



STATE OF WASHINGTON  
DEPARTMENT OF HEALTH  
DIVISION OF RADIATION PROTECTION

7171 Cleanwater Lane, Bldg. 5 \* P.O. Box 47827 \* Olympia, Washington 98504-7827  
TDD Relay 1-800-833-6388

October 5, 2004

Garrett N. Brown, Ph.D.  
Radiation Safety Officer  
ISORAY  
350 Hills Street Suite 106  
Richland, Washington 99352

Dear Dr. Brown:

Enclosed is the Sealed Source & Device registration for your CSERION CS 131 Brachytherapy Seed, SS&D registry number WA-1220-S-101-S. Also enclosed is Amendment No. 1 to License Number WN-L0213-1 authorizing distribution of the <sup>131</sup>Cseed. In accordance with your letter of August 13, 2004, our evaluation of your SS&D application is subject to WAC 246-254-120, "Fees for Licensing and Compliance Actions." It is the purpose of this section of Title 246 of the Washington Administration Code to recover the cost to the department of staff activities, such as the review of your Sealed Source and Device evaluation. This portion of WAC provides that we charge a fee of \$100.00 per hour.

Our staff's time directly associated with your SS&D evaluation totals 21 hours. At \$100.00 per hour the fee is \$ 2,100.00.

Please return the lower portion of the enclosed billing with your remittance to Department of Health, within 30 days.

Your cooperation in this matter is appreciated.

Sincerely,

A handwritten signature in black ink, appearing to read "Arden C. Scroggs".

Arden C. Scroggs, Supervisor  
Radioactive Materials Section

Enclosures: Sealed Source & Device Registration No. WA-1220-S-101-S  
License Amendment No.1

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

**NO.:** WA-1220-S-101-S

**DATE:** 17 September 2004

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**SOURCE TYPE:**

Sealed Brachytherapy Source

**MODEL:**

CS-1  
Lawrence CSERION Cs-131 Brachytherapy Seed  
( also known as <sup>131</sup>Cseed )

**DISTRIBUTOR:**

IsoRay  
Suite 106  
350 Hills Street  
Richland, WA 99352

**MANUFACTURER:**

IsoRay  
Suite 106  
350 Hills Street  
Richland, WA 99352

**ISOTOPE:**

Cesium-131

**MAXIMUM ACTIVITY:**

65 mCi (2.41 GBq) Internal Activity  
2-5 mCi Average Air Kerma Strength/Assay Activity

**LEAK TEST FREQUENCY:**

Not Required

**PRINCIPAL USE:**

(AA) Manual Brachytherapy

**CUSTOM SOURCE:**

\_\_\_ YES     X  NO

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

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**SOURCE TYPE:** Sealed Brachytherapy Source

**DESCRIPTION:**

The IsoRay Model CS-1 brachytherapy seed is a small, cylindrical, sealed source that consists of a welded titanium capsule containing the low energy gamma (X-ray) emitting isotope, cesium-131 ( $T_{1/2} = 9.7$  d), adsorbed onto an internal inorganic substrate. The nominal external seed dimensions (4.5 mm length and 0.8 mm diameter) and patient-contacting material (titanium) are identical to other commercially available brachytherapy sources for radiation oncology.

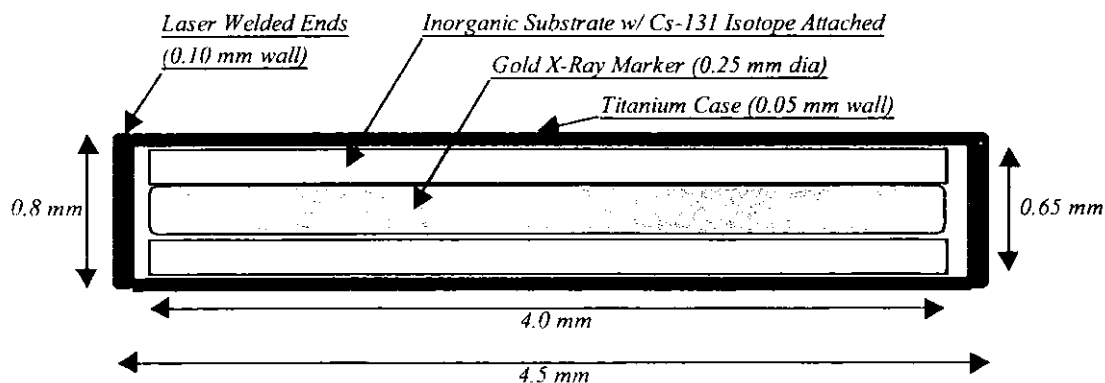
The brachytherapy seed contains a cylindrical inorganic substrate onto which a thin coating of radioactive cesium-131 is applied. A 0.25 mm diameter gold wire is placed within in the central annulus of the core. The gold wire serves as an X-ray marker for radiographic visualization of individual brachytherapy source locations. The internal core materials are inserted into a tube of commercially pure, grade 2 titanium (4.3 mm long, 0.8 mm OD, 0.7 mm ID). Titanium end caps (0.8 mm diameter, 0.1 mm thick) are precision laser welded in place.

