International Isotopes Inc.

April 05, 2012

Lymari Sepulveda
U.S. NRC
FSME/DMSSA/LISD/LB
Two White Flint North Mailstop 8 E24
11545 Rockville Pike
Rockville, MD 20852

Subject: Response to Request for Additional Information - Amend NR-1235-S-101-S.

Dear Ms. Sepulveda,

The following additional information is provided to support my November 29, 2011 letter requesting an amendment to Sealed Source and Device Registration (SS&DR) NR-1235-S-101-S. I have duplicated your questions before each of my responses.

1. Description/Construction

RAI 1. 1 *Please clarify the wall thickness tolerance requested. With respect to the wall thickness tolerance provided in your request (0.045 + 0.020 / - 0.005 in) - could you provide a drawing and description that specifies exactly what the new wall thickness design is?*

Are the changes in wall thickness to both capsules (i.e. inner and outer capsules) and both methods of source capsule fabrication (i.e. single and double end cap design)? Please provide a drawing that includes the new wall thickness tolerance.

Response to RAI 1.1:

After submitting the request to amend NR-1235-S-101-S I realized that the range in wall thickness tolerance could be confusing. It would have been better to maintain the wall thickness tolerance at ± 0.005 inches and instead define a range for wall thickness. In lieu of revising NR-1235-S-101-S to indicate wall thickness as 0.045 + 0.020 / - 0.005 inch I believe it is more appropriate, and achieves the same dimensional range, to indicate wall thickness as 0.045 – 0.060 inch ± 0.005 inch.

The November 29, 2011 request to revise NR-1235-S-101-S suggested a revision to the second sentence of the first paragraph in Description Section to reflect the change in side wall thickness tolerance as:

The sidewalls are **0.045 + 0.02 / - 0.005** inches thick.

Instead it would be more appropriate to revise this sentence as follows:

The sidewalls **range from** 0.045 **to 0.60 inches ±** 0.005 inches thick.

As mentioned in the request, the purpose of increasing the wall thickness is to narrow the active source diameter without adding a sleeve. The active source dimensions are solely a function of the inner capsule. I would however like to apply the wall thickness revision to both the inner and outer capsule, as there may be a customer in the future that requires a source that has thicker inner and outer capsule walls.

Revised Drawings, INIS-DWG-0001 REV C and INIS-DWG-0002 REV C are enclosed as requested.

RAI 1. 2 Are there any changes in the manufacturing or assembling process with respect to the change in wall thickness?

Response to RAI 1.2:

There are no changes to the manufacturing or assembling process with respect to the change in wall thickness.

RAI 1. 3 On page 2 of 7 of your registration certificate states that fillers or spacers material may be utilized when the volume of the inner capsule is greater than the volume of Co-60 needed to achieve the desired source activity. In page 2 of 3 of you application it state that the revision of wall thickness allows for the reduction of the active source diameter without requiring of the use of sleeve.

Please clarify if the terms fillers or spacers refers to the term sleeve. If not, please explain what does the term sleeve stands for and how this is integrated in the construction of the source?

Response to RAI 1.3:

I would consider the sleeve a spacer. Spacers are sized to fill a certain void volume within a source capsule. Filler material would be considered a component that is mixed with the Co-60 source matrix to achieve a desired activity concentration. For example un-irradiated 1 mm x 1mm Co-59 pellets may be mixed with irradiated 1 mm x 1mm Co-60 pellets to reduce the activity concentration (Ci/g) of the source matrix.

RAI 1. 4 On page 2 of 8 in Enclosure 1 of your request you requested that the bottom end wall thickness be change from 0.025 +/- 0.005 to 0.025 +0.005/-0.0055. Please confirm that the integrity of the source will not be affected by this change. Also, please clarify if the change of the bottom end wall thickness will be applicable to both inner and outer capsule.

Please explain why the change in the bottom end wall thickness was not addressed in the Analysis of the Applicability of Previous Testing on page 4 of 8 in Enclosure 1.

