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REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY) - 1/30/07

No.: NR-1235-S-101-S DATE: November 7, 2006 PAGE 1 OF 7

SOURCE TYPE: Irradiator and Teletherapy Sources

MODEL: INIS-SF-X.X-YY-Z Series

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

ISOTOPE: MAXIMUM ACTIVITY:

Cobalt-60

Teletherapy Source

(b)(2)High

Cobalt-60

Gamma Irradiation Sources

(b)(2)High

LEAK TEST FREQUENCY: 6 Months

PRINCIPAL USE: (AD) Photon-emitting Teletherapy Units
(J) Gamma Irradiation, Category I
(K) Gamma Irradiation, Category II
(L) Gamma Irradiation, Category III
(M) Gamma Irradiation, Category IV

CUSTOM SOURCE: _____ YES X NO

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SOURCE TYPE: Irradiator and Teletherapy Sources

DESCRIPTION:

This Model INIS-SF-X.X_YY-Z Series source capsules contain 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. The sidewalls are 0.045 ± 0.005 inches thick. The open ends of both the inner and outer stainless steel housings will be seal-welded. **Stainless steel, spheres, disks or plugs of the same alloy as the capsule housing may be utilized as filler or spacers material when the volume of the inner capsule is greater than the volume of Co-60 needed to achieve the desired source activity.** These sources are intended to be used in medical teletherapy devices and gamma irradiators.

The Model INIS-SF-X.X-YY-Z Series consists of five sealed source models. Model INIS-SF-X.X-YY-AD is for use in teletherapy devices. Models INIS-SF-X.X-YY-J, INIS-SF-X.X-YY-K, INIS-SF-X.X-YY-L and INIS-SF-X.XYY-M are for use in Category I, Category II, Category III and Category IV irradiators, respectively.

Isotope and Maximum Activity		
Model Number	Isotope	Maximum Activity
INIS-SF-X.X-YY-AD	Co-60	(b)(2)High
INIS-SF-X.X-YY-J	Co-60	
INIS-SF-X.X-YY-K	Co-60	
INIS-SF-X.X-YY-L	Co-60	
INIS-SF-X.X-YY-M	Co-60	

There are two methods of source capsule fabrication. The differences are the minimum length of the capsules, and the bottom end wall thickness. The capsules can have single or double end cap designs. The single end cap design is bored to match the inside dimension and has a bottom end wall thickness of 0.025 ± 0.005 inches and uses a single end cap at the other end that measures 0.045 ± 0.005 inches thick. When using a double

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DESCRIPTION (Cont.):

end cap design the end caps measure 0.045 ± 0.005 inches thick. International Isotopes (INIS) will have a vendor fabricate the source capsules and end caps in accordance with the INIS Quality Assurance program. INIS has a Specifications Document that will be used to complete dimensional inspection and acceptance of 100% of the fabricated capsules. The dimension specifications of the capsules are summarized below:

Model INIS-SF-X.X-YY-Z Series	Max Diameter		Min Diameter		Max Length	
	inches	cm	inches	cm	inches	cm
Outer Capsule	1.25	3.175	0.375	0.9525	8.00	20.32
Inner Capsule	1.090	2.7686	0.225	0.5715	7.750	19.685

Model INIS-SF-X.X-YY-Z Series	Min Length Single End Cap		Min Length Double End Cap	
	inches	cm	inches	cm
Outer Capsule	0.375	0.9525	0.60	1.524
Inner Capsule	0.19	0.4826	0.32	0.8128

The digits of the model number (denoted by "X.X-YY") identify the dimensions of the source. The first digits identify the diameter, in centimeters, rounded to the nearest decimal. The last two digits identify the length, in centimeters, rounded to the nearest whole number. The letter Z designates the source type.

For example, a medical teletherapy source with a diameter of 2.75 centimeters and a length of 12.25 centimeters would be identified as model number INIS-SF-2.8-12-AD.

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SOURCE TYPE: Irradiator and Teletherapy Sources

DIAGRAM:

See Attachments 1 and 2.

