August 30, 2006

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

Subject: Response to Discontinuation of Safety Evaluation for Source Model Nos. INIS-SF-CS-1J and INIS-SF-CS-2J.

Dear Mr. Harris,

I received your letter dated July 26, 2006 regarding the discontinuation of the safety evaluation for source model numbers INIS-SF-CS-1J and – 2J. This response is intended to provide the additional information necessary to support completion of the safety evaluation.

The International Isotopes Inc. source designs were developed to over encapsulate specific Cs-137 source models registered under MA-1059-S-200-S and MA-1059-S-204-S. Both of theses safety evaluations contain the following statement under the Conditions of Normal Use section:

"The recommended working life of each source is 15 years after which it is recommended that the user should arrange for the source to be inspected and assessed by a suitably qualified authority to extend the working life, or dispose of the product through a suitable disposal route".

These Safety Evaluations provide no additional guidance to the source user as to the inspection and assessment criteria or who would be considered a "suitably qualified authority". This lack of clarity has unintentionally resulted in sources being removed from service and placed into long-term storage or disposed of. With the high cost associated with radioactive source disposal many licensees opt for long term storage. In today's environment of heightened source security International Isotopes Inc. views over encapsulation of these sources as a beneficial service for both the source user and regulatory authorities.

It is our hope that this response adequately addresses the five issues you raised in your letter. Please find International Isotopes Inc.'s response to those issues in the proceeding pages. 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
Enclosures as stated

International Isotopes Inc. Response

1. *You indicated that you intend to triple encapsulate existing double encapsulated irradiator sources that have been previously registered but have exceeded their useful life. Please indicate the specific model numbers, and matching SS&D registration certificate numbers, of the sources you intend to triple encapsulate, as well as provide detailed descriptions on how each of these double encapsulated sources would be mounted inside the third encapsulation.*

Response:

The specific source model numbers intended for over encapsulation are the Models CDC.800 and CDC.700. These sources are registered under MA-1059-S-200-S and MA-1059-S-204-S respectively. These sources where previously designated as the X8 and X7, which would also be acceptable for over encapsulation as CDC.800 and CDC.700. Also note the CDC.700 is a single encapsulation source that is doubly encapsulated in various outer encapsulations as described in MA-1059-S-204-S. The Model INIS-SF-CS-1J has been sized to over encapsulate the Model CDC.800. The Model INIS-SF-CS-2J has been sized to over encapsulate the Model CDC.700 with the outer capsules identified in MA-1059-S-204-S with the exception of Outer Capsule VZ-1612 and X38/2.

The Models CDC.800 and CDC.700 will not be physically mounted inside of the third encapsulation. The third encapsulation will have an internal volume sufficient to contain the CDC.800 or CDC.700 with minimal clearance.

2. *You provided a test report for the source capsules (third encapsulation). However, it is not evident that the testing was conducted on fully assembled source capsules containing doubly encapsulated sources with Cs-137, that have reached the end of their useful life. Please provide procedures for, and results of, prototype testing for such fully assembled source capsules. Please also indicate how the tested source capsules were evaluated to determine containment of the radioactive material, such as leak testing.*

Response:

The prototype sources tested where indeed dummy sources. A Dummy Source is defined by ANSI/HPS N43.6-1997 as a: "Facsimile of a sealed source of exactly the same material and construction as a sealed source but containing, in place of the radioactive material, a substance resembling it as closely as practicable in physical and chemical properties".

The advantage to performing prototype testing with dummy sources in lieu of radioactive sources is that the potential for an uncontrolled release of radioactive material during the testing is completely eliminated as is radiation exposure to personnel conducting the tests and examining the tested specimens. It is also worth noting that many of the advanced material testing labs do not possess a radioactive materials license. Utilizing dummy sources in lieu of radioactive prototypes is quite common in the industry and is preferred when the prototype source geometry supports the non radioactive leak test methods described in ANSI/HPS N43.6-1997 Annex A.

For testing purposes, dummy sources where constructed using the same materials and dimensions that will be utilized in manufacturing the third encapsulation of the actual sources. Facsimiles of the Model CDC.800 and CDC.700 where constructed using stainless steel slugs, (one slug per prototype) with dimensions consistent with the CDC.800 and CDC.700. Because the CDC.800 and CDC.700 are in themselves sealed sources, utilizing a solid slug of stainless steel was deemed acceptable because the intent of the prototype testing was to verify the third encapsulation maintained leak tight integrity following the tests.

The internal void volume (free volume) between the third encapsulation and the inner slugs were verified to be greater than 0.1 cm^3 which supported non-radioactive leak testing of the prototype sources in accordance with Annex A of ANSI/HPS N43.6-1997, refer to the dimension tables provided below.

INIS-SF-CS-1J	
Third Encapsulation	
Inner Length:	0.820 cm
Inside Diameter:	0.518 cm
Inner Volume:	0.173 cm^3
Encapsulated Slug	
Outer Length:	0.300 cm
Outside Diameter:	0.300 cm
Outside Volume:	0.021 cm^3
Free Volume:	0.157 cm^3

INIS-SF-CS-2J	
Third Encapsulation	
Inner Length:	1.397 cm
Inside Diameter:	0.889 cm
Inner Volume:	0.867 cm^3
Encapsulated Slug	
Outer Length:	1.0 cm
Outside Diameter:	0.5 cm
Outside Volume:	0.196 cm^3
Free Volume:	0.671 cm^3

In addition to sealed source testing these sources where successfully tested against the Special Form criteria described in Title 49 Code of Federal Regulations Part 173.469. Reference IAEA Certificate of Competent Authority USA/0735/S-96, Revision 0, attached.

