



International Isotopes Inc.
& *International Isotopes Idaho Inc.*

April 17, 2006

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

Subject: Application for Sealed Source and Device Evaluation and Registration
INIS-041706.

Dear Mr. Harris,

International Isotopes Inc. is seeking to register Cs-137 source capsules on the Nuclear Regulatory Commission's Sealed Source & Device Registry. Please find the enclosed Application for Safety Review INIS-041706 along with a check for \$2200.00 as required by 10 CFR 170.31, Category 9. C.

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

cc:

J. J. Miller file (JJM-2006-14)

B-14

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Application for Safety Review
INIS-041706

SUMMARY DATA

Date: April 17, 2006

Sealed Source Type: Gamma Irradiator Source

Models: INIS-SF-CS-1J
INIS-SF-CS-2J

Applicant:

International Isotopes Idaho Inc
4137 Commerce Circle
Idaho Falls, ID 83401
(Manufacturer/Distributor)

For further information, contact:
John J. Miller, CHP
Radiation Safety Officer
(208) 524-5300

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Isotope and Maximum Activity:

Model Number	Isotope	Maximum Activity
INIS-SF-CS-1J	Cs-137	(b)(2)High
INIS-SF-CS-2J	Cs-137	

Leak Test Frequency: Six months.

Principal Uses: Gamma Irradiation Category I

Custom Source: No

DESCRIPTIVE DATA

Description:

This source design consists of a triply encapsulated Cs-137 (typically as cesium chloride powder) constructed as follows:

A doubly encapsulated irradiator source which has exceeded its useful life as a result of decay or reaching an administrative working life limitation is over encapsulated in a Type 304 stainless steel capsule.

The following criteria must be met in order for a Cs-137 irradiator source to be considered acceptable for recycling:

- The source is marked with a Model and/or Serial number and can be linked to a specific Registry of Radioactive Sealed Sources and Devices Safety Evaluation of a Device,
- The source is constructed from a Series 300 Stainless Steel to ensure material compatibility with the INIS Type 304 S.S. 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
- The source successfully passes either a *vacuum bubble test* or *hot liquid bubble test* in accordance with ANSI/HPS N43.6-1997 Annex A Paragraph A.2.2.1 or A.2.2.2 respectively.
- The source passes a visual inspection indicating it is free of defects
- The source's outside dimensions are compatible with the International Isotopes Inc, source design.

If the above criteria are met then the source the source will be considered acceptable for over encapsulation.

The INIS outer capsules are constructed of Type 304 Stainless Steel. The capsules are cylindrical in shape with one open end and one closed machined end. After the capsule

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has been loaded with the recycled Cs-137 source(s) the open end is closed using a Type 304 Stainless Steel end cap which is seal welded utilizing a TIG welder. Welding parameters will be defined by procedure and will be dependent on the capsule dimensions. Source dimension specifications are summarized in the following table:

Model	O.D (in)	Length (in)	Wall thickness (in)	Bottom Thickness (in)	Cap Thickness (in)
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 will be labeled with the active isotope (Cs-137), source model and serial number, and radioactive tri-foil symbol. Due to the small size of these sources, labeling will be accomplished with a laser.

In addition to the source, all shielded transportation containers will be conspicuously labeled with the isotope present, the nominal activity, the month and year of assay and bear the warning "CAUTION: RADIOACTIVE MATERIAL" along with the radioactive trefoil radiation symbol in magenta on a yellow background.

Safe handling instructions are included with the source.

Drawings: Refer to Attachment 1.

Conditions of Normal Use:

Under normal use conditions, a Model INIS-SF-CS-1J or -2J source would be placed into a shielded device. The construction of these devices provides substantial radiation shielding and protects the source from physical damage as well. These devices 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.

Limitations And/Or Other Considerations Of Use:

1. The sources shall be distributed to persons specifically licensed or authorized to possess such a source in accordance with 10 CFR 35.600 or equivalent agreement or foreign agency equivalent.
2. Handling, storage, use, transfer and disposal of the sources will be determined by the licensing authority at a given location.

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3. The sources shall not be subjected to conditions that exceed the test conditions identified in ANSI/HPS N43.6-1997 that pertain to a source with classification, 96C66546.
4. The probable effect of severe environmental conditions, such as accidents and fire, would be a minimal release of radioactivity since the Cs-137 is contained within three stainless steel encapsulations.
5. This registration sheet and the information contained within the references shall not be changed without the written consent of the Nuclear Regulatory Commission.

