



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

EDUARDO J. SANCHEZ, M.D., M.P.H.
COMMISSIONER

1100 W. 49th Street • Austin, Texas 78756
1-888-963-7111 • <http://www.dshs.state.tx.us>

Date: 11-15-05

DEAR:

Jonathan Rivera

This correspondence is in response to your open records request received on 11-14-05 for documents maintained by the Radiation Safety Licensing Branch. The following is submitted in response to your request:

- ☒ Enclosed is the information you requested. The documents are considered *public information*.
- ☐ ** Some portions of the documents you requested are *confidential* and are redacted based on the enclosed citations. ** Per our conversation on _____ you agreed that information made *confidential* under these citations could be withheld without this agency seeking an Attorney General's ruling.
- ☐ All of the documents you requested contain *confidential* information and are being referred to the Office of General Counsel (OGC) for possible referral to the Attorney General's (A.G.'s) office for an opinion regarding the releasability of the information. If forwarded to the A.G.'s office, you will receive a copy (from OGC) of the letter which the department has sent to the A.G.'s office requesting an Open Records decision, and which sets out the basis for the department's position.
- ☐ Some or portions of the documents you requested are *confidential* and are being referred to OGC for possible referral to the A.G.'s office for an opinion as stated above. Enclosed are part of the documents which are releasable and not referred to OGC and/or A.G.'s office.
- ☐ The documents or portions of the documents previously withheld from disclosure have been determined to be *releasable*, either by OGC or the A.G.'s office, and are *enclosed*.
- ☐ The documents previously withheld from disclosure have been determined to be *confidential*, either by OGC or the A.G.'s office, therefore, further release of information is not possible based on the enclosed citations.
- ☐ Our records reflect that we do not regulate a facility/agency by the name/address you provided.

Other:

STATUS OF REQUEST:

- | | |
|----------------------------------------------|---------------------------------------------------------------|
| <input checked="" type="checkbox"/> Complete | <input type="checkbox"/> Incomplete, documents to follow |
| <input type="checkbox"/> No charge | <input type="checkbox"/> Fee \$_____ Submit bill with payment |

Thank you for your open records request. If you have any questions regarding this information please call (512) 834-6688 ext. 2202 or email: chrissie.toungate@dhsh.state.tx.us

*Thank-you!
Chrissie*

Chrissie Toungate, Custodian of Records
Regulatory Licensing Unit
Radiation Safety Licensing Branch
1100 West 49th Street
Austin, TX 78756

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E-5

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SOURCE
(Amended in Entirety)

NO.: TX-1153-S-102-S

DATE: December 10, 2003

PAGE 1 OF 6

DEVICE TYPE: Sealed source

MODEL: BM06 Series (BM06-33, BM06-37, BM06-57, BM06-68, BM06-60, BA06-22)

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

ISOTOPE: Ba-133(BM06-33), Cs-137(BM06-37), Co-57(BM06-57), Na-22(BM06-22)
Co-60(BM06-60), Ge-68(BM06-60)

<u>MODEL NUMBER</u>	<u>MAXIMUM ACTIVITY</u>
BM06-33, BM06-37, BM06-68 BM06-22	0.5 millicuries (18.5 MBq)
BM06-57	15 millicuries (555 MBq)
BM06-60	0.1 millicurie (3.7 MBq)

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: Medical reference source (X)

CUSTOM SOURCE: _____ YES X NO

CUSTOM USER:

DESCRIPTION:

These sources consist of the radioisotope in a chloride complex uniformly dispersed in high impact epoxy casting resin (Emerson & Cuming Stycast 1264 or equivalent) color coded to visually differentiate the radioisotopes, which is then cured in a 30 ml dose calibrator vial. The epoxy containing the dispersed radioactivity is sandwiched between two layers of epoxy which does not contain radioactive material. A rubber septum or equivalent material is chemically welded into the neck of the vial and a color coded (again to visually differentiate the radioisotopes) screw top cap is chemically welded onto the vial so that disassembly without destruction of the vial is not possible. Each source is supplied to the customer in a shielded storage pig. Physical dimensions of the sources are approximately 1.25 in. x 3 in. for all models.

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SOURCE
(Amended in Entirety)**

NO.: TX-1153-S-102-S

DATE: December 10, 2003

PAGE 2 OF 6

DEVICE TYPE: Sealed source

LABELING:

Each source and storage pig is conspicuously labeled with the source isotope and activity and bears the warning "CAUTION: RADIOACTIVE MATERIAL" as well as the trefoil radiation symbol in magenta on a yellow background, the designer's name, and the name of the manufacturer. Each label also contains the source model number, serial number and a reference date for the source activity. The label will be affixed to the exterior of the vial and will be laminated to prevent wear as a result of use.

DIAGRAM:

Attachment 1 is a sample label. Attachment 2 is a cutaway diagram of an assembled source in a storage pig.

CONDITIONS OF NORMAL USE:

The sources are designed for use in a medical or commercial pharmacy environment and are not expected to experience extreme environmental factors. The sources are intended for use as reference standards to check the response of dose calibrators used to measure research, diagnostic, and therapeutic radiopharmaceuticals. The expected useful life of the Co-57 and Ge-68 sources will be approximately 2 years. The manufacturer expects that the working life of the Cs-137, Ba-133, Na-22 and Co-60 sources will be at least 5 years.

PROTOTYPE TESTING:

A prototype BM06-57 source was constructed and tested in accordance with ANSI/HPS N43.6-1997 "Sealed Radioactive Sources - Classification" and achieved a sealed source classification of ANSI 97C22312. Only a prototype BM06-57 was tested because the maximum activity of this model is significantly higher than the other models and a failure of the source that would release radioactive material would be more readily detected. There is no difference in the construction materials or assembly methods for the different models.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SOURCE
(Amended in Entirety)

NO.: TX-1153-S-102-S

DATE: December 10, 2003

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DEVICE TYPE: Sealed source

EXTERNAL RADIATION LEVELS:

Maximum radiation levels for these sources are as follows:

Model BM06-57

Contact	- 292.6 mrem/hr	(2.926 mSv)
5 cm	- 68.3 mrem/hr	(683 μ Sv)
30 cm	- 5.9 mrem/hr	(59 μ Sv)
100 cm	- 1.2 mrem/hr	(12 μ Sv)

Model BM06-37

Contact	- 45.2 mrem/hr	(452 μ Sv)
5 cm	- 11.8 mrem/hr	(118 μ Sv)
30 cm	- 1.6 mrem/hr	(16 μ Sv)
100 cm	- 0.13 mrem/hr	(1.3 μ Sv)

Model BM06-33

Contact	- 38.8 mrem/hr	(388 μ Sv)
5 cm	- 10.3 mrem/hr	(103 μ Sv)
30 cm	- 1.4 mrem/hr	(14 μ Sv)
100 cm	- 0.09 mrem/hr	(0.9 μ Sv)

Model BM06-68

Contact	- 218.9 mrem/hr	(2.189 mSv)
5 cm	- 37.3 mrem/hr	(373 μ Sv)
30 cm	- 3.0 mrem/hr	(30 μ Sv)
100 cm	- 0.4 mrem/hr	(4.0 μ Sv)