Response to RAI 1.4:

The bottom wall thickness revision was requested in error. Initially I felt that the bottom wall thickness could be revised without additional testing but then after conducting an engineering analysis I did not believe the change could be made without additional testing. I decided to keep the bottom wall thickness as is but failed to update the suggested revision to the language in the SS&DR.

There is no need to revise the forth sentence of the third paragraph in Description Section to reflect a change in end wall thickness tolerance as was previously requested.

RAI 1. 5 On page 4 of 8 in Enclosure 1 of your request you state, "The amendment requests that the upper tolerance be increased from +0.005 inches to +0.020 inches which would authorize a side wall thickness of 0.065 inches; which corresponds to a 30% increase in current maximum side wall thickness." What does 30% correspond to and how was this number determined?

Response to RAI 1.5:

This statement was simply a comparison between the wall thickness that would be acceptable of the current design (0.045 in) taking into account the wall thickness tolerance (0.005 in) and the requested design revision increasing the wall thickness.

	Wall thickness	+	Tolerance	=	Maximum Wall thickness
Current Design:	0.045 in.	+	0.005 in	=	0.05 in.
Revised Design(1):	0.045 in.	+	0.02 in	=	0.065 in.
Revised Design(2):	0.06 in	+	0.005 in	=	0.065 in.

(1)	Original requested revision maintained a single wall thickness and revised tolerance form ± 0.005 in. to + 0.02 in. – 0.005 in.
(2)	A revision to the originally requested amendment provides for a range in wall thickness, from 0.045 in. to 0.06 in. with the tolerance remaining at ± 0.005 in.

The 30% increase in the maximum capsule wall thickness is calculated as:
(0.065 inch - 0.05 inch) ×100% = 30%.

RAI 1. 6 Your request includes adding principle use code AE to the other principle use codes. Gamma Sterotactic Radiosurgery Units often use multiple sources. Is there a limit to the number of sources that should be used with a Gamma Sterotactic Radiosurgery Unit? Is there a limit to the activity of the sources with respect to the number of sources that might be used in a Gamma Sterotactic Radiosurgery Unit?

Response to RAI 1.6:

This is correct; Gamma Sterotactic Radiosurgery Units often use multiple sources. The number and maximum activity of each source will be dictated by the device. For example, the OUR Scientific Inc. Model RGS (SS&DR CA1050D101S) consists of 30 sources with a maximum activity of 210 Ci per source. It is imperative that the number of sources and maximum activity of each source complies with the limitations of the Device SS&DR, whether the device is a Gamma Sterotactic Radiosurgery unit or another device that utilizes multiple sources such as an irradiator. To address this limitation I suggest adding the following new bullet to the Limitations and/or Other Conditions of Use Section of NR-1235-S-101-S:

- The quantity of sources and maximum activity of each source distributed for use in a device whose use is governed by a specific SS&DR shall comply with the source quantity and activity limitations specified in the device SS&DR.

2. Labeling

RAI 2. 1 Will there be any changes in the labeling with respect to the changes requested in your amendment?

Response to RAI 2.1:

There are no changes needed for labeling. Dimensional information is not included on the source label or nameplate that is provided with the source or source set to be attached to the device. Dimensional information is provided to the end user through "as-built" drawings of the source(s). In cases where multiple sources are provided as a set for a device (for example an irradiator that holds multiple sources) the nameplate that is provided includes the total number of sources, the activity per source and serial number for each source.

3. Prototype Testing

RAI 3. 1 In your testing results in Enclosure 1 on page 5 of 8, the testing temperatures listed on the right side are incorrect. Class 5 temperature tests are performed to 600°C (1 hour) and thermal shock 600°C to 20°C. Please clarify if tests need to be redone according to the correct levels.