HEALTH AND SAFETY DATA

Safety Analysis Summary:

The Cs-137 Source designs described within this application have been proven capable to withstand the conditions of normal use. These sources will be used in a professional setting, installed in well maintained devices. Under conditions of normal use, the source will not be subjected to physical or environmental factors such as abrasion, corrosion, impact, puncture, or temperature/pressure extremes that would result in source failure.

The source designs meet the ANSI/HPS N43.6-1997 that pertain to a source with classification, 96C66546.

Manufacturer's Safety Analysis of Sealed Source Review:

Environmental testing performed under the direction of International Isotopes Inc. showed that the INIS-SF-CS-1J and INIS-SF-CS-2J design meets the performance classification ANSI 96C66546 per ANSI/HPS N43.6-1997.

Test	Class	Description	Test Report 05170 Page Reference
Temperature	6	-40°C (20 min), +800°C (1 hr) thermal shock 800°C to 20°C	Page 20-23
Pressure	6	25 kN/m ² abs to 170 MN/m ² abs.	Page 29-36
Impact	5	5 kg from 1 meter	Page 8-10
Vibration	4	90 min 25-80 Hz at 1.5 mm amp. Peak to peak and 80-2000Hz at 20g	Page 16-18
Puncture	6	1 kg from 1 meter	Page 5-7

A copy of the test report and leak test results is contained in Attachment 2, Test Report 05170 *Environmental Testing of the 1/4 and 1/2 Inch Diameter Stainless Steel Capsule*, dated March 23, 2006.

Bend Test: Not Applicable

Radiation Profile:

Source activity will be limited to the maximum activity allowed for the device in which they will be installed. U.S. Nuclear Regulatory Commission or (Foreign Government Agency equivalent) approved irradiator devices are so designed to limit the dose rate to the operator, and collocated persons to radiation exposures which have been deemed As

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Low As Reasonably Achievable. Radiation profiles will vary among different irradiator devices. Sources will be transported in approved packages that limit the on contact package dose rates and transportation indexes to levels that coincide with Department of Transportation Regulations.

Dose profiles for (b)(2)High Cs-137 Irradiator Source, Model INIS-SF-CS-1J and Model INIS-SF-CS-2J were determined using MicroShield 6.10. Dose rates at 5, 30 and 100 cm relative to the side and top of the source were calculated and recorded below.

17-5h
EX-2

Model INIS-SF-CS-1J

Distance	Side	Top
5 cm	1.00E+06 Rad/hr	9.13E+05 Rad/hr
30 cm	3.37E+04 Rad/hr	3.22E+04 Rad/hr
100 cm	3.11E+03 Rad/hr	3.07E+03 Rad/hr

Model INIS-SF-CS-2J

Distance	Side	Top
5 cm	1.09E+06 Rad/hr	1.02E+06 Rad/hr
30 cm	3.43E+04 Rad/hr	3.32E+04 Rad/hr
100 cm	3.13E+03 Rad/hr	3.11E+03 Rad/hr

Manufacturing and Distribution Controls:

International Isotopes Inc. (I³) provides for design control, procurement control, process quality control and final quality assurance. I³ has developed a Quality Assurance program which has been verified to meet the standards of ANSI/AMSE NQA-1, a copy of the International Isotopes Inc. Quality System Description is included in Attachment 3. Periodic internal audits by I³ quality assurance staff or consultants validates the effectiveness of the quality assurance program.

Sources distributed within the United States will only be transferred to persons licensed in accordance with 10 CFR Part 35 or equivalent agreement state regulations. Sources distributed to persons outside of the United States will be exported in accordance with 10 CFR § 110.23, *General license for the export of byproduct material* or Specific Export License requirements, as applicable, and any additional regulations imposed by Government of the country of import. Sources will not be distributed that exceed the maximum activity allowed for the device in which they will be installed.

Prior to shipment each source will be leak tested utilizing both radioactive and non-radioactive means, as described in ANSI/HPS N 43.6-1997. A Technical Data Sheet will be included with each source or source set. This sheet will include the Leak Test Results, Recommended Use and Storage, and Radiation Safety Recommendations.



TITLE:		Number:	Effective Date:
Purchase Specification for INIS-SF-CS-1J and -2J Capsules		I4-SD-018	TBD
PRI:		Page:	Superseded Date:
Steve Laflin		Page 1 of 2	Original
PRI Signature and Date:		Document Control Signature and Date:	Quality Assurance Signature and Date:
DRAFT			

1.0 Physical Specifications

- 1.1 Material shall be 304 Stainless Steel
- 1.2 Sidewall shall be 0.045 ± 0.005 inches thick.
- 1.3 Welded caps shall be 0.055 ± 0.005 inches thick
- 1.4 Bottom wall shall be 0.025 ± 0.005 inches thick.
- 1.5 The capsule shall have a maximum length of 0.675 ± 0.05 inches and a minimum length of 0.448 ± 0.005 inches.
- 1.6 The capsule shall have a maximum diameter of 0.440 ± 0.05 inches and a minimum diameter of 0.294 ± 0.05 inches.