Model BM06-22

Contact	- 470 mrem/hr	(4.7 mSv)
5 cm	- 78 mrem/hr	(780 μ Sv)
30 cm	- 6.0 mrem/hr	(60 μ Sv)
100 cm	- 0.6 mrem/hr	(6.0 μ Sv)

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SOURCE
(Amended in Entirety)

NO.: TX-1153-S-102-S

DATE: December 10, 2003

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DEVICE TYPE: Sealed source

EXTERNAL RADIATION LEVELS (Continued):

Model BM06-60

Contact - 160 mrem/hr	(1.6 mSv)
5 cm - 30 mrem/hr	(300 μ Sv)
30 cm - 1.0 mrem/hr	(10 μ Sv)
100 cm - 0.2 mrem/hr	(2.0 μ Sv)

Note: Dose rates for model BM06-57 and BM06-68 measured on prototype sources manufactured by International Isotopes Idaho, Inc. and corrected to the maximum activities for these sources. Dose rates for Models BM06-33, 37, 22, and 60 measured on NIST traceable sources of similar construction and geometry and corrected to the maximum activities for these sources.

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 U. S. Nuclear Regulatory Commission. Periodic audits by International Isotopes Idaho, Inc. Quality Assurance staff will ensure that the program continues to perform at an acceptable level.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The sources shall be distributed to persons specifically licensed by the NRC, an Agreement State or a Licensing State.
- Handling, storage, use, transfer and disposal to be determined by the licensing authority but should be, at a minimum, in accordance with the product information pamphlet provided by the distributor.
- 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 97C22312.
- The sources should be stored and transported in the manufacturer's shielded case.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the Texas Department of Health, Bureau of Radiation Control.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SOURCE
(Amended in Entirety)

NO.: TX-1153-S-102-S

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DEVICE TYPE: Sealed source

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE(Continued):

- International Isotopes Idaho, Inc. provides for design control, procurement control, process quality control, and final quality assurance pertaining to the manufacture of these sources. Distribution will be directly from the manufacturer's facility to the customer.

- Licensees in possession of sources that have decayed below their useful range of activities may contact International Isotopes Idaho, Inc. for instructions regarding return to the manufacturer. In most cases this will be as a limited quantity of radioactive material as specified in 49 CFR 173.421.

SAFETY ANALYSIS SUMMARY:

The BM06 Series sources are intended for use as quality control and reference sources for dose calibrators and are expected to maintain their integrity throughout the useful life of the source if not subjected to extreme conditions of handling or environment. Rupture of the encapsulating material would not reasonably be expected to allow dispersion of radioactive material due to the epoxy matrix with which the radioactive material is mixed.

The most severe accident scenario involving these sources would be a fire, and would most likely result in a release of radioactive material. Temperatures exceeding 200 degrees C would result in combustion of the resin in which the radioisotope is dispersed, as well as the plastic which constitutes the vial.

- Based on review of the information and test data submitted for the BM06 Series sources and the references cited below, we conclude the these sources are acceptable for licensing purposes as described within this certificate.

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

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SOURCE
(Amended in Entirety)

NO.: TX-1153-S-102-S

DATE: December 10, 2003

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DEVICE TYPE: Sealed source

REFERENCES:

The following supporting documents for the Series BM06 reference sources are hereby incorporated by reference and are made a part of this registry document.

- International Isotopes Idaho, Inc. application dated July 12, 2002 signed by John J. Miller, CHP, Radiation Safety Officer, with enclosures thereto.
- International Isotopes Idaho, Inc. letter dated September 18, 2002 signed by John J. Miller, CHP, Radiation Safety Officer, with enclosures thereto.
- International Isotopes Idaho, Inc. letter dated October 16, 2002 with enclosures thereto.
- International Isotopes Idaho, Inc. letters dated August 20, 2003 and November 27, 2003 signed by John J. Miller, CHP, Radiation Safety Officer.

ISSUING AGENCY:

Texas Department of Health
Bureau of Radiation Control

Date: December 10, 2003

Reviewer: J. Scott Kee
J. Scott Kee

Date: December 10, 2003

Concurrence: David Fogle
David Fogle


REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: TX-1153-S-102-S

DATE: December 10, 2003

ATTACHMENT 1

SOURCE LABEL

 CAUTION RADIOACTIVE MATERIAL	BM06-57	C0-57	<i>Manufactured and distributed for RadQual, LLC, Aurora, OH, by International Isotopes Idaho, Inc., Idaho Falls, ID</i>
	0.00 mCi	00.0 MBq	
	Serial Number: BM0657XXX-XX		
	Reference Date: 3 Oct 02		
Bench/mark by RadQual			

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY EVALUATION OF DEVICE

NO.: TX-1153-S-102-S

DATE: December 10, 2003

ATTACHMENT 2

BM06 Series

TX-1153-S-102-S		REV		DATE		BY		APPROVE	
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NOTES

- SOURCE ACTIVITY CONSISTS OF BARIUM-133 DISPENSED UNIFORMLY IN A HIGH IMPACT EPOXY RESIN BEING HAVE COLOR CODED PER TABLE USING EPOXY COLOR PASTE FOR ATOMCAST EPIDUR-PCR EPOXY.
- PRODUCT NOMINAL ACTIVITY SHALL BE REFERENCED TO LABEL DATE. NOMINAL ACTIVITY TOLERANCE SHALL NOT BE $\pm 10\%$ FOR ≤ 1 YEAR AT TIME OF SHIPMENT.
- LINEAL CALIBRATION SHALL BE RADIOACTIVITY CONTENT DETERMINED BY EXPOSURE CHAMBER MEASUREMENT WITH BROAD ENERGY COMPUTED AT THE 95% CONFIDENCE LEVEL. OVERALL, CARRIES OF CALIBRATION SHALL BE 0.5% NIST MEASUREMENT SYSTEM STANDARDIZATION SHALL BE NIST, TRACEABLE.
- RADIOPURITY TO MEET BARIUM-133 SPECIFICATIONS AT TIME OF CALIBRATION, PARTICULARLY 0.01-0.02 & 0.03-0.04 EXCLUSIVE OF 0.05-0.06, 0.07-0.08.
- REPORT THE ACTIVITY CALIBRATIONS USING THE FORMAT REQUIRED FOR EACH MODEL AS REQUIRED IN NRC 10CFR 35.45.
- CONTAMINATION/LEAKAGE TESTING OF EACH SOURCE SHALL BE PER PROCEDURE FOR CONTAMINATION TEST OF REF. SOURCE; LIMIT 5×10^{-4} dpm.
- CERTIFICATES, DISCLOSURE & LABELING PER NRC 10CFR 35.45.
- SOURCE SET NO. BM06-01 CONSISTS OF THE EACH OF BM06-02 (0.01-0.02), BM06-03 (0.03-0.04) AND BM06-04 (0.05-0.06).
- THE PRODUCTS SHOWN IN THIS DRAWING ARE CLASS I MEDICAL AND MEET THE ANSI N434-1997 PERFORMANCE CLASSIFICATION OF CARRIER FOR CALIBRATION SOURCES.

