



International Isotopes Inc.

November 2, 2006

Mr. Timothy Harris, Section Chief
Mail Stop T-8FS
11555 Rockville Pike
Rockville, MD 20852

Subject: Request to Amend NR-1235-S-101-S.

Dear Mr. Harris,

International Isotopes Inc. requests to amend Registry of Sealed Sources and Devices Safety Evaluation of Sealed Source number NR-1235-S-101-S as follows:

Page 2, Description: Include in the first sentence Types 304L, 316 and 316L in the description of the stainless steel housings. This sentence could be re-worded as follows: "The Model INIS-SF-X.X-YY-Z Series source capsules contains Co-60 as a metal or alloy in various physical geometries such as disks, cylinders and spheres and are doubly encapsulated in Type 304/304L or 316/316L stainless steel housings".

Page 2, Description: Include the following sentence: "Stainless steel, spheres, disks or plugs of the same alloy as the capsule housing may be utilized as filler or spacer material when the volume of the inner capsule is greater than the volume of Co-60 needed to achieve the desired source activity". This sentence could be inserted in the first paragraph as the next to last sentence.

Page 4, Labeling: Authorize the use of Laser Marking to label either the end cap or outer source capsule with the isotope, model number and serial number. The first sentence of this Section could be modified to read: "One outer end cap or capsule for each source is engraved or laser marked with the isotope (Co-60), source model and serial number".

International Isotopes Inc. believes amending NR-1235-S-101-S may be accomplished without the need of additional prototype testing. Justification is provided below:

Addition of Type 304L and 316/316L Stainless Steels:

International Isotopes Inc. has determined that it would be appropriate to include Types 304L, 316 and 316L stainless steels as suitable materials to manufacture Co-60 source Models INIS-SF-X.X-YY-Z, in accordance with NR-1235-S-101-S and requests the addition of these alloys of stainless steels to the safety evaluation. It should be noted that source capsules and caps will be of the same alloy; that is a Type 304 cap could not be welded onto a Type 316 capsule. A review of similar Sealed Source and Device Safety Evaluations confirms that sealed sources of this type are constructed of Types 304, 304L, 316 and 316L stainless steels. Based on an comparison of the mechanical and chemical properties of these alloys International Isotopes Inc. believes that no additional testing would be necessary to include the Types 304L, 316 and 316L stainless steels in the sealed source and device safety evaluation. In addition, no change in the fabrication process or

TIG welding parameters would be necessary because the *Standard Welding Procedure Specification (WPS) for Gas Tungsten Arc Welding of Austenitic Stainless Steel (M-8/P-8/S-8, Group 1). 1/16 through 1-1/2 inch Thick ER3XX, As-Welded Condition, AWS B2.1-8-024:2001* is pertinent to all four alloys of stainless steel identified above. The tables below provide a summary of the composition and mechanical properties of these alloys.

AISI type	Composition % (maximum unless shown as a range)						Mechanical Properties			
	Cr	Ni	Mo	Si	Mn	C	Yield Strength MPa	Tensile Strength MPa	Elongation %	Hardness HB
304	18.0 - 20.0	8.0 - 10.5	-	1.0	2.0	.3	241	565	60	149
304L	18.0 - 20.0	8.0 - 12.0	-	1.0	2.0	0.08	228	545	60	143
316	16.0 - 18.0	10.0 - 14.0	2.0 - 3.0	1.0	2.0	.3	248	565	55	149
316L	16.0 - 18.0	10.0 - 14.0	2.0 - 3.0	1.0	2.0	0.08	234	558	55	146

Table derived from Table 28-11, Perry's Chemical Engineers' Handbook Seventh Edition

The slight variations in the mechanical properties would not alter the prototype test results because the stresses associated with the conditions under which the sealed source tests are conducted are far below the stresses that would result in failure of any of the alloys. The most notable differences between the alloys may be found in the chemical composition. The Types 316 and 316L alloys contain molybdenum, which results in better overall corrosion resistance than the Type 304 and 304L. While this may appear to be an obvious benefit, the fact that these sources are not used in a corrosive environment eliminates any advantage gained. The Type 304L and 316L alloys have a lower carbon content than the non-L counterparts. The lower carbon content reduces the susceptibility for carbide weld precipitation, which in turn provides for a higher corrosion resistance in the weld. Again, without being utilized in a corrosive environment the added corrosion resistance gained in using the Types 304L, 316 and 316L is not really necessary. However flexibility in the stainless steel alloy that maybe used to fabricate the INIS-SF-X.X-YY-Z is warranted to support various customer specifications.

Use of Types 304/304L, 316/316L Stainless Steel as Filler or Spacers:

International Isotopes Inc. requests authorization to use Types 304/304L or 316/316L stainless steel, in the form of discs, spheres or plugs as spacers or filler in cases where the active source volume of the inner capsule is larger than the volume of Co-60 disks, cylinders or spheres needed to achieve the desired source activity. When a stainless steel alloy is utilized as filler or spacer material the alloy would be the same as that utilized for the end caps and capsules. Authorizing the use of the abovementioned stainless steel alloys as filler or spacer material is not expected to alter the performance or integrity of the source because the material is the same as that used in the manufacturing of the capsule and the density of the stainless steel is consistent with the density of the Co-60 pellets, discs or spheres which make up the active source matrix.

Laser Marking Outer end Cap or Capsule:

The current safety evaluation states that the isotope, model and serial number will be engraved on one end cap of the source. For small diameter sources the resulting size of

this label provides little value for the end user. International Isotopes Inc. requests that laser marking the outer end cap or capsule with the isotope, model, and serial number is an authorized method of labeling the source. Laser marking is extremely precise in that the mark can be as shallow as 0.0001 inches. Laser marking is indelible and can only be removed by grinding or sanding the surface of the metal. Marking the outer capsule in this manner is not expected to alter the performance or integrity of the source and is not believed to warrant additional prototype testing.

Should you have any questions, please contact me by phone at (208) 524-5300 or by email at jjmiller@intisoid.com.

Sincerely,



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