International Isotopes Inc.

March 19, 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

Subject: Clarifications to February 23, 2018 Request for Additional Information Response
Docket No.: 030-37557

Dear Mr. Struckmeyer,

International Isotopes Inc. (INIS) is providing clarifications to our February 23, 2018 response to requested additional information.

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.

I should have been more specific as to the clarification I sought; namely the highlighted wording in the above paragraph. Please rewrite this sentence to state a more accurate meaning.

Response:

This was a typographical error. The statement should read: "[v]aries with irradiation hours. Stones received from MURR ~~will be held for decay~~ may be held for 500+ days after the end of irradiation before the counting process begins."

RAI 10.

Worst-case scenario.

(A) *In your application, on page 15 of 17, the table shows one-year decay concentrations. In your response to the RAIs, on page 8 of 12, the table shows similar one-year decay concentrations. Please clarify why the values for the nuclides listed in the RAI response differ from those in the application.*

The values for radionuclide activity provided in the response to the RAI's are slightly higher than those provided in the application because the end of irradiation concentrations for P-32 and S-35 were set to 0 in the new model. The reasoning behind setting the P-32 and S-35

concentrations to 0 were; for P-32, the half-life is such that after a 1 year decay the concentration of P-23 would be negligible and for S-35, the energy emitter per decay results in a negligible dose to the wearer. By setting these concentrations to 0, the concentrations of the remaining radionuclides would be slightly higher. Both complete tables are provided below:

Stone Size:	5	Ct
	1	g
End of Irradiation Radionuclide Conc.:	8.85E-05	uCi/g
Decay time:	365	d

	Half-Life	Initial Conc. (uCi/g)	1 Y Decay Conc. (uCi/g)	Exempt Conc. (uCi/g)	Ratio
Cs-134	751.90	8.8524E-05	6.32309E-05	9.0E-05	7.03E-01
Mn-54	312.50	8.8524E-05	3.93965E-05	1.0E-03	3.94E-02
Na-22	949.00	8.8524E-05	6.78078E-05	3.7E-04	1.83E-01
P-32	14.28	8.8524E-05	1.78923E-12	2.0E-04	8.95E-09
S-35	87.90	8.8524E-05	4.97794E-06	6.0E-04	8.30E-03
Sc-46	83.85	8.8524E-05	4.33185E-06	4.0E-04	1.08E-02
Ta-182	114.50	8.8524E-05	9.71505E-06	4.0E-04	2.43E-02
Zn-65	243.80	8.8524E-05	3.13603E-05	1.0E-03	3.14E-02
				Sum of ratios:	1.00E+00

Stone Size:	5	Ct
	1	g
End of Irradiation Radionuclide Conc.:	8.93E-05	uCi/g
Decay time:	365	d

	Half-Life	Initial Conc. (uCi/g)	1 Y Decay Conc. (uCi/g)	Exempt Conc. (uCi/g)	Ratio
Cs-134	751.90	8.9264E-05	6.37599E-05	9.0E-05	7.08E-01
Mn-54	312.50	8.9264E-05	3.97260E-05	1.0E-03	3.97E-02
Na-22	949.00	8.9264E-05	6.83750E-05	3.7E-04	1.85E-01
P-32	14.28	0.0000E+00	0.00000E+00	2.0E-04	0.00E+00
S-35	87.90	0.0000E+00	0.00000E+00	6.0E-04	0.00E+00
Sc-46	83.85	8.9264E-05	4.36809E-06	4.0E-04	1.09E-02
Ta-182	114.50	8.9264E-05	9.79632E-06	4.0E-04	2.45E-02
Zn-65	243.80	8.9264E-05	3.16226E-05	1.0E-03	3.16E-02
				Sum of ratios:	1.00E+00

The reason appears to be due to readjustment of the one-year decay concentrations such that the sum of the ratios will equal 1.0 in each case; is that correct? Yes, this is correct.

Also, the reason for having the sum of the ratios equal to 1.0 appears to be because of the assumption that the initial concentrations of each nuclide are equivalent; is that correct? Yes this is correct.

If the answer to both questions is in the affirmative, it may not be necessary to add any details. Complete tables provided for clarification.