LABELING:

One **outer** end cap or **capsule** for each source is engraved or **laser marked** with the isotope (Co-60), source model and serial number. Refer to Attachments 1 and 2.

CONDITIONS OF NORMAL USE:

Under normal use conditions, a Model INIS-SF-X.X-YY-Z Series source would be placed into a heavily shielded device. 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, medical clinic, or irradiator facility.

The useful life of the source is approximately 10 years.

PROTOTYPE TESTING:

The manufacturer reported that the source capsule achieved an ANSI N43.6 classification of 96E53424, for medical teletherapy and gamma irradiation. A bend test was also performed using the guidance from ISO 2919:1999(E) using a static force equal to 2000N (204 kg).

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SOURCE TYPE: Irradiator and Teletherapy Sources

EXTERNAL RADIATION LEVELS:

The following Axial and Radial dose rates were calculated by INIS for the teletherapy and irradiator sources:

	(b)(2)High	Teletherapy Source	
Distance (cm)		Axial	Radial
5		4.29E+06 Rad/hr	4.47E+06 Rad/hr
30		1.88E+05 Rad/hr	1.92E+05 Rad/hr
100		1.75E+04 Rad/hr	1.85E+04 Rad/hr

High Ex-2

	(b)(2)High	Irradiator Source	
Distance (cm)		Axial	Radial
5		1.47E+06 Rad/hr	1.86E+06 Rad/hr
30		7.88E+04 Rad/hr	8.39E+04 Rad/hr
100		7.95E+03 Rad/hr	8.11E+03 Rad/hr

High Ex-2

QUALITY ASSURANCE AND CONTROL:

International Isotopes Idaho Inc. maintains a quality assurance and control program which has been deemed acceptable for licensing purposes by the NRC. A copy of the program is on file with NRC.

International Isotopes Idaho Inc. has established a Quality Management System, based on ASME-NQA-1 and 21 CFR 210 and 21 CFR 820, current Good Manufacturing Practices.

INIS inspects all incoming parts for proper dimensions and materials. Furthermore, INIS has quality assurance measures that provide controls for cobalt loading, capsule welding, and post fabrication leak tests.

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SOURCE TYPE: Irradiator and Teletherapy Sources

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The sources shall be distributed only to persons specifically licensed by the NRC or an Agreement State.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority. In view that these sources exhibit high dose rates, the sources should be handled only by properly qualified personnel using adequate remote handling equipment and procedures.
- The sources shall be leak tested at intervals not to exceed 6 months using techniques and equipment capable of detecting 185 Bq (0.005 μ Ci) of removable contamination.
- The source assemblies shall not be subjected to conditions that exceed its ANSI N43.6-1997 classification, 96E53424.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

Based on our review of the information and test data cited in the references below and claimed ANSI N43.6 classification, we conclude that the Model INIS-SF-X.X-YY-Z Series sources are acceptable for licensing purposes.

Furthermore, we conclude that sources would be expected to maintain its containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

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SOURCE TYPE: Irradiator and Teletherapy Sources

REFERENCES:

The following supporting documents for International Isotopes Idaho Inc. series of teletherapy and gamma irradiation sources are hereby incorporated by reference and are made part of this registration document.

- International Isotopes Idaho Inc.'s application dated October 15, 2004, with enclosures thereto with enclosures thereto.
- International Isotopes Idaho Inc.'s letter dated March 2, 2005, with enclosures thereto.
- International Isotopes Idaho Inc.'s letter dated January 5, 2006.
- International Isotopes letter dated November 2, 2006.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: November 7, 2006

Reviewer:

Nima Ashkeboussi
Nima Ashkeboussi

Date: November 7, 2006

Concurrence:

