

The < 1,000 dpm removable contamination level criterion for irradiated gemstones after cleaning (Step 7.4.4 of OP-TPZ-001) is derived from the acceptable surface contamination levels for beta-gamma emitters from Table P.5 of NUREG 1556 Volume 12. The removable contamination criterion was established to prevent the spread of contamination in uncontrolled areas as the result of handling irradiated gemstones.

The 5000 dpm/100 cm^2 criterion for removable contamination in the work area (Step 7.4.26.4 of OP-TPZ-001) was set at 5 times the level of the acceptable removable surface contamination levels for beta-gamma emitters from Table P.5 of NUREG 1556 Volume 12. Noting that the values provided in Table P.5 pertain to unrestricted areas while the work area that the 5000 dpm/100 cm^2 criterion is within our radiological buffer area and is an administrative control that was established as a means of preventing the spread of contamination.

The 5000 dpm/100 cm^2 criterion for removable contamination in the area to be welded (Step 7.2.6.3 of OP-TPZ-002) on a topaz irradiation canister was set at 5 times the level of the acceptable removable surface contamination levels for beta-gamma emitters from Table P.5 of NUREG 1556 Volume 12. This is another administrative control that we apply to the process to minimize the spread of contamination during the handling, preparation and welding of an irradiation canister.

The only contamination criteria from above that is associated with contamination levels on irradiated gemstones is the 1000 dpm criterion from Step 7.4.4 of OP-TPZ-001. We consider this level of activity negligible when compared to the activity levels of irradiated topaz upon release. Consider that 1000 dpm is approximately 17 Bq. A pack of irradiated gemstones is between 7,000 and 8,000 grams. The lowest exempt concentration value for a major isotope (Cs-134) is 3.3 Bq/g. If Cs-134 was the only isotope present and the gemstones were released at the exempt concentration value of 3.3 Bq/g, the total activity present would be between 23,100 to 26,400 Bq. A removable contamination level of 1,000 dpm would account for less than 0.1% of the total activity of the gemstones.

RAI 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.

Response: The gamma spectroscopy system is equipped with an automated sample changer that allows the analysis of a group of samples without having the operator load and unload the samples from the sample chamber. The petri dish geometry is set into a sample holder designed for this geometry. The 1 L and 500 mL Marinelli beakers are placed in the sample holder designed for the Marinelli beaker geometry. A photo of a petri dish and 1 L Marinelli beaker in their respective sample holders is provided below:

Note that the lid for the petri dish sample holder is placed over the sample during actual operation. The 1 L and 500 mL Marinelli beakers are the same diameter and use the same sample holder.

RAI 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.

Response: The 1000 cps decision point is an operational control that is based on process history. Stones that are above 1000 cps with the NaI(Tl) probe result in an unreasonably long dead-time when analyzed on the HPGe gamma spectroscopy system. Dead times in excess of 30% cause the system to abort the sample count and if this occurs the system is locked up until an operator can reset the system.

The 350 cps above the average count rate of the stones being counted is another operational control that was put into place to help the technician identify a “hot stone”. The 350 cps level is high enough above the average count rate of the stones to be easily identified during a scan.

These decision points have proven to be effective. The purpose of the quick sort is to ensure that the activity in the gemstones is as homogeneous as possible across the entire package. This assumption is verified by dividing the package into 3 bags of similar mass. Comparing the gamma spec results from each of the bags provides that indication. Below is a summary of the gamma spectroscopy results for the major gamma emitting isotopes and the P-32 and S-35 results for a pack.

Pack ID: KLS6-511

Mass (g):	bag -01 2567 Bq/g	bag -02 2565 Bq/g	bag -03 2559 Bq/g	Mean	Std
Na-22	0.19	0.22	0.22	0.21	0.01
Sc-46	0.25	0.23	0.24	0.24	0.01
Mn-54	27.24	27.45	27.53	27.40	0.15
Zn-65	2.86	2.76	3.02	2.88	0.13
Cs-134	0.17	0.20	0.20	0.19	0.01
Ta-182	12.92	12.57	12.28	12.59	0.32
P-32	1.81	2.46	2.06	2.11	0.33
S-35	0.00	0.00	0.00	0.00	0.00

The data above suggests that the activity concentration in the gemstones is considerably homogeneous.

There are times when the quick sorting process misses a hot stone or stones or fails to remove all of the beryl stones that may be comingled in the topaz pack. In these cases, a review of the analysis results will identify that hot stones or beryl stones may have been missed.

Below is a summary of a pack of stones that indicated the presence of “hot stones” in one of the 3 bags.

Pack ID: JBL4-601

Mass (g):	bag -01 2553 Bq/g	bag -02 2574 Bq/g	bag -03 2483 Bq/g	Mean	Std
Na-22	0.16	0.20	0.19	0.18	0.02
Sc-46	1.19	1.28	1.27	1.25	0.05
Mn-54	17.77	17.73	17.82	17.77	0.04
Zn-65	0.00	0.00	0.10	0.03	0.06
Cs-134	0.12	3.92	0.00	1.35	2.23
Ta-182	51.32	61.64	54.87	55.94	5.24
P-32	1.90	2.06	2.30	2.09	0.20
S-35	0.00	0.00	0.00	0.00	0.00

Mass (g):	bag -01 2553 Bq/g	bag -02R 2573 Bq/g	bag -03 2483 Bq/g	Mean	Std
Na-22	0.16	0.17	0.19	0.17	0.02
Sc-46	1.19	1.22	1.27	1.23	0.04
Mn-54	17.77	17.25	17.82	17.61	0.32
Zn-65	0.00	0.00	0.10	0.03	0.06
Cs-134	0.12	0.00	0.00	0.04	0.07
Ta-182	51.32	60.64	54.87	55.61	4.71
P-32	1.90	2.06	2.30	2.09	0.20
S-35	0.00	0.00	0.00	0.00	0.00

In the first set of data the concentration of Cs-134 is significantly higher than the concentrations measured in bags -01 and -03. As a result, Bag-02 was re-quick sorted and 1 gram (5 carats) of gemstones where removed. The bag was reanalyzed and all of the gemstones that contained Cs-134 had been removed.

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-2018-11