Response to RAI 3.1:

This was a typographical error, there is no need to conduct additional tests. The source design has been successfully tested to a Class 6; -40^{o}C (20 min) to +800^{o}C (1 hr) and thermal shock +800^{o}C to +20^{o}C. Refer to Section 5 of Test Report 04492, enclosed.

RAI 3. 2 *In your testing results in Enclosure 1 on page 5 of 8 in the test results section, it states, "Failure of an INIS-SF-X.X-YY-Z test specimen subjected to the temperature test would be expected to occur along the welded end(s) of the specimen. This conclusion is based on the methods and materials of construction. … The most likely failure on the INIS-SF-X.X-YY-Z source design resulting from temperature extremes would be due to incomplete fusion of the metal-to-metal weld or to voids within the weld"*

Could you provide more information on the increase in the wall thickness and the new design and explain how this increase will not contribute to failures of the sources with respect to high temperatures or thermal shock?

Please show that the change in the design will not contribute to failures associated to incomplete fusion of the metal-to-metal weld or to voids within the weld.

Response to RAI 3.2:

As part of the manufacturing process the finished weld of the inner and outer source capsule is visually inspected using a remote camera system and tested in accordance with the ISO 9978-1992 (ANSI/HPS N43.6-1997) leak testing requirements. Incomplete fusion of the metal-to-metal weld would be identified during the inspection and leak testing process. While this doesn't happen often we have identified incomplete fusion of the metal-to-metal weld during our inspection and testing process subsequently rejecting the capsule. Once a finished source has been successfully inspected and tested in accordance with our acceptance criteria the finished source is considered to meet the ANSI/HPS N43.6-1997 Classification that it had been designed and tested against.

As mentioned in the analysis, the most likely failure associated with temperature extremes would occur in the weld. However, the likelihood of a weld failure in a source with a capsule wall thickness of 0.060 ± 0.005 inches would not be any different than that of a source capsule with a wall thickness of 0.045 ± 0.005. This is because our source design consists of at least one recessed end cap. Regardless of wall thickness the source capsule is machined to create a shoulder to accept the end cap. The critical dimension associated with the weld is the gap between the recessed end cap and the source capsule, which does not vary with capsule wall thickness. This gap typically ranges from 0.003 to 0.006 inches. Weld voids are prevented by ensuring the gap between the weld surfaces is consistent and, in addition to ensuring clean weld surfaces, welding parameters such as amperage, rotational speed, and electrode size are selected to ensure complete melting of the metal. We believe this level of detail regarding weld gap and welding parameters was beyond the scope of information that should be included in the safety evaluation and was never provided in the original or subsequent amendments to the Source Safety Evaluation. These dimensional details along with the specific welding parameters are included on the "as-built" drawings of the source capsule and on the Weld Parameter Settings for the Source Model, both of which are maintained on file in the source manufacturing record and are provided to the source end user.

4. Quality Assurance Program

RAI 4. 1 *Please explain why a revision is being requested for the Quality Assurance and Control Standards to ISO 9001 and ISO 13[4]85.*

Response to RAI 4.1:

In August 2011 INIS was certified against the Quality Management System requirements of ISO-9001:2008, *Quality management systems — Requirements* and ISO-13485:2003, *Medical devices — Quality management systems — Requirements for regulatory purposes;* copies of these certificates were included with the November 29, 2011 application for an amendment. The purpose of achieving these certifications was twofold, (1) certification was consistent with the Company's commitment to continuous improvement, and (2) certification to international quality standards facilitates the sale and distribution of our Co-60 source products internationally. The revisions made to our quality assurance program to achieve ISO-9001:2008 and ISO-13445:2003 certification did not remove any previous quality assurance commitments associated with the Model INIS-SF-X.X-YY-Z source design that had been made in the initial application for safety evaluation.

I hope that these responses have adequately addressed your requests for additional information. Should you have any questions, please contact me by phone at (208) 524-5300 or by email at jjmiller@intisoid.com.