John P. Jankovich
John P. Jankovich

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ATTACHMENT 1

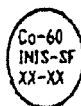
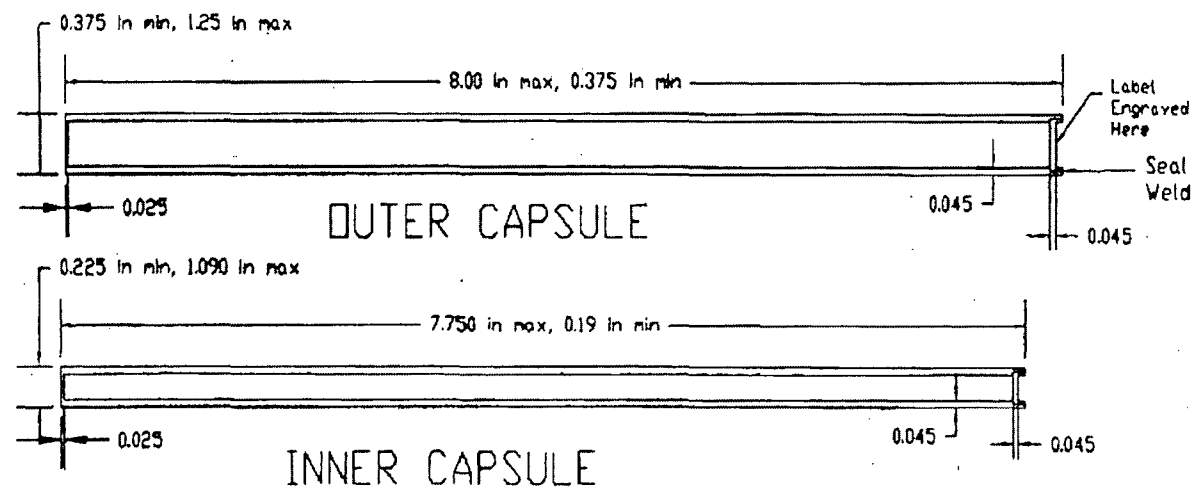
DATE: November 7, 2006

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All dimensions in inches

All components fabricated from 304 SST

Fusion seal weld on the full circumference of all end caps



Typical Labeling

Single End Cap Design

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ATTACHMENT 2

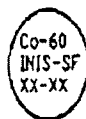
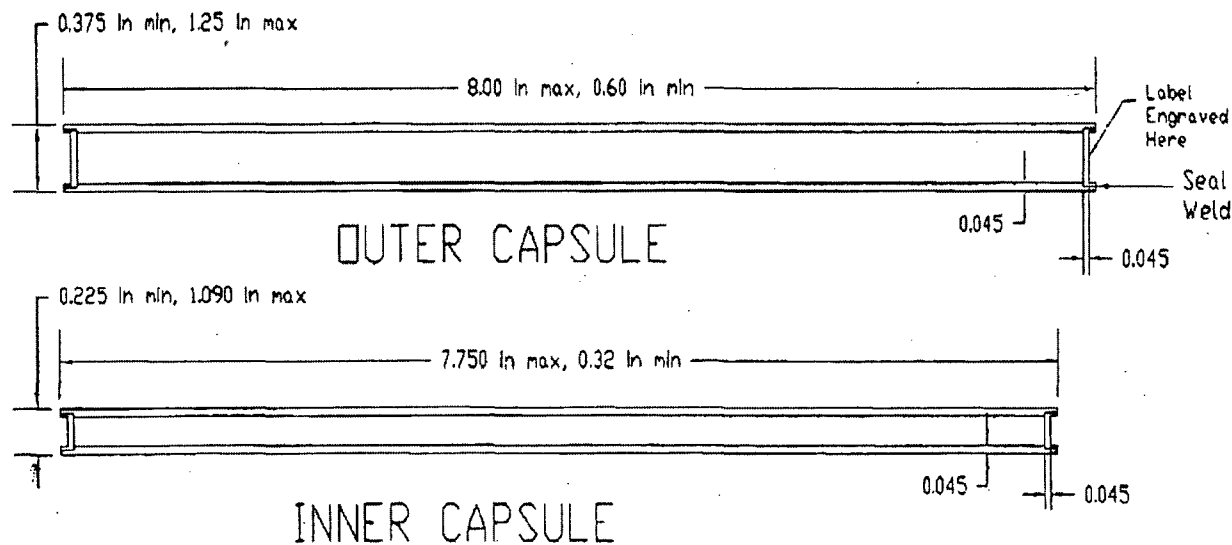
DATE: November 7, 2006