2.0 Biological Specifications

- 2.1 None.

3.0 Chemical Specifications

- 3.1 None

4.0 Radiological Specifications

- 4.1 None

5.0 Mechanical Specifications

- 5.1 None.

6.0 Documentation

- 6.1 A specific drawing shall be generated for each capsule size to be manufactured.
- 6.2 A CMTR is required for all materials used in fabrication of these capsules.
- 6.3 Upon receipt and successful completion of the receipt inspection, each lot shall be issued a Quality Release Form (Form -I4-52).

7.0 Receipt Inspection Requirements

- 7.1 Perform a 100% receipt inspection of all capsules. Verify all dimensions and wall thickness measurements.



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TITLE:	Number:	Effective Date:
Purchase Specification for INIS-SF-CS-1J and -2J Capsules	I4-SD-018	TBD
	Page:	Superceded Date:
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DRAFT

8.0. Approved Vendors

8.1 R&D Assembly and Machine
527 South Utah Ave
Idaho Falls, Idaho 83401

8.2 ACCRA Machine
1220 North 825 East
A Shelley, Idaho 83274



TITLE: Cs-137 RE-ENCAPSULATION PROCEDURE		Number: I4-OP-60	Effective Date: TBD
PRI: Steve Laflin		Page: 1 of 7	Superceded Date: original
PRI Signature and Date: DRAFT	Document Control Signature and Date:	Quality Assurance Signature and Date:	

Procedure User Signature and Initial Log

print name	signature	initials

1.0 PURPOSE

To outline the procedure for re-encapsulation of cesium-137 source capsules and to document source measurement, leak test, and other information required on each sealed source certificate.

2.0 POTENTIAL HAZARDS

The hazards associated with the implementation of this procedure include:

- Potential exposure to radioactive material.
- Industrial hazards associated with the inspection and handling of transportation packages such as rigging, crane operations, forklift operations, pinch points, manual lifting, strains, trips, slips and falls.

3.0 APPLICABILITY AND LIMITATIONS

This procedure addresses re-encapsulation of one or more Cs-137 sealed sources in the INIS-SF-CS-1J and INIS-SF-CS-2J capsules. Only sealed sources meeting the criteria established in Section 7.4 are eligible for re-encapsulation.

4.0 DEFINITIONS

Sealed Source – Any source that is of a design which has been successfully tested against the criteria of ANSI/HPS N43.6 or ISO 2919-1999 and is listed in the National Sealed Source and Device Registry.

Special Form – A solid form or capsule design which has been successfully tested against the criteria established in 49 CFR § 173.469 or equivalent foreign regulations.



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5.0 RESPONSIBILITIES

5.1 I³ Quality

- 5.1.1 Verify this procedure is the most current revision.
- 5.1.2 Ensures INIS source capsules and caps are within specification.
- 5.1.3 Reviews completed procedure and releases sources for shipment.

5.2 I³ Radiation Safety Officer

- 5.2.1 Authorizes distribution of completed sources.

5.3 I³ Technician

- 5.3.1 Performs steps outlined in this procedure to include filling of capsules, assaying capsules, welding of capsules and decontaminating as required.

6.0 Equipment and Materials

- 6.1 Qualified doubly encapsulates Cs-137 sealed source(s)
- 6.2 INIS-SF-CS-1J and or INIS-SF-CS-2J components per I³ drawing, DWG.
- 6.3 Q-tip smears
- 6.4 Leak testing apparatus
- 6.5 Certificate of Analysis Template

7.0 PROCEDURE

- 7.1 Operation Supervisor (OP) verify that technicians performing the welding and N.D.T. (Leak Testing) of Sealed Sources are qualified and certifications are current.