(B) In the alternate scenario described in your response to the RAIs on page 8 of 12, the dose due to Mn-54 is the largest of those for which calculations were made. Please explain why the worst-case scenario should not be a dose resulting from a combination of two or more of these nuclides.

The worst-case scenario dose of 374.75 mrem on-contact and 2.20 mrem at 4.0 cm from Mn-54 would not be exceeded if 2 or more nuclides would contribute to the dose because the resulting radionuclide concentrations would have to decrease in order to meet the sum of the ratio less than 1 criteria. A simple way to demonstrate this is by assuming that Mn-54 and Zn-65 are the only radionuclides present in the gemstone. Mn-54 was chosen because it results in the highest dose to the wear at it's exempt concentration value. Zn-65 was selected because it has the same exempt concentration value of Mn-54. The results are summarized in the table below.

	Exempt Conc. (uCi/g)	Dose at Exempt Conc. On-Contact (mr/hr)	Dose at Exempt Conc. 4.0 cm (mr/hr)	1 Y Decay Conc. (uCi/g)	Ratio	On-Contact Dose (mr/hr)	4.0 cm Dose (mr/hr)
Mn-54	1.0E-03	374.75	2.20	5.568E-04	5.57E-01	208.7	1.22
Zn-65	1.0E-03	271.74	1.57	4.432E-04	4.43E-01	120.4	0.70
				Sum of the ratio:	1.00E+00	329.1	1.92

As you can see the resulting dose to the wearer is less than that if only Mn-54 was present at its exempt concentration value and greater than the dose to the wearer if only Zn-65 was present at its exempt concentration value.

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.

It may have been more appropriate for the last sentence above to say "…and <u>why</u> they are chosen." Although this may be repeating information provided elsewhere, I do not understand why (or how) a particular geometry is chosen – i.e., what constitutes "proper sample holder geometries." Please provide additional information, or specify where in your application or RAI response this information is provided.

We use currently use the 1 L Marinelli Beaker and 47 mm petri dish sample holders and this is based on the quantity of gemstones that are being analyzed and the sample carrier that fits the geometry. The Canberra Gamma Analyst has 5 types of sample carriers for the standard sample

geometries. INIS utilizes two types of sample carriers, the 18 Sample Capacity Marinelli Type (second row of manufacturer's Table 3) and the 36 Sample Capacity Adjustable Height Type, (third row of manufacturer's Table 3).

Table 3 Standard Counting Geometry Capacities

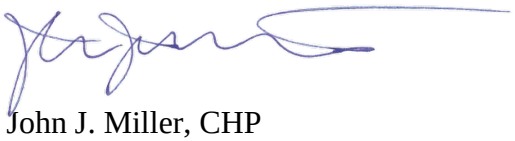
Geometry	Carrier Required	Sample Capacity*
Marinelli Beaker greater than 15.2 cm (6 in.) in diameter (e.g. 3 L and 4 L Marinelli Beaker)	Marinelli Type	12
Marinelli Beaker less than or equal to 15.2 cm (6 in.) in diameter (e.g. 2 L, 1 L and 500 mL Marinelli beakers)	Marinelli Type	18
Flat Base Samples less than 7.6 cm (3 in.) in diameter (e.g. 20 mL vial, 47 mm Petri dish, 125 mL bottle)	Adjustable Height Type	36
Flat Base Samples less than 12.7 cm (5 in.) and greater than 7.6 cm (3 in.) in diameter (e.g. 100 mm Petri dish)	Adjustable Height Type	18
Miscellaneous samples such as 20 mL vial, 47 mm Petri dish, 125 mL bottle, less than 7.4 cm (2.9 in.) in diameter	Small Sample Cup Holder	36

*Stated sample capacity assumes all sample in the load are of the same sample type – mixed loads will have intermediate sample capacities (e.g. six 4 liter Marinelli beakers can be combined with up to eighteen 5 cm (2 in.) planchets). When using the adjustable height sample carrier, the sum of the sample height and the height above the detector cannot exceed 12.7 cm (5 in.).

The 500 mL Marinelli beaker geometry has not been used for several years because the pack size for the topaz has been such that the 1 L Marinelli beaker geometry meets our current needs. If customer pack sizes change that make the 500 mL Marinelli beaker geometry useful then we would utilize this geometry again and purchase the required calibration standards to support its use.

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
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