3. *Describe in detail the effects the wear and tear of a double encapsulated source that has reached the end of its useful life, would have on the integrity of the complete triple encapsulated source.*

Response:

International Isotopes Inc. has established specific criteria that the CDC.800 and CDC.700 must meet in order to be considered acceptable for over encapsulation. These criteria were listed on the original application but will be provided again with additional clarifying detail below:

- The CDC.800 or CDC.700 source must be marked with a Model and/or Serial number that can link the source to MA-1059-S-200-S or MA-1059-S-204-S.
- The source is constructed from a Series 300 Stainless Steel to ensure material compatibility with the INIS outer capsule.
- The source successfully passes either the *wipe (smear) test* or *dry wipe test* in accordance with ANSI/HPS N43.6-1997 Annex A Paragraphs A.2.1.1 or A.2.1.2 respectively. This wipe test must be performed within six months of over encapsulation.
- The source successfully passes either a *vacuum bubble test, hot liquid bubble test, or Helium pressurization bubble test* in accordance with ANSI/HPS N43.6-1997 Annex A Paragraph A.2.2.1, A.2.2.2 or A.2.2.3 respectively. This test must be performed within six months of over encapsulation.
- The source passes a visual inspection indicating it is free of defects. If required this visual inspection may be aided with the use of a magnifying device.
- The CDC.800 or CDC.700 outside dimensions are verified compatible with the International Isotopes Inc, source design.

The “wear and tear” of a doubly encapsulated source that has reached its useful life is expected to be minimal, adhering to the criteria listed above ensures any wear and tear associated with an old source will not hinder the ability to over encapsulate the source and extend its useful life.

4. *Describe the specifics of the fabrication technology and procedure you intend to use for re-encapsulation. In addition, describe the quality assurance tests that you intend to perform upon completion of the over encapsulation process. Provide information that demonstrates these quality assurance tests are sufficient to indicate that the prototype test results apply to the re-encapsulation process, used in routine fabrication.*

Response:

International Isotopes Inc. has qualified two local machine shops to fabricate the INIS source capsules and caps. It should be noted that these machine shops currently supply International Isotopes Inc. with the stainless steel capsules used for Co-60 irradiator and teletherapy sources manufactured under NR-1235-S-101-S. The capsules and caps must also be accompanied by a Certified Mill Test Report (CMTR) and be verified to meet the dimensions, within specification, of the INIS-SF-CS-1J and -2J drawings this verification is documented on a quality release form. CMTRs and quality release forms are maintained in the completed source file.

Source fabrication will be conducted in an uncontaminated hot cell. It should be noted all handling of the sources will be performed remotely inside of the hot cell. The CDC.800 or CDC.700 and outer capsule and cap are cleaned with a 50/50% isopropyl alcohol/de-mineralized water solution prior to welding. Gas Tungsten Arc Welding (GTAW) often referred to as TIG welding is utilized to fusion weld (no filler metal) the outer capsule and cap. The outer capsule is secured to a welding carousal so that the rotational speed and weld time can be set and adjusted remotely from outside the hot cell. Welding parameters, such as weld speed and amperage are recorded for each source to be welded. Prior to welding any source, a test capsule and cap of the same material and dimensions is welded at the amperage and speed utilized for the specific capsule dimensions. After the test weld is completed the welded test capsule is visually inspected. Adjustments to the welding parameters will be made as necessary. 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, provides the basis for the weld parameter specifications and allowable ranges. Refer to the attached Draft Cs-137 CDC.800/CDC.700 Over Encapsulation Procedure, I4-OP-60 for additional detail.

Quality assurance tests of the completed sources will include leak testing utilizing both radioactive and non-radioactive test procedures. Completed sources must successfully pass either a *vacuum bubble test, hot liquid bubble test, or Helium pressurization bubble test* in accordance with ANSI/HPS N43.6-1997 Annex A Paragraph A.2.2.1, A.2.2.2 or A.2.2.3 respectively. This test is performed by with at least two individuals present. The individual performing the test must be qualified to do so, the second individual observes the test and determines if the source passed the test. Following the leak test the completed source must pass either the *wipe (smear) test* or *dry wipe test* in accordance with ANSI/HPS N43.6-1997 Annex A Paragraphs A.2.1.1 or A.2.1.2 respectively.

In response to the last sentence of NRC Comment 4; *Provide information that demonstrates these quality assurance tests are sufficient to indicate that the prototype test results apply to the re-encapsulation process, used in routine fabrication;* the intent of the quality assurance tests is to indicate that a completed source is in fact sealed, i.e. not leaking. Assurance that the prototype test results may be applied to a completed sealed source capsule rests on the quality assurance program that has been developed to ensure sources are fabricated using a certified materials and a proven welding standard.

5. *You provided a copy of International Isotopes Inc. Quality System Description. Please also provide a copy of the entire Quality Assurance Manual.*

Response: Copy is enclosed.

Additional International Isotopes Inc. Request

International Isotopes Inc. has determined that it would be appropriate to include Types 304L, 316 and 316L stainless steels as suitable materials for the Models INIS-SF-CS-1J and -2J sealed source 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 that 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-CS-1J and -2J is warranted to support various customer specifications.