REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A SEALED SOURCE

No.: NR-1235-S-103-S DATE: October 4, 2006

SEALED SOURCE TYPE: Gamma Irradiator Source

MODEL: INIS-SF-CS-1J and INIS-SF-CS-2J

MANUFACTURER/DISTRIBUTOR: International Isotopes Idaho, Inc.
4137 Commerce Circle
Idaho Falls, ID 83401

ISOTOPE: MAXIMUM ACTIVITY:

Cesium-137 (b)(2)High

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: Gamma Irradiation, Category I (J)

CUSTOM SOURCE: _____ YES __X__ NO

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DESCRIPTION:

The Model Nos. INIS-SF-CS-1J and INIS-SF-CS-2J are source capsules designed to triple-encapsulate (over-encapsulate) Cs-137 double-encapsulated irradiator sources that have been previously used and passed International Isotopes' quality assurance measures, for use in Category I irradiators. The INIS-SF-CS-1J source capsule is sized to over-encapsulate an AEA Technology QSA, Inc. Model No. CDC.800 Series source. The INIS-SF-CS-2J source capsule is sized to over-encapsulate an AEA Technology QSA, Inc. Model No. CDC.700 source, with the exception of the X38/2, X31, X31/1, and VZ-1612 outer capsules, and the X7 inner capsule (single capsule).

The INIS-SF-CS-1J and INIS-SF-CS-2J source capsules are constructed of Type 304, 304L, 316, or 316L stainless steel and are cylindrical in shape with one open end and one closed machined end. After the capsule has been loaded with the recycled double-encapsulated Cs-137 source, the open end is sealed using a welded Type 304, 304L, 316, or 316L stainless steel end cap. The capsule has the same type of stainless steel as the end cap. Gas Tungsten Arc Welding (GTAW) is used to fusion weld the outer capsule and cap. The dimensions of the source capsules are as specified in the following table:

Model	Outer Diameter (inches)	Length (inches)	Wall Thickness (inches)	Bottom Thickness (inches)	Cap Thickness (inches)
INIS-SF-CS-1J	0.294 ± 0.005	0.448 ± 0.005	0.045 ± 0.005	0.025 ± 0.005	0.055 ± 0.005
INIS-SF-CS-2J	0.440 ± 0.005	0.675 ± 0.005	0.045 ± 0.005	0.025 ± 0.005	0.055 ± 0.005

LABELING:

The side of each source is labeled with the active isotope (Cs-137), model and serial number, and the radioactive tri-foil symbol. Due to the small size of these sources, labeling is accomplished by laser.

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DIAGRAM:

See Attachment 1.

CONDITIONS OF NORMAL USE:

The Model Nos. INIS-SF-CS-1J and INIS-SF-CS-2J source capsules are designed to be used in Category I irradiators. The irradiators are typically located in a protected environment such as a laboratory or medical clinic. The useful life of the source is dependent on the 30.17 year half-life of Cs-137 and is expected to be approximately 30 years.

PROTOTYPE TESTING:

The Model Nos. INIS-SF-CS-1J and INIS-SF-CS-2J source capsules have been tested in accordance with ANSI/HPS N43.6-1997 and have achieved a performance classification of ANSI 96C63546.

EXTERNAL RADIATION LEVELS:

International Isotopes Idaho, Inc. provided calculated maximum radiation levels for sources containing (b)(2)High Cs-137. These radiation levels are delineated in the following table: High Ex-2

Model	Dose at 5 cm	Dose at 30 cm	Dose at 100 cm
Side			
INIS-SF-CS-1J	1.00×10^5	3.37×10^3	3.11×10^2
INIS-SF-CS-2J	1.09×10^5	3.43×10^3	3.13×10^2
Top			
INIS-SF-CS-1J	9.13×10^4	3.22×10^3	3.07×10^2
INIS-SF-CS-2J	1.02×10^5	3.32×10^3	3.11×10^2

External Radiation Levels in Rad/hr

SEALED SOURCE TYPE: Gamma Irradiator Source

QUALITY ASSURANCE AND CONTROL:

International Isotopes Idaho, Inc. maintains a quality assurance and quality control program which has been deemed acceptable for licensing purposes by the Nuclear Regulatory Commission. Periodic audits by International Isotopes Idaho, Inc. Quality Assurance staff or consultants will ensure that the program continues to perform at an acceptable level.

International Isotopes Idaho, Inc. has established the following criteria for the Model Nos. CDC.800 and CDC.700 double-encapsulated sources to be considered acceptable for over-encapsulation:

- The CDC.800 or CDC.700 source must be marked with a Model and/or Serial number that can link the source to its corresponding SSD Certificate.
- The CDC.800 or CDC.700 source is constructed from a Series 300 Stainless Steel to ensure material compatibility with the INIS-SF-CS-1J or INIS-SF-CS-2J outer capsule.
- The CDC.800 or CDC.700 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 CDC.800 or CDC.700 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 CDC.800 or CDC.700 source passes a visual inspection indicating it is free of defects.
- The CDC.800 or CDC.700 source's outside dimensions are verified compatible with the International Isotopes, Inc. INIS-SF-CS-1J or INIS-SF-CS-2J source.

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SEALED SOURCE TYPE: Gamma Irradiator Source

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The sources shall be distributed to persons specifically licensed to use Category I irradiators as specified in Table 4 of ANSI/HPS N43.6-1997.
- Handling, storage, use, transfer and disposal to be determined by the licensing authority.
- The sources shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.
- The sources shall not be subjected to conditions that exceed their ANSI/HPS N43.6-1997 classification of ANSI 96C63546.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the U.S. Nuclear Regulatory Commission.

SAFETY ANALYSIS SUMMARY:

The INIS-SF-CS-1J and INIS-SF-CS-2J sources are intended for use in Category I irradiators and are expected to maintain their integrity for normal conditions of use and likely accidental conditions.

Based on review of the information and test data submitted for the INIS-SF-CS-1J and INIS-SF-CS-2J sources and the references cited below, we conclude that these sources are acceptable for licensing purposes as described within this certificate.

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REFERENCES:

The following supporting documents for International Isotopes Idaho, Inc. Model INIS-SF-CS-1J and INIS-SF-CS-2J sources are hereby incorporated by reference and are made a part of this registry document.

- International Isotopes application dated April 17, 2006, letter dated August 30, 2006, and emails dated July 7, 2006, September 5,2006, September 21, 2006, September 26, 2006, September 27, 2006, and October 3, 2006, with enclosures thereto.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: October 4, 2006 Reviewer: /RA/
Nima Ashkeboussi

Date: October 4, 2006 Concurrence: /RA/
John P. Jankovich