**LABELING:**

Because of their small size, individual brachytherapy sources do not directly exhibit identifying marking, labeling or warnings. Multiple sources will be supplied in a primary container such as a glass vial or preloaded cartridges. The primary container will be placed inside a shielded storage container. The shielded storage container will be placed inside a shipping container meeting DOT requirements for shipment of radioactive materials. Examples of labels for each of these containers appear in Figures 1 – 3. The labels will be made of durable materials that remain legible during the expected conditions of transportation and use.

**DIAGRAM:**

A diagram of the IsoRay Model CS-1 brachytherapy seed showing components, dimensions, and the method of sealing appears below:



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**SOURCE TYPE:**

Sealed Brachytherapy Source

**CONDITIONS OF NORMAL USE:**

IsoRay Model CS-1 brachytherapy seeds are indicated for the treatment of malignant disease (e.g., head and neck, brain, breast, prostate, etc.) in a clinical setting and may be used in topical, interstitial, and intracavitary applications for tumors with known radiosensitivity. The seeds may be used as a primary treatment or in conjunction with other treatment modalities, such as external beam radiation therapy, chemotherapy or as treatment for residual disease after excision of primary tumors.

Seeds are typically supplied non-sterile in radiation shielded packaging. The sources are capable of withstanding autoclave conditions. Sources may be implanted using any appropriate, FDA-approved device (e.g., 18-gauge brachytherapy needle, seed applicator, tubing, etc.). Radiological protection devices should be utilized during implantation procedures. When protective barriers are not practical, (e.g., certain surgical stages), the user must rely on time and distance to minimize radiation exposure.

**PROTOTYPE TESTING:**

IsoRay Model CS-1 Brachytherapy Seeds were classified and subjected to environmental test conditions and stresses as defined in ISO 2919-1999, "Radiation Protection – Sealed Radioactive Sources – General Requirements and Classification." The seeds successfully passed all of the required test conditions and are classified as ISO 99C53211, where the last five digits define the test conditions and requirements as shown in the following table. The cesium-131 isotope is classified as Group 3: Moderate Toxicity.

Test	Classification	Test Conditions
Low Temperature High Temperature	5	-40°C (20 min) w/ thermal shock to 20°C; +600°C (1 hr) w/ thermal shock to 20°C
External Low Pressure External High Pressure	3	Two 5 min periods at 25 kPa absolute; Two 5 min periods at 2 Mpa absolute
Impact	2	50 g steel weight dropped from 1 meter height
Vibration	1	No Test Required
Puncture	1	No Test Required
Bending	1	No Test Required
Steam Autoclave	Optional	121°C at 29.8 psig for 20 min

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**SOURCE TYPE:** Sealed Brachytherapy Source

**EXTERNAL RADIATION LEVELS:**

The radiation dose rates in air at various distances from the Model CS-1 source were calculated using a gamma dose rate constant of 0.637 cGy/hr-mCi (637 mR/hr) at 1 cm. The dose rate constant is based on Air Kerma Rate measurements of actual seeds by the National Institute for Standards and Technology and has been confirmed using Monte Carlo calculations.

Distance from the source (cm)	Dose Rate (mR/hr) Maximum activity (50 mCi)	Dose Rate (mR/hr) Typical activity (3.3 mCi)
5	1300	84
30	35	2.3
100	3.2	0.21

**QUALITY ASSURANCE AND CONTROL:**

Prior to distribution, the following quality control tests will be completed:

Test	Method	Acceptance Criteria
Radionuclidic Purity	Gamma Analysis	> 99.9% Cs-131; < 0.01% Ba-131; < 0.1% Cs-132; < 0.05% all other radioisotopes
Weld Inspection	Visual – w/ Magnification	Silver in color, with no cracks or holes
Leak Test	ISO 9978	≤ 0.185 kBq (≤ 0.005 μCi) per seed
Radioassay	Dose Calibrator	0.2 to 50.0 mCi ± 5% apparent activity
External Dimensions	Gauging	0.8mm ± 10% OD; 4.5 mm ± 10% length
Seed Assembly	Visual	No foreign material, dents, or scratches
Labeling	Visual	Information is legible, accurate and complete

IsoRay maintains a quality assurance program that is based on ISO 9001 requirements and is designed to comply with US Food and Drug Administration Quality System Requirements for medical devices. Elements of the quality system that are directly applicable to this brachytherapy seed are included in the application for safety evaluation of this sealed source.