No.: NR-1235-S-101-S

All dimensions in inches

All components fabricated from 304 SST

Fusion seal weld on the full circumference of all end caps



Typical Labeling

Double End Cap Design

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NO.: TX-1153-S-104-S

DATE: March 31, 2006

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SOURCE TYPE: Calibration point source

PROTOTYPE TESTING:

One prototype each of a model BM03-57L and a model BM03-57A, containing approximately 120 and 90 uCi respectively of Co-57, were constructed and subjected to environmental tests described in ANSI/HPS N43.6-1997 "Sealed Radioactive Sources - Classification" and achieved a classification of 97C22212.

EXTERNAL RADIATION LEVELS:

Radiation exposure rates for theses sources were modeled by the manufacturer using information available in Microshield 6.0, and are shown below. Calculated dose rates are shown in units of mR/hr / uSv/hr.

	BM03-22I	BM03-57L	BM03-68L
	(b)(2)High		
On Contact	3,000 / 300	1,550 / 155	1,420 / 142
5 cm	49.5 / 4.95	24.1 / 2.41	22.8 / 2.28
30 cm	1.6 / 0.16	0.8 / 0.08	0.7 / 0.07
100 cm	0.14 / 0.014	0.07 / 0.007	0.07 / 0.007

	BM03-22A	BM03-57A	BM03-68A
	(b)(2)High		
On Contact	15,300 / 1,530	15,300 / 1,530	7,000 / 700
5 cm	247 / 24.7	239 / 23.9	114 / 11.4
30 cm	7.8 / 0.78	7.6 / 0.76	3.4 / 0.34
100 cm	0.7 / 0.07	0.68 / 0.068	0.33 / 0.033

QUALITY ASSURANCE AND CONTROL:

All manufacturing of the Model BM03-XXA and BM03-XXL sources and related operations are to be carried out in manufacturing processes consistent with the current Good Manufacturing Practices Final Rule, Quality System Regulation, 21 CFR Part 820, under the supervision of the Quality Assurance group at International Isotopes Inc.

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SOURCE TYPE: Calibration point source

QUALITY ASSURANCE AND CONTROL (Cont.):

A Technical Data Sheet will be provided with each source. Information provided on this sheet will include Leak Test Results, recommendations for source use and storage, radiation safety recommendations, source model and lot number. A Certificate of Calibration will also be provided with each source and will include information on the radioisotope and its physical properties (i.e., half-life, emission energies and intensities), a physical description of the source, method of calibration and uncertainty.

International Isotopes, Inc. provides for procurement control, process quality control, and final quality assurance for the manufacture of these sources.

Licensed entities possessing sources that have decayed below a useful activity may contact the manufacturer/distributor for instructions regarding return of the sources.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

1. These sources shall be distributed to persons specifically licensed by the NRC or an Agreement State.
2. Handling, storage, use, and transfer: To be determined by the licensing authority. In view that these sources can exhibit high dose rates on contact, the sources should be handled by experienced licensed personnel using adequate handling equipment and procedures.
3. The sources shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 185 Bq (0.005 μ Ci) of removable contamination.
4. Storage/transportation shields will be provided depending upon the radioisotope and total activity of the individual source.
5. The sources shall not be subjected to conditions that exceed the ANSI/HPS N43.6-1997 classification of 97C22212.
6. This registration sheet and the information contained within the references shall not be changed without the written consent of the Texas Department of State Health Services, Radiation Safety Licensing Branch.

SAFETY ANALYSIS SUMMARY:

Based on review of the model BM03-XXA and BM03-XXL sources, the ANSI classification for the sources, and the information cited below, we conclude that these sources are acceptable for licensing purposes.