STANDARD MODEL TABLE			
ASST. P/N	MODEL NO.	ISOTOPE	COLOR CODE
-01	BM06-02	Na-22	YELLOW
-02	BM06-03	Co-60	BLUE
-03	BM06-04	Cs-137	GREEN
-04	BM06-05	Na-22	BLK
-05	BM06-06	Co-60	RED
-06	BM06-07	Co-60	WHITE

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

NO.: TX-1153-S-102-S

DATE: October 22, 2002

PAGE 1 OF 5

DEVICE TYPE: Sealed source

MODEL: BM06 Series (BM06-33, BM06-37, BM06-57)

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

ISOTOPE: Ba-133(BM06-33), Cs-137(BM06-37), Co-57(BM06-57)

MODEL NUMBER

MAXIMUM ACTIVITY

BM06-33
BM06-37
BM06-57

0.5 millicuries (18.5 MBq)
0.5 millicuries (18.5 MBq)
15 millicuries (555 MBq)

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: Medical reference source (X)

CUSTOM SOURCE: ☐ YES ☒ NO

CUSTOM USER:

DESCRIPTION:

These sources consist of the radioisotope in a chloride complex uniformly dispersed in high impact epoxy casting resin (Emerson & Cuming Stycast 1264 or equivalent) color coded to visually differentiate the radioisotopes, which is then cured in a 30 ml dose calibrator vial. The epoxy containing the dispersed radioactivity is sandwiched between two layers of epoxy which does not contain radioactive material. A rubber septum or equivalent material is chemically welded into the neck of the vial and a color coded (again to visually differentiate the radioisotopes) screw top cap is chemically welded onto the vial so that disassembly without destruction of the vial is not possible. Each source is supplied to the customer in a shielded storage pig. Physical dimensions of the sources are approximately 1.25 in. x 3 in. for all models.

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

NO.: TX-1153-S-102-S

DATE: October 22, 2002

PAGE 2 OF 5

DEVICE TYPE: Sealed source

LABELING:

Each source and storage pig is conspicuously labeled with the source isotope and activity and bears the warning "CAUTION: RADIOACTIVE MATERIAL" as well as the trefoil radiation symbol in magenta on a yellow background, the designer's name, and the name of the manufacturer. Each label also contains the source model number, serial number and a reference date for the source activity. The label will be affixed to the exterior of the vial and will be laminated to prevent wear as a result of use.

DIAGRAM:

Attachment 1 is a sample label. Attachment 2 is a cutaway diagram of an assembled source in a storage pig.

CONDITIONS OF NORMAL USE:

The sources are designed for use in a medical or commercial pharmacy environment and are not expected to experience extreme environmental factors. The sources are intended for use as reference standards to check the response of dose calibrators used to measure research, diagnostic, and therapeutic radiopharmaceuticals. The expected useful life of the Co-57 sources will be approximately 2 years. The manufacturer expects that the working life of the Cs-137 and Ba-133 sources will be at least 5 years.

PROTOTYPE TESTING:

A prototype BM06-57 source was constructed and tested in accordance with ANSI/HPS N43.6-1997 "Sealed Radioactive Sources - Classification" and achieved a sealed source classification of ANSI 97C22312. Only a prototype BM06-57 was tested because the maximum activity of this model is significantly higher than the other models and a failure of the source that would release radioactive material would be more readily detected. There is no difference in the construction materials or assembly methods for the different models.

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

NO.: TX-1153-S-102-S

DATE: October 22, 2002

PAGE 3 OF 5

DEVICE TYPE: Sealed source

EXTERNAL RADIATION LEVELS:

Maximum radiation levels for these sources are as follows:

Model BM06-57

Contact -	292.6 mrem/hr	(2.926 mSv)
5 cm -	68.3 mrem/hr	(683 μ Sv)
30 cm -	5.9 mrem/hr	(59 μ Sv)
100 cm -	1.2 mrem/hr	(12 μ Sv)

Model BM06-37

Contact -	45.2 mrem/hr	(452 μ Sv)
5 cm -	11.8 mrem/hr	(118 μ Sv)
30 cm -	1.6 mrem/hr	(16 μ Sv)
100 cm -	0.13 mrem/hr	(1.3 μ Sv)

Model BM06-33

Contact -	38.8 mrem/hr	(388 μ Sv)
5 cm -	10.3 mrem/hr	(103 μ Sv)
30 cm -	1.4 mrem/hr	(14 μ Sv)
100 cm -	0.09 mrem/hr	(0.9 μ Sv)

Note: Dose rates for model BM06-57 measured on prototype source manufactured by International Isotopes Idaho, Inc. and corrected to 15 mCi (555 MBq). Dose rates for Models BM06-33 and 37 measured on NIST traceable sources of similar construction and geometry and corrected to the maximum activities for these sources.

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 U. S. Nuclear Regulatory Commission. Periodic audits by International Isotopes Idaho, Inc. Quality Assurance staff will ensure that the program continues to perform at an acceptable level.

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

NO.: TX-1153-S-102-S

DATE: October 22, 2002

PAGE 4 OF 5

DEVICE TYPE: Sealed source

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The sources shall be distributed to persons specifically licensed by the NRC, an Agreement State or a Licensing State.
- Handling, storage, use, transfer and disposal to be determined by the licensing authority but should be, at a minimum, in accordance with the product information pamphlet provided by the distributor.
- 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 97C22312.
- The sources should be stored and transported in the manufacturer's shielded case.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the Texas Department of Health, Bureau of Radiation Control.
- International Isotopes Idaho, Inc. provides for design control, procurement control, process quality control, and final quality assurance pertaining to the manufacture of these sources. Distribution will be directly from the manufacturer's facility to the customer.
- Licensees in possession of sources that have decayed below their useful range of activities may contact International Isotopes Idaho, Inc. for instructions regarding return to the manufacturer. In most cases this will be as a limited quantity of radioactive material as specified in 49 CFR 173.421.

SAFETY ANALYSIS SUMMARY:

The BM06 Series sources are intended for use as quality control and reference sources for dose calibrators and are expected to maintain their integrity throughout the useful life of the source if not subjected to extreme conditions of handling or environment. Rupture of the encapsulating material would not reasonably be expected to allow dispersion of radioactive material due to the epoxy matrix with which the radioactive material is mixed.

The most severe accident scenario involving these sources would be a fire, and would most likely result in a release of radioactive material. Temperatures exceeding 200 degrees C would result in combustion of the resin in which the radioisotope is dispersed, as well as the plastic which constitutes the vial.

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

NO.: TX-1153-S-102-S

DATE: October 22, 2002

PAGE 5 OF 5

DEVICE TYPE: Sealed source

SAFETY ANALYSIS SUMMARY (Continued):

Based on review of the information and test data submitted for the BM06 Series sources and the references cited below, we conclude the these sources are acceptable for licensing purposes as described within this certificate.

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

REFERENCES:

The following supporting documents for the Series BM06 reference sources are hereby incorporated by reference and are made a part of this registry document.

- International Isotopes Idaho, Inc. application dated July 12, 2002 signed by John J. Miller, CHP, Radiation Safety Officer, with enclosures thereto.
- International Isotopes Idaho, Inc. letter dated September 18, 2002 signed by John J. Miller, CHP, Radiation Safety Officer, with enclosures thereto.
- International Isotopes Idaho, Inc. letter dated October 16, 2002 with enclosures thereto.