Sincerely,

John J. Miller, CHP
Radiation Safety Officer

JJM-2012-18

Enclosures as Stated

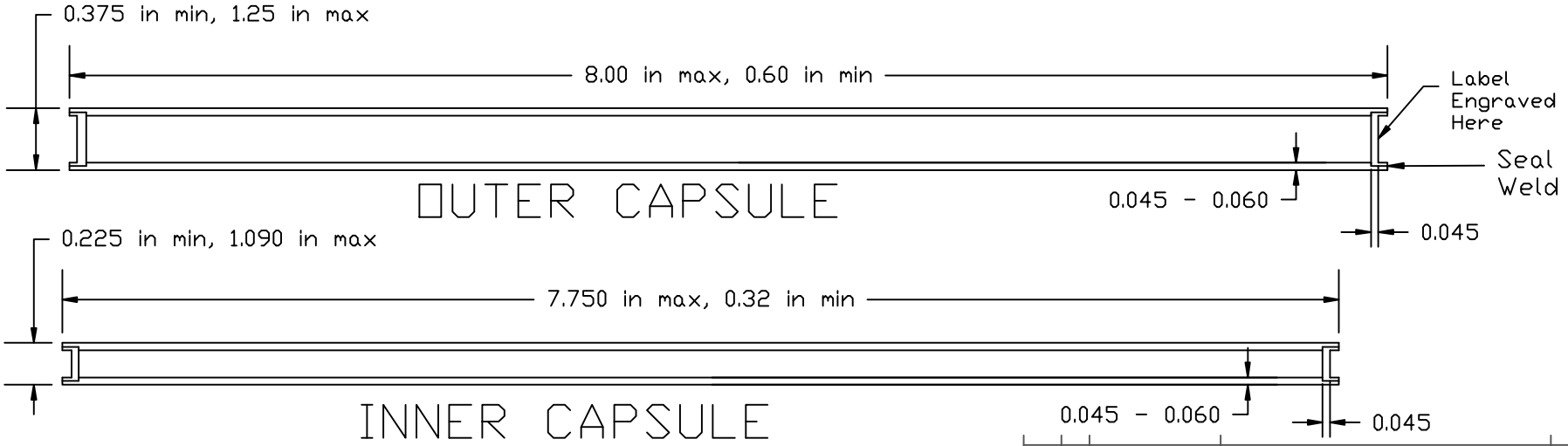
All dimensions in inches

All componants fabricated from 304, 304L, 316 or 316L SST.

Caps and capsule bodies shall be fabricated from the same alloy

Fusion seal weld on the full circumfrence of all end caps

REVISIONS				
LTR.	DESCRIPTION	BY	DATE	APPROVED
A	Add Dimensions & Material	DL	2-3-05	DL
B	Add 304L, 316 & 316L alloys	DL	9-1-06	DL
C	Add Wall Range	KH	12-15-11	KH



Co-60
INIS-SF
XX-XX

Typical Labeling

ITEM NO.	DWG. SIZE	PART OR IDENTIFYING NO.	DESCRIPTION	QTY

International Isotopes Inc.
(Including International Isotopes Idaho Inc. subsidiary)

TOLERANCE	DRAWN:	DATE:	INIS-SF-XX-YY-Z Double Welded Cap Design
.XX ±.010	KH	12/15/11	
.XXX ±.005	CHECKED: SA	12/15/11	
FRACT. ±1/64	APPROVED SA	12/15/11	
ANGLES ±30'	ENG: N/A		
SCALE: NONE	Sheet 1 OF 1		DWG. NO. INIS-DWG-0001 REV. C