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SAFETY EVALUATION OF SEALED SOURCE

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**SOURCE TYPE:** Sealed Brachytherapy Source

**LIMITATIONS AND OTHER CONSIDERATIONS OF USE:**

- The sealed sources shall be distributed only to specific licensees of the Washington State Department of Health, the U.S. Nuclear Regulatory Commission, or an Agreement State.
- Handling, Storage, Use, Transfer and Disposal: To be determined by the licensing authority. Given that these sealed sources exhibit high surface dose rates when unshielded, these sources should be handled by experienced licensed personnel using adequate remote handling equipment and procedures.
- Leak testing beyond that performed by the manufacturer is not required due to the short half-life (9.7 days) of Cs-131.
- Since the seeds are non-sterile when shipped, they must be sterilized upon receipt prior to use using either steam (autoclave) or ethylene oxide (EtO). Dry heat sterilization must not be used.
- Sources shall not be exposed to conditions that exceed the ISO 2919 classification of 99C53211. Despite excellent corrosion resistance of titanium, seeds are not to be exposed to concentrated acids or bases.
- Licensees should observe the manufacturer's instructions for handling and using the Cs-131 sources which are provided with each shipment of seeds. When not in use, seeds should be stored in shielded containers in a controlled area.
- Any excess seeds must be disposed in accordance with applicable rules and regulations. Unused sources may be returned to the distributor.
- This registration sheet and the information contained with the references shall not be changed without the written consent of the Washington State Department of Health.

**SAFETY ANALYSIS SUMMARY:**

Based on review of the IsoRay Model CS-1 brachytherapy sealed source, its ISO 2919/ANSI N43.6/ANSI N44.1 classification, and the information and test data cited below, we conclude that the IsoRay Model CS-1 sealed source is acceptable for licensing purposes.

Furthermore, we conclude that this source should maintain its integrity under normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

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SAFETY EVALUATION OF SEALED SOURCE

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**SOURCE TYPE:** Sealed Brachytherapy Source

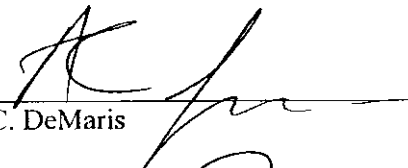
**REFERENCES:**

This Certificate of Registration is based on information contained in the following supporting documents which are hereby incorporated by reference and made a part of this registry document:

- Application for Safety Evaluation and Registration of IsoRay Model CS-1 Brachytherapy Sealed Source, dated May 20, 2004.
- Letter and attachment dated 24 August 2004.

**ISSUING AGENCY:** Washington State Department of Health, Office of Radiation Protection  
Box 47827, Olympia, Washington 98504 360-236-3220.

Date: 17 Sept 04

REVIEWED BY:   
for C. DeMaris

Date: 23 September 04

CONCURRENCE:   
A. Grumbles

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

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**SOURCE TYPE:**

Sealed Brachytherapy Source


Cs-131 Brachytherapy Seed Model CS-1	
IsoRay, Richland, WA 99352 USA	
Lot Number:	
Assay Date:	
Number of Sources:	<b>CAUTION</b>  <b>Radioactive Materials</b>
Total Activity: mCi	
<b>NON-STERILE</b>	
<b>Caution: Cesium-131 Radioactive Material</b>	

Figure 1. Example of primary seed container labeling


<b>Cs-131 Brachytherapy Seed Model CS-1</b>			
Manufactured By: <b>IsoRay, Inc.</b> 350 Hills Street, Suite 106 Richland, WA 99352 USA Phone: 509-375-1202	Certificate Number:		
	Lot Number:		
	Number of Seeds:	Reference Date:	Implant Date:
	Total Apparent Activity (mCi):		
	Total Air Kerma $\mu\text{Gy m}^2 \text{h}^{-1}$ (U):		
<b>CAUTION</b>  <b>Radioactive Materials</b>	Caution: Federal law restricts this device to sale by or on the order of a physician		Midpoint Apparent Activity (mCi):
			Midpoint Air Kerma $\mu\text{Gy m}^2 \text{h}^{-1}$ (U):
			Patient Name or ID:
Caution: Radioactive Material Cesium-131		Physician Name:	
		<b>SINGLE USE ONLY</b>	<b>WARNING: NON-STERILE</b>

Figure 2. Example of shielded storage container labeling

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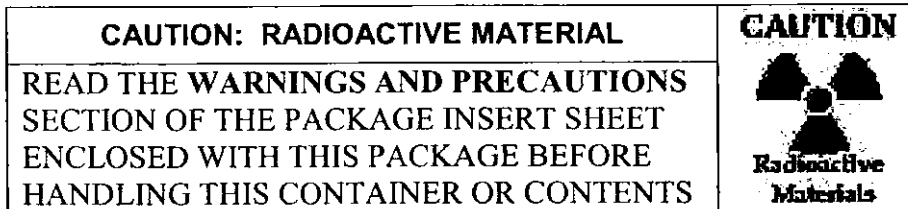


Figure 3. Example of package insert warning label