ISSUING AGENCY:

Texas Department of Health
Bureau of Radiation Control

Date: October 22, 2002

Reviewer:

J. Scott Kee
J. Scott Kee

Date: October 22, 2002

Concurrence:

David Foote
David Foote


REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: TX-1153-S-102-S

DATE: October 22, 2002

ATTACHMENT 1

SOURCE LABEL

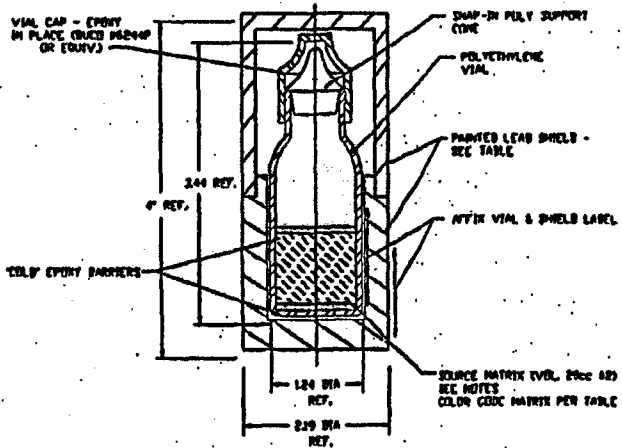
 CAUTION RADIOACTIVE MATERIAL	BM06-57	C0-57
	0.00 mCi	00.0 MBq
	Serial Number: BM0657XXX-XX	
	Reference Date: 3 Oct 02	
Bench/mark by RadQual		Manufactured and distributed by RadQual, LLC, Aurora, OH, by International Isotopes Idaho, Inc., Idaho Falls, ID

SAFETY EVALUATION OF DEVICE

DATE: October 22, 2002

ATTACHMENT 2

BM06 Series



ASSY. P/N	MODEL NO.	M/C LINE	COLOR CODE
-01	BH06-37	C6-37	RED
-02	BH06-33	BA-133	BLACK
-03	BH06-37	CS-137	GREEN

[illegible]

This drawing and the information contained within is proprietary to Southall, LLC and may not be used or reproduced without written authorization.

LICENSE REVIEW SHEET

1. NAME NEORX MANUFACTURING GROUP INC DBA: ATTN: 2. ADDRESS: 3100 JIM CRISTAL RD CITY: DENTON ZIP CODE: 76207260 STATE: TX					LOG No: 2005040442 3. LICENSE No: L05433 AMENDMENT No: N/A 4. EXP. DATE: 11/30/2006 REVIEWER: JKEE	
LOG IN DATE	INSP. CAT	USE CODE	# SITES	TOT	FEE PAID: DATE: BILLING No:	
04/05/2005	04			N		
ACTION TYPE DEVICE/SOURCE SHEET			COPIES TO REGION(S) (1-11)		FINANCIAL ASSURANCE REQ'D N EMERGENCY PLAN REQ'D N ADDITIONAL COMMENTS:	
F4 Transfer SS&D sheet to USNRC						
CHANGES TO BE MADE IN PERMIT:						
STOR-AGE / USE LOCATION						
13. RSO					T&E:	
12. USERS					T&E:	
5. ISOTOPES		6. FORM	7. ACTIVITY	8. USE		REGISTRY
SIGNED BY: John J. Miller, CHP, RSO		APPL/LTR DATED 3/31/05	LTR DATED	LTR DATED	LTR DATED	
SUMMARY OF CHANGES: International Isotopes, Inc. requests transfer of SS&D sheet TX-1153-S-102-S to USNRC. 2 copies of entire SS&D file (TX-1153-S-102-S), including 3.5" floppy disk from International Isotopes, and mail to Nuclear Regulatory Commission. <i>- copy of transmittal letter to SS&D folder?</i> <i>L05433-DK - 4/23</i>						
DEF LTR DATE: REVIEWER:			COMPLETED DATE: 4/25/05 /df REVIEWER: JSK			
COMMENT CODE 12	LOGOUT DATES & INITIALS FOR LETTERS ABOVE			FINAL LOGOUT DATE INITIALS: 4/27/05 + e		



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

EDUARDO J. SANCHEZ, M.D., M.P.H.
COMMISSIONER

1100 W. 49th Street • Austin, Texas 78756
1-888-963-7111 • <http://www.dshs.state.tx.us>

April 27, 2005

U.S. Nuclear Regulatory Commission
Attn: Mr. John Jankovich
T-8F3
Washington, D.C. 20555

RE: Registry Sheet TX-1153-S-102-S

Dear Mr. Jankovich,

International Isotopes Inc. has requested transfer of the Registry of Radioactive Sealed Sources and Devices Safety Evaluation of Source No. TX-1153-S-102-S to the U. S. Nuclear Regulatory Commission. In response to this request and upon our understanding that this transfer is agreeable to the Commission we are forwarding two (2) copies of the complete file to your office. We confirm that this office will issue no further amendments to this Safety Evaluation.

If I may be of further assistance concerning the transfer of this document to your offices please contact me at (512) 834-6688 ext. 2212; or by electronic mail at scott.kee@tdh.state.tx.us.

Sincerely,

A handwritten signature in dark ink, appearing to read "J. Scott Kee".

J. Scott Kee, Chief
Medical and Academic Licensing Program
Radiation Safety Licensing Branch

Enclosures: a/s

bcc:file

cc: Mr. J. J. Miller, CHP
Radiation Safety Officer
International Isotopes, Inc.
4137 Commerce Circle
Idaho Falls, Idaho 83401



International Isotopes Inc.
& International Isotopes Idaho Inc.

LQ5433

(-) SS + K sheet

te

Scott

TX-1153-S-102-S

Log# 2005-04-0442

RECEIVED

APR 04 2005

DSHS-RADIATION SAFETY

March 31, 2005

Mr. Scott Kee
Division of Licensing, Registration and Standards
Bureau of Radiation Control, Texas Department of Health
1100 West 49th Street
Austin, Texas 78756-3189

Subject: Transfer Sealed Source & Device Certificate TX-1153-S-102-S

Dear Mr. Kee,

Could you please transfer Sealed Source & Device Certificate TX-1153-S-102-S, from Texas Bureau of Radiological Control to the U.S. Nuclear Regulatory Commission.

Please contact me by phone at (208) 524-5300 or by email at jjmiller@intisoid.com should you have any questions regarding this request.

