

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

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

DATE: March 17, 2005

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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

[]

Cobalt-60

Gamma Irradiation Sources

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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

CUSTOM SOURCE: _____ YES X _____ NO

Information in this record was deleted
in accordance with the Freedom of Information
Act, exemptions 2
FOIA 2006-0087

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DESCRIPTION:

The 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 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. These sources are intended as replacement sources for use in medical teletherapy devices and gamma irradiators.

The Model INIS-SF-X.X-YY-Z Series consists of four 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, and INIS-SF-X.X-YY-L are for use in Category I, Category II, and Category III irradiators, respectively.

Isotope and Maximum Activity		
Model Number	Isotope	Maximum Activity
INIS-SF-X.X-YY-AD	Co-60	} }
INIS-SF-X.X-YY-J	Co-60	
INIS-SF-X.X-YY-K	Co-60	
INIS-SF-X.X-YY-L	Co-60	

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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 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.

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DESCRIPTION (Cont.):

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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DIAGRAM:

See Attachments 1 and 2.

LABELING:

One end cap for each source is engraved with the active isotope (Co-60), source model and serial number. Refer to Attachments 1 and 2.

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.

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 97E53524, 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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EXTERNAL RADIATION LEVELS:

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

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QUALITY ASSURANCE AND CONTROL:

International Isotopes Idaho Inc. maintains a quality assurance and control program which has been deemed acceptable for licensing purposes by 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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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 experienced licensed personnel using adequate remote handling equipment and procedures.
- The source 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
- The source assemblies shall not be subjected to conditions that exceed its ANSI N43.6-1997 classification, 97E53524.
- 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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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.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: March 17, 2005

Reviewer: *Nima Ashkeboussi*
Nima Ashkeboussi

Date: March 17, 2005

Concurrence: *John P Jankovich*
John P Jankovich