OP Signature: _____ Date _____

Name of Welder: _____

Name of N.D.T. Inspector: _____

7.2 Acquire customer loading request information and record in space below.

Customer Name: _____ P.O. Number: _____

Number of INIS-SF-CS-1J: _____ Activity per source: _____

Number of INIS-SF-CS-2J: _____ Activity per source: _____



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TITLE: Cs-137 RE-ENCAPSULATION PROCEDURE	Number: I4-OP-60	Effective Date: TBD
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7.3 List Cs-137 source(s) to be re-encapsulated

Item	Manufacturer	Model/Serial Number	At least one number required		Current Activity (Ci)
			SS&D Number	Special Form CoC	
1					
2					
3					
4					
5					

Use additional sheets as necessary

7.4 Verify the Cs-137 source(s) comply with the following:

- 7.4.1** The source is constructed from a Series 300 Stainless Steel to ensure material compatibility with the INIS Type 304 S.S. outer capsule. – This information should be included in the Sealed Source Safety Evaluation and/or Special Form CoC document
- 7.4.2** 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. – Attach survey records to this procedure.
- 7.4.3** The source successfully passes either a vacuum bubble test or hot liquid bubble test in accordance with ANSI/HPS N43.6-1997 Annex A Paragraph A.2.2.1 or A.2.2.2 respectively. – Attach completed leak test sheets.
- 7.4.4** The source passes a visual inspection indicating it is free of defects.
- 7.4.5** The source's outside dimensions are compatible the International Isotopes Inc, source design.
- 7.4.6** Initial the appropriate columns in the table below. Note Item numbers correspond to the Item numbers from Section 7.3.

Item	7.4.1		7.4.2		7.4.3		7.4.4		7.4.5	
	PASS	FAIL	PASS	FAIL	PASS	FAIL	PASS	FAIL	PASS	FAIL
1										
2										
3										
4										
5										

Use additional sheets as necessary



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7.5 Determine INIS Source model number(s) and serial number(s). Record Items from Step 7.4 that will be over encapsulated in each INIS source. NOTE, serial number is in the format of MMY-## where -## is the next sequential number of source model number built for the current month.

INIS Model Number	Serial Number	Item(s) from Step 7.4	Total Activity (Ci)

Use additional sheets as necessary

7.6 Coordinate with I³ Quality Assurance Manager to procure necessary INIS source capsules and lids.

7.7 Coordinate with I³ Quality Assurance Manager to laser mark each source capsule with the isotope, Cs-137, INIS Model and Serial Number, and radioactive tri-foil symbol.

NOTE: All work with Cs-137 sources is to be performed in the Cs-137 Hot Cell

7.8 Clean the Cs-137 source capsule(s) to be over encapsulated by dipping in a 50% - 50% isopropyl alcohol – de-mineralized water bath and pat dry.

7.9 Prepare INIS capsules for welding and transfer into the Cs-137 source welding hot cell.

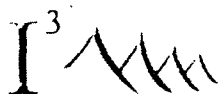
7.10 Prepare INIS Cs-137 sources in accordance with the table from Step 7.5

7.11 Set up welder in accordance with the weld log.

7.12 Weld INIS Cs-137 sources in accordance with the table from Step 7.5.

INIS Model Number	Serial Number	Qualified Welder Signature	Weld Date

Use additional sheets as necessary



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7.13 Perform a leak check on the completed INIS Cs-137 source by placing source capsule in leak chamber filled with a mixture of 50% H₂O and 50% Alcohol and vacuum to -20 inches of water for 2 minutes. Observe for any bubbles present. Document leak test results on Source Certificate for each source.

INIS Model Number/ Serial No.	Results	NDT Signature	Leak Test Date

Use additional sheets as necessary

7.14 Perform a wet Q-Tip smear of outer sealed source. Count the smear. When source smear is less than 1000 dpm, place in clean container (quart can). Document survey results in space provided below, and complete Sealed Source Certificate.

Contamination Survey Instrument Data							
Instrument	Serial No.	Cal. Due	Efficiency	Background Count Rate R _b (cpm)	Background Count Time t _s (min)	Sample Count time t _b (cpm)	MDA (dpm)

$$MDA = \{3 + 3.29[R_b t_s (1 + (t_s/t_b))^{1/2}]\} / \{\text{Efficiency} \times t_s\}$$

INIS Model and Serial No.	Gross Count Rate (cpm)	Net Count Rate (cpm)	Wipe Results (dpm)	Technician initial	Date

Use additional sheets as necessary



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7.15 If sealed source is not to be removed from hot cell following smear test, then identify outside of clean container and log on Isotope Storage board all pertinent information.