Sincerely,

John J. Miller, CHP
Radiation Safety Officer

cc:

J. J. Miller file (JJM-2005-05)

John Jankovich
Mail Stop 8 F5
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

LICENSE REVIEW SHEET

1. NAME NEORX MANUFACTURING GROUP INC DEA: ATTN: 2. ADDRESS 3100 JIM CHRISTAL RD CITY DENTON ZIP CODE 76207260 STATE TX					LOG No: 2003090043 3. LICENSE No: L05433 AMENDMENT No: 4. EXP. DATE: 11/30/2008 REVIEWER: JKEE	
LOG IN DATE 09/02/2003	INSP. CAT 04	USE CODE	# SITES	TOT Y - N	FEE PAID: DATE: BILLING No:	
ACTION TYPE DEVICE/SOURCE SHEET		COPIES TO REGION(S) (1-11):			FINANCIAL ASSURANCE REQ'D Y-N EMERGENCY PLAN REQ'D Y-N ADDITIONAL COMMENTS: <div style="text-align: right; padding-right: 20px;"> <i>Please fax to:</i> <i>John J. Miller, C.H.P.</i> <i>(208) 524-1411</i> </div>	
5. CHANGES TO BE MADE IN PERMIT: (▲) sealed source evaluation						
STORAGE / USE LOCATION						
11. RSO T&E:						
12. USERS T&E:						
5. ISOTOPES	6. FORM	7. ACTIVITY	8. USE		REGISTRY	
SIGNED BY: John J. Miller, CHP, Corp. RSO		APPL/LTR DATED 8/20/03	LTR DATED 11/27/03	LTR DATED	LTR DATED	
SUMMARY OF CHANGES: (▲) Sealed source evaluation # TX-1153-S-102-S to add new sources.						
DEF LTR DATE:			COMPLETED DATE: 12/10/03			
REVIEWER:			REVIEWER: JSK <i>WJM</i>			
COMMENT CODE 12	LOGOUT DATES & INITIALS FOR LETTERS ABOVE			FINAL LOGOUT DATE 12/10/03 INITIALS: /s/		



International Isotopes Inc.
(Including International Isotopes Idaho Inc. subsidiary)

FAX**RECEIVED
TDH****DEC 10 2003****BUREAU OF
RADIATION CONTROL**

To: Scott Kee
Fax No.: (512) 834-6690
Pages: 1 including cover
Date: 12/09/03
From: John Miller
Subject: Request to Fax copy of Source Safety Evaluation

Scott,

Could you please fax me a copy of the Sealed Source Safety Evaluation, TX-1153-S-102-S, as amended before you send via mail.

Thank You,

John J. Miller CHP
Radiation Safety Officer
International Isotopes Idaho, Inc.
4137 Commerce Circle
Idaho Falls, ID 83401

Phone: 208.524.5300
Fax: 208.524.1411

ProtectTexas™

Texas Department of Health

Eduardo J. Sanchez, M.D., M.P.H.
Commissioner of Health

1100 West 49th Street
Austin, Texas 78756-3199

Bureau of Radiation Control
(512) 834-6688

Ben Delgado
Chief Operating Officer

Nick Curry, M.D., M.P.H.
Executive Deputy Commissioner

December 10, 2003

U.S. Nuclear Regulatory Commission
Attn: Ms. Tracy Kime
Source Containment and Devices Branch
Office of Nuclear Material Safety
and Safeguards
Document Control Desk
P1-37
Washington, D.C. 20555

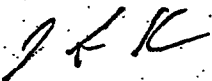
RE: Registry Sheet TX-1153-S-102-S

Dear Ms. Kime,

Enclosed is the Safety Evaluation of Source sheet TX-1153-S-102-S for International Isotopes Idaho, Inc. This sheet is issued to document amendment to the safety evaluation of sealed sources manufactured by this company. We would appreciate you distributing copies of this sheet to the other State Programs and NRC Regions, as appropriate.

Thank you for your cooperation and efforts.

Sincerely,



J. Scott Kee, Chief
Medical and Academic Licensing Program
Division of Licensing, Registration
and Standards
Bureau of Radiation Control
Texas Department of Health

bcc: File
JSK:sk



International Isotopes Inc.
& International Isotopes Idaho Inc.

November 27, 2003

Mr. Scott Kee
 Division of Licensing, Registration and Standards
 Bureau of Radiation Control
 Texas Department of Health
 1100 West 49th Street
 Austin, Texas 78756-3189

Subject: Device Safety Evaluation No. TX-1153-S-102-S

Dear Mr. Kee,

This letter provides the dose rates which would be associated with Source Models BM06-22 (Na-22 Dose Calibrator Source), BM06-60 (Co-60 Dose Calibrator Source) and BM06-68 (Ge-68 Dose Calibrator Source) at the maximum respective activities. Since a linear relationship exists between dose rate and activity, the dose rates associated with the maximum activities has been extrapolated from the dose rates submitted on August 20, 2003 summarized in the table below.

Distance	BM06-68 ⁽¹⁾ (201 uCi)	BM06-22 ⁽²⁾ (50 uCi)	BM06-60 ⁽³⁾ (50 uCi)
Dose rates in mrem/hr			
Contact	88	47	80
5 cm	15	7.8	15
30 cm	1.2	0.6	0.5
100 cm	0.15	0.06	0.1
Notes			
1. Dose rate measured on prototype manufactured by International Isotopes			
2. Modeled radiation dose rate profile, MicroShield v 5.03			
3. Dose rate measured on NIST traceable source of similar geometry at 37.7 uCi, measured dose rates corrected to nominal activity of 50 uCi.			

Extrapolated dose rates associated with the maximum activities are as follows.

Distance	BM06-68 ⁽¹⁾ (500 uCi)	BM06-22 ⁽²⁾ (500 uCi)	BM06-60 ⁽³⁾ (100 uCi)
Dose rates in mrem/hr			
Contact	218.9	470	160
5 cm	37.3	78	30
30 cm	3.0	6	1
100 cm	0.4	0.6	0.2

4137 Commerce Circle, Idaho Falls, Idaho 83401
 Phone: 208-524-5300, 800-699-3108 Fax: 208-524-1411
 Website: www.intisoid.com

November 27, 2003

Mr. Scott Kee

Page 2 of 2

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

cc:

J. J. Miller File. JJM-2003-14



International Isotopes Inc.
& International Isotopes Idaho Inc.

August 20, 2003

Mr. David Fogle ^{SK}
Division of Licensing, Registration and Standards
Bureau of Radiation Control
Texas Department of Health
1100 West 49th Street
Austin, Texas 78756-3189

RECEIVED
TDH

AUG 25 2003

BUREAU OF
RADIATION CONTROL

Subject: Device Safety Evaluation No. TX-1153-S-102-S

Dear Mr. Fogle:

Please amend the above referenced safety evaluation to include Models BM06-22 (Na-22 Dose Calibrator Source), BM06-60 (Co-60 Dose Calibrator Source) and BM06-68 (Ge-68 Dose Calibrator Source).

The new models will be identical in size, construction, manufacturing and labeling as the previously approved models. As this is the case, additional testing of the sources is not deemed necessary. Nominal and maximum activities for the new Models are listed in the table below:

	BM06-68	BM06-22	BM06-60
Nominal Activity	0.2 mCi	0.2 mCi	0.05 mCi
Maximum Activity	0.5 mCi	0.5 mCi	0.1 mCi
Useful Life	2 years	5 years	5 years

Measured and calculated radiation profiles are included in the table below.