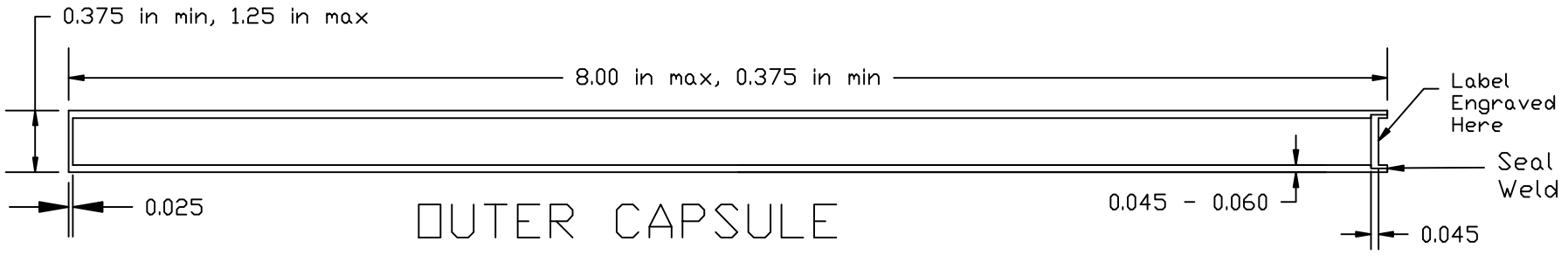
All dimensions in inches

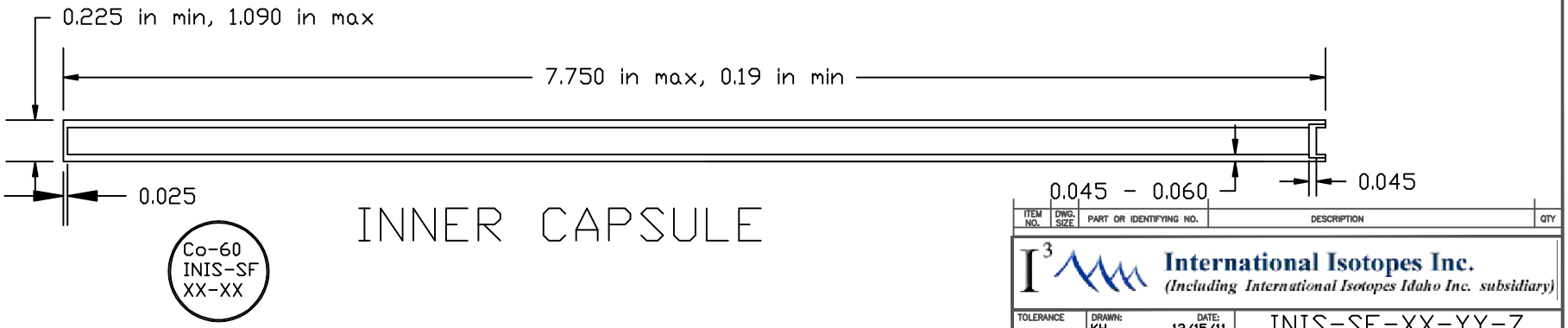
All componants fabricated from 304, 304L, 316 or 316L SST

Caps and capsule bodies shall be fabricated from the same alloy

Fusion seal weld on the full circumfrence of all end caps

REVISIONS				
LTR.	DESCRIPTION	BY	DATE	APPROVED
A	Add Dimensions & Material	DL	2-3-05	DL
B	Add 304L, 316 & 316L Alloys	DL	9-1-06	DL
C	Add Wall Range	KH	12-15-11	KH





Co-60
INIS-SF
XX-XX

Typical Labeling

ITEM NO.	DWG. SIZE	PART OR IDENTIFYING NO.	DESCRIPTION	QTY

International Isotopes Inc.
(Including International Isotopes Idaho Inc. subsidiary)

TOLERANCE	DRAWN:	DATE:	INIS-SF-XX-YY-Z Single Welded Cap Design	
.XX ±.010	KH	12/15/11		
.XXX ±.005	CHECKED: SA	12/15/11		
FRACT. ±1/64	APPROVED SA	12/15/11		
ANGLES ±30'	ENG: N/A		DWG. NO. INIS-DWG-0002	REV. C
SCALE: NONE	Sheet 1 OF 1			