7.16 Forward this procedure and any accompanying paperwork or certificates to Q.A. for approval.

8.0 REFERENCES

8.1 ANSI/HPS N43.6-1997, *Sealed Radioactive Sources-Classifications*

8.2 ISO 9978 *Radiation protection - Sealed radioactive sources -Leakage test methods.*

8.3 INIS Drawing, DWG No. INIS-SF-CS-040606

8.4 Weld Standard

8.5 N.D.T. Examiner Standard

9.0 ATTACHMENTS

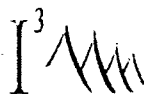
9.1 Sealed Source Certificate



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Attachment 9.1



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**SEALED SOURCE CALIBRATION
CONTAMINATION AND LEAK TEST CERTIFICATE
OF CS-137 SOURCE FOR**

CUSTOMER: _____

ACTIVITY

¹³⁷I MODEL NUMBER: INIS-SF-CS-

Ci
TBq

SERIAL NUMBER: MMYY-##

REFERENCE DATE: MM/DD/YYY

Each source is manufactured by , encapsulated in cylindrical Co-60 pellets 1.0 mm tall by 1.0 mm in diameter with inner and outer stainless steel capsules

Physical Data

Isotope: Cs-137
Half-life: 11018.3 days
 λ : 6.29E-05 d⁻¹

Energy (MeV) Yield
 γ_1 661.65 85.10%
From Ba-137m

Type
Removable Contamination
Leakage Test

Method
Wet Swab
Vacuum Bubble

Results
< 1000 dpm
No Leakage Observed

NDT Class II Technician: _____
Signature

_____ Date

NDT Class II Verifier: _____
Signature

_____ Date

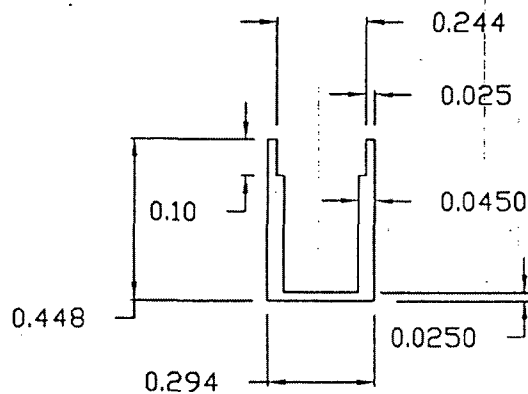
Quality Assurance: _____
Signature

_____ Date

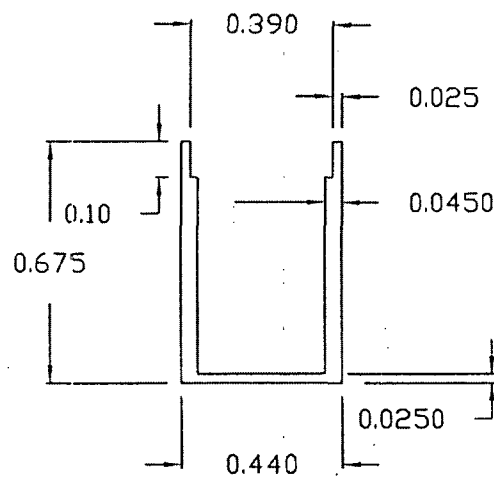
Leak Test Gauge Description

Manufacturer: ASHCROFT
Model/Serial Number: 251009AWL02L/1671 S

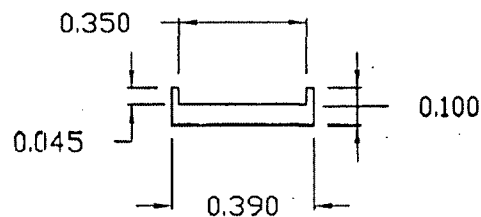
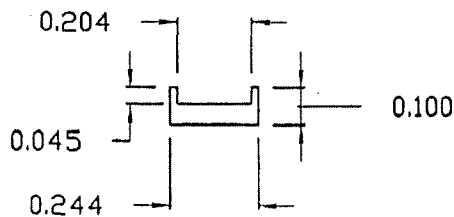
Calibration Date: 4-Mar-06
Calibration Due Date: Sep-06



INIS-SF-CS-1J



INIS-SF-CS-2J



REVISIONS					
LTR.	ECO NO.	DESCRIPTION	BY	DATE	APPROVED
		FIRST ISSUE			

All materials:
Type 304 S.S.

REV. NO.	DWG. SET	PART OR IDENTIFYING NO.	DESCRIPTION	QTY

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TOLERANCE	DRAWN: Darin Loris	DATE: 4/8/68	CS-137 SOURCE CAPSULES
XX :.008	CHECKED:		
.001 :.005	APPROVED:		
FRACT. :1/64	ENG:		
ANGLES :30°	SCALE : 2	Sheet 1 of 1	DWG. NO. INIS-SF-CS-040608
			REV.