Distance	BM06-68 ⁽¹⁾ (201 uCi)	BM06-22 ⁽²⁾ (50 uCi)	BM06-60 ⁽³⁾ (50 uCi)
Contact	88 mrem/hr	47 mrem/hr	80 mrem/hr
5 cm	15 mrem/hr	7.8 mrem/hr	15 mrem/hr
30 cm	1.2 mrem/hr	0.6 mrem/hr	0.5 mrem/hr
100 cm	0.15 mrem/hr	0.06 mrem/hr	0.1 mrem/hr
Notes			
1. Dose rate measured on prototype manufactured by International Isotopes			
2. Modeled radiation dose rate profile, MicroShield v 5.03			
3. Dose rate measured on NIST traceable source of similar geometry at 37.7 uCi, measured dose rates corrected to nominal activity of 50 uCi.			

September 15, 2003


David Fogle

Page 2 of 2

A revision to Drawing B004001 to include the new models, nuclides and color codes is attached with this letter for inclusion in the Sealed Source and Devices Safety Evaluation. An electronic copy in *.DOC format is enclosed.

Thank you for evaluating this amendment request. Should you have any questions, please contact me by phone at (208) 524-5300 or by email at jjmiller@intisoid.com.

Sincerely,

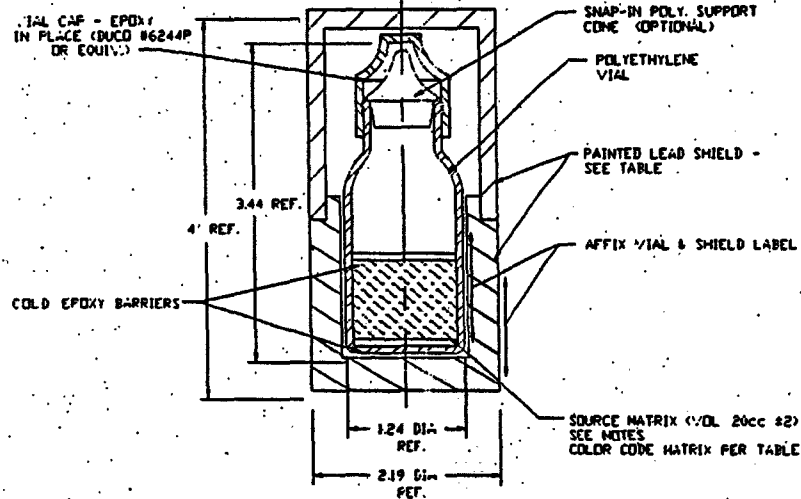
A handwritten signature in black ink, appearing to read 'JJM', followed by a long horizontal line extending to the right.

John J. Miller, CHP
Radiation Safety Officer

Enclosures

cc: J. J. Miller Letter File (JJM-2003-09)

Attachment 1
August 20, 2003
Mr. David Fogle



STANDARD MODEL TABLE			
ASSEMBLY PART	MODEL NO.	NUCLIDE	COLOR CODE
-01	BH06-22	Na-22	YELLOW
-02	BH06-60	Co-60	BLUE
-03	BH06-37	Cs-137	GREEN
-04	BH06-33	Bi-133	BLK
-05	BH06-57	Co-57	RED
-06	BH06-68	Ge-68	WHITE

REVISIONS			
REV.	REV. NO.	DESCRIPTION	DATE
		FIRST ISSUE	

NOTES

- SOURCE ACTIVITY CONSISTS OF RADIOACTIVE DISPERSED UNIFORMLY IN A HIGH IMPACT EPOXY RESIN RESIN MAY BE COLOR CODED PER TABLE USING EPOXY COLOR PASTE FOR STYCAST EPOXY OR EQUIV.
- PRODUCT NOMINAL ACTIVITY SHALL BE REFERENCED TO LABEL DATE. NOMINAL ACTIVITY TOLERANCE SHALL NOT BE $> +20\%$ NOR $< -10\%$ AT TIME OF SHIPMENT.
- NUCLIDE CALIBRATION SHALL BE RADIOACTIVITY CONTENT DETERMINED BY IONIZATION CHAMBER MEASUREMENT, WITH RANDOM ERRORS COMPUTED AT THE 99% CONFIDENCE LEVEL. OVERALL ERRORS OF CALIBRATION SHALL BE $\pm 5\%$. MAXIMUM MEASUREMENT SYSTEM STANDARDIZATION SHALL BE NIST. TRACEABLE.
- RADIOACTIVITY TO MEET RADIOACTIVE SPECIFICATIONS AT TIME OF CALIBRATION, PARTICULARLY CO-57 $< 99.9\%$ CO-57 EXCLUSIVE OF $< 0.30\%$ CO-56, CO-58.
- REPORT THE ACTIVITY CALIBRATIONS USING THE FORMAT REQUIRED FOR EACH MODEL AS REQUIRED IN MFG. SOP.
- CONTAMINATION/LEAKAGE TESTING OF EACH SOURCE SHALL BE PER PROCEDURE FOR CONTAM/LEAK. TEST OF REF. SOURCES: LIMIT 5×10^{-4} UCL.
- CERTIFICATES, INSERTS & LABELING PER SOP.
- SOURCE SET NO. BH06-90 CONSISTS OF ONE EACH OF BH06-57 (CO-57), BH06-37 (CS-137) AND BH06-33 (BI-133).
- THE PRODUCTS SHOWN IN THIS DRAWING ARE CLASS I MEDICAL AND MEET THE ANSI N436-1997 PERFORMANCE CLASSIFICATION OF C22212 FOR CALIBRATION SOURCES.

REV. NO.	REV. NO.	DATE OF IDENTIFYING NO.	DESCRIPTION	CTV
RADQUAL, LLC				
TOLERANCE		DATE: 8/14/03		
JUL 1: 200		CALIBRATION "E" VIAL SOURCES		
JUL 2		BH06-22 (Na-22), BH06-33 (Bi-133), BH06-37 (Cs-137), BH06-57 (Co-57), BH06-68 (Ge-68)		
PART: 1-14		REV. NO. 8004001 Rev 1		
ANAL: 2		REV.		
SCALE: 1 = 4		Sheet 1 of 1		

This drawing and the information contained within is proprietary to Radqual, LLC and may not be used or reproduced without written authorization.

MANU./DIST.: International Isotopes Idaho Inc.

REGISTRATION

#:

TX1153S102SREFERENCES: L5433LOG NO.: 2002-08-0002

Log Date:

SOURCE INFORMATION SOUGHT	✓/D - OK/DEF		COMMENTS
	1st rev.	2nd rev.	
Applicant's name and address	✓	DT✓	NRC will not do non-byproduct ssd Not custom use.
Manufacturer's/distributor's name and address	✓	DT✓	
Custom user's name and address	✓	DT✓	
Model number	✓	DT✓	
Type (from Reg. Guide 2.2)	✓	DT✓	
User's authority to possess (specific, general, both, exempt)	N/A	DT✓	Accelerator produced material in NRC jurisdiction.
Radionuclides, activity (max w/% error), form	✓	DT✓	
DESCRIPTION			
If applicant is requesting to register more than one source on a certificate, are designs similar enough to do so?	✓	DT✓	- plastic vials!
Source design with complete engineering drawings (dimensions, tolerances, list of materials)	✓	DT✓	
Assembly methods (welds, etc.) Verify integrity?	✓	DT✓	
Is source ANSI classification sufficient: Radiography - Unprotected - 43515 Radiography - In Device - 43313 Medical - Radiography - 32312 Medical - γ Teletherapy - 53524 γ Gauges - Unprotected - 43333 γ Gauges - In Device - 43232 β Gauges, Low Energy γ Gauges, or X-ray fluor - 33222 Oil Well Logging - 56522 Portable Moist/Density - 43333 Neutron Applications - 43323 Calib. Sources > 30 μCi - 22212 γ Irradiators (IV) - 53424 γ Irradiators (II, III) - 43424 γ Irradiators (I) - 43323 Chromatography - 32211 Static Eliminators - 22222 Smoke Detectors - 32222 (from ANS/HPS N43.6-1997)	✓	DT✓	
Corrosion between unlike materials (aluminum & steel, depleted uranium & steel, etc.) see "Corrosion" information	N/A	DT✓	
Well logging sources must be nondis- persible and nonsoluble.	N/A	DT✓	
See "ANSI and Other Standards" list for references for particular source designs (radiography, brachytherapy, etc.)	N/A	DT✓	

Rev. 09/2000

MORE INFO SENT:

INITIALS:

Faxed to John Miller Page 1
REVIEW COMPLETED: 10/11/02
10/22/02

INITIALS: J & K PHM

COMMENT CODE	DATE & INITIALS	LOGOUT DATE	MAPPER UPDATE
-06, 12	8/9/02-JSK-9/9/02-TC	10-21-02 JSK	10-21-02 JSK

Log Date:

SOURCE INFORMATION SOUGHT	✓/D - OK/DEF		COMMENTS
	1st rev.	2nd rev.	
LABELING			
Copy of label?	D	DTV	Need copy of label - Label received 9/19/02
Materials, dimensions, colors [note on certificate if labeling is exempt from the color requirements of §289.202(z)(1)]	D	DTV	Need dimensions and materials.
Permanent attachment and location(s) - visible to users?	D	DTV	
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)	D	DTV	Need mdl.#, S/N, isotope, activity, mfr., assay date.
CONDITIONS OF USE			
Expected life of the source (years, operations)	D	DTV	2 yrs. - 5 yrs
Maximum allowable temperature, vibration, shock, corrosion, etc. (during operation and accidental)	✓	DTV	ambient temp. in cond
How the source will be used	✓	DTV	
PROTOTYPE TESTING			
Test methods & conditions (for source)	✓	DTV	
Test results?	✓	DTV	
Years of use (incidents, failures, etc.)	N/A	DTV	
Similarities to other sources if they are used as basis	N/A	DTV	
QUALITY ASSURANCE			
Materials, subassemblies, services. Assembly methods (welding, etc.)	✓	DTV	- QA NRC approved
Dimensions and tolerances	✓	DTV	
Activity, radiation levels, leak tests	✓	DTV	
QA manual	✓	DTV	See file #1153S101S
RADIATION PROFILES			
Survey instrument used (type, window, sensitivity, etc.)	✓	DTV	
Conditions of survey?	D	DTV	Identify factors affecting measurements. 9/19/02 ltr.
Distance from source/surface (ANSI 538)	✓	DTV	
Shutter ON & OFF/source shielded	N/A	DTV	
Scatter (product in beam)	N/A	DTV	
Guards and shields in place	N/A	DTV	
γ surveys meet inv ² law? non-γ surveys?	✓	DTV	

REFERENCES: L5433LOG NO.: 2002-08-0002

Log Date:

SOURCE INFORMATION SOUGHT	✓/D - OK/DEF 1st rev. 2nd rev.	COMMENTS
ACCOMPANYING DOCUMENTATION		
Leak test results and radiation surveys	✓ <i>OK</i>	Confirm proper transportation documents supplied. <i>9/9/02 H</i>
Transportation documents	D <i>OK</i>	
Use, maintenance, calibration, leak test, damage/failure, specific warnings, and radiation survey instructions if applicable	✓ <i>OK</i>	
For GL distribution verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations	N/A <i>OK</i>	
FOREIGN MANUFACTURERS		
Drop ship?		This section of checklist not applicable.
Leak tests and radiation surveys?	<i>OK</i>	
QA in the U.S.A.?		
FOR GL SOURCES		
Sources are calibration, reference or stabilization sources containing Am-241, Pu, or Ra-226. [§289.251(h)(4)(A)]		This section of checklist not applicable.
How does applicant determine that customer holds a specific license? [§289.251(h)(4)(A)(i) or (ii)]		
Does GL label contain the following information?: [40.52(f)(3)(ii)(a) or (b)] The receipt, possession, use, and transfer of this sealed source, Model _____, Serial No. _____, are subject to a general license and the regulations of the Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label. CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS (AMERICIUM-241) OR (PLUTONIUM-238) OR (PLUTONIUM-239). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.	<i>OK</i>	
_____ Name of Manufacturer or Importer or The receipt, possession, use, and transfer of this sealed source, Model _____, Serial No. _____, are subject to a general license and the regulations of any Licensing State. Do not remove this label. CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE. _____ Name of Manufacturer or Importer		



Texas Department of Health

Eduardo J. Sanchez, M.D., M.P.H.
Commissioner of Health

1100 West 49th Street
Austin, Texas 78756-3189
1-888-963-7111

Radiation Control
(512) 834-6688

Gary R. Bego
Chief Operating Officer

Charles E. Bell, M.D.
Executive Deputy Commissioner

October 22, 2002

U.S. Nuclear Regulatory Commission
Attn: Ms. Tracy Kime
Source Containment and Devices Branch
Office of Nuclear Material Safety
and Safeguards
Document Control Desk
P1-37
Washington, D.C. 20555

RE: Registry Sheet TX-1153-S-102-S

Dear Ms. Kime,

Enclosed is the Safety Evaluation of Source sheet TX-1153-S-102-S for International Isotopes Idaho, Inc. This sheet is issued to document the safety evaluation of a new source model to be manufactured by this company. We would appreciate you distributing copies of this sheet to the other State Programs and NRC Regions, as appropriate.

Thank you for your cooperation and efforts.

Sincerely,

J. Scott Kee, Chief
Medical and Academic Licensing
Division of Licensing, Registration
and Standards
Bureau of Radiation Control

bcc: File

Enclosure: a/s

I⁴

International Isotopes Idaho Inc.
A Subsidiary of International Isotopes Inc.

FAX

RECEIVED
TDH
OCT 16 2002
BUREAU
RADIATION CONTROL

To: Scott Key
Fax No.: (512) 834-6690
Pages: 7 including cover
Date: 10/16/02
From: John Miller
Subject: Source Application Log No. 2002-08-0002

Scott,

The ANSI tests performed to achieve a classification of 97C22312 are as follows:

Temperature Test: Source maintained at -40°C for 20 minutes and then $+80^{\circ}\text{C}$ for 60 minutes
External Pressure Test: 25kN/m^2 abs (3.6 lbf/in^2) to atmosphere
Impact Test: 200 grams dropped from 1 meter
Vibration Test: Not Performed
Puncture Test: 1 gram from 1 meter.

After each test the source was inspected and a wipe test was performed.

The actual test equipment utilized and results of the wipe test is included in the procedure accompanying this cover sheet.

If you have any other questions please do not hesitate to call me at 208 524-5300.


Thank You,

John J. Miller CHP
Radiation Safety Officer
International Isotopes Idaho, Inc.
4137 Commerce Circle
Idaho Falls, ID 83401

I4



International Isotopes Idaho Inc.
A Subsidiary of International Isotopes Inc.

TITLE: Sealed Source Testing for Dose Calibrators		Number: DC-Test	Effective Date: 07/08/02
PRI: Steve Leflin		Page: Page 1 of 6	Superseded Date: None
PRI Signature and Date: Not required - One time use procedure	Document Control Signature and Date: Not required - One time use procedure	Quality Assurance Signature and Date:  7/8/02	

1.0 Purpose

1.1 To provide a standardized method of leak testing Dose Calibrators.

2.0 Potential Hazards

2.1 The potential of radiation exposure and/or contamination exists during the performance of this procedure. Dosimetry should be worn and caution exercised while performing this procedure. This procedure is to be performed by trained operators who must take appropriate steps to minimize radiation exposure to themselves and surrounding personnel and must follow all radiation and safety procedures.

3.0 Applicability and Limitations

3.1 This procedure applies to sealed source testing Dose Calibrators only.

4.0 Definitions

4.1 None

5.0 Responsibilities

5.1 I4 Quality – Oversee the performance of this procedure and review the testing results.

5.2 I4 Technician – Assist with the performance of this procedure as required.

6.0 Equipment and Materials

6.1 One Dose Calibrator, fabricated per the draft manufacturing procedure.

6.2 Pressure chamber.

6.3 Oven

6.4 Dry Ice

6.5 Antifreeze Solution

6.6 Testing Hammer #1, 200 grams (7 ounces), used for the impact test

14



International Isotopes Idaho Inc.
A Subsidiary of International Isotopes Inc.

TITLE:	Number:	Effective Date:
Sealed Source Testing for Dose Calibrators	DC-Test	07/08/02
	Page:	Superseded Date:
	2 of 6	None

6.7 Testing Hammer #2, 1 gram, used for the puncture test

6.8 Steel plate, used as backing for the impact and puncture tests

7.0 Procedure

7.1 Preparation and Staging for Dose Calibrator Testing

7.1.1 Verify that the Dose calibrator are complete and have been fabricated per the appropriate manufacturing procedure.

Verification performed by

Date

7/9/02

7.1.2 Stage the required materials and equipment in the testing area(s).

Materials staged by

Date

7/9/02

7.2 Impact Tests

7.2.1 Place the steel plate on the floor where the impact testing will be performed.

7.2.2 Place the Dose Calibrator on the steel plate.

7.2.3 Position the 200 gram (7 ounce) testing hammer at least 1 meter above the Dose Calibrator

7.2.4 Drop the testing hammer on the Dose Calibrator.

7.2.5 Perform a dry wipe test on the source as follows:

7.2.5.1 Wipe all external surfaces of the Dose Calibrator with a piece of dry filter paper.

7.2.5.2 Measure the activity on the filter paper and record on the data page at the end of this procedure.

7.3 Puncture Tests

7.3.1 Place the steel plate on the floor where the puncture testing will be performed.

7.3.2 Place the Dose Calibrator on the steel plate with the top.

I4



International Isotopes Idaho Inc.
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TITLE:	Number:	Effective Date:
Sealed Source Testing for Dose Calibrators	DC-Test	07/08/02
	Page:	Superseded Date:
	3 of 6	None

7.3.3 Position the 1 gram testing hammer at least 1 meter above Dose Calibrator with the pin down.

7.3.4 Drop the testing hammer on the dose calibrator.

7.3.5 Perform a dry wipe test as follows:

7.3.5.1 Wipe all external surfaces of the Dose Calibrator with a piece of dry filter paper.

7.3.5.2 Measure the activity on the filter paper and record on the data sheet at the end of this procedure

7.4 External Pressure Test

7.4.1 Place the Dose Calibrator in the testing chamber.

7.4.2 Seal the Test Chamber.

7.4.3 Draw a vacuum on the test chamber of at least 3.6 psiv (7.4 in Hg).

7.4.4 Hold the vacuum for five minutes.

7.4.5 Vent the chamber and allow it to return to atmospheric pressure.

7.4.6 Draw a vacuum on the test chamber of at least 3.6 psiv (7.4 in Hg).

7.4.7 Hold the vacuum for five minutes.

7.4.8 Vent the chamber and allow it to return to atmospheric pressure.

7.4.9 Remove the Dose Calibrator from the testing chamber and perform a dry wipe test as follows:

7.4.9.1 Wipe all external surfaces of the Dose Calibrators with a piece of dry filter paper.

7.4.9.2 Measure the activity on the filter paper and record on the data page at the end this procedure.

7.5 Low Temperature Test

7.5.1 Prepare a bath of antifreeze solution sufficient to immerse the Dose Calibrator.

I4

**International Isotopes Idaho Inc.***A Subsidiary of International Isotopes Inc.*

TITLE:	Number:	Effective Date:
Sealed Source Testing for Dose Calibrators	DC-Test	07/08/02
	Page:	Superseded Date:
	4 of 6	None

7.5.2 Seal the Dose Calibrator in plastic.

7.5.3 Place about 2 pounds of dry ice into the antifreeze bath.

7.5.4 Place the Dose Calibrator into the antifreeze bath.

7.5.5 Monitor the temperature of the bath.

7.5.6 When the temperature of the bath -40°C (-40°F), record the start time on the data page at the end of this procedure.

7.5.7 Monitor the bath temperature for at least twenty minutes.

NOTE: The bath temperature must remain below -40°C (-40°F) for at least Twenty minutes.

7.5.8 Record the stop time on the data page at the end of this procedure.

7.5.9 Remove the Dose Calibrator from the bath and perform a dry wipe test as follows:

7.5.9.1 Wipe all external surfaces of the Dose Calibrator with a piece of dry filter paper.

7.5.9.2 Measure the activity on the filter paper and record on the data page at the end of this procedure.

7.6 High Temperature Test

7.6.1 Pre-heat the oven to 80°C (176°F).

7.6.2 Place the Dose Calibrator in the testing oven.

7.6.3 When the oven temperature reaches 80°C (176°F), record the start time on the data page at the end of this procedure.

7.6.4 Monitor the oven temperature for at least sixty minutes.

NOTE: The oven temperature must remain above 80°C (176°F) for at least sixty minutes.

7.6.5 Record the stop time on the data page .

7.6.6 Remove the Dose Calibrator from the oven and perform a dry wipe test as follows:

I⁴

International Isotopes Idaho Inc.
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TITLE:	Number:	Effective Date:
Sealed Source Testing for Dose Calibrators	DC-Test	07/08/02
	Page:	Superseded Date:
	5 of 6	None

7.6.6.1 Wipe all external surfaces of the Dose Calibrator with a piece of dry filter paper.

7.6.6.2 Measure the activity on the filter paper and record on the data page.

7.7 Data Analysis

7.7.1 I4 Quality review the data collected and recorded on the Data Page.

Note: The Dose Calibrators shall pass as leak free if the measured activity on each of the swipes is less than 5 nCi.

7.8 Conclusion

7.8.1

	Pass	Fail	Data Analysis Performed By
Dose Calibrator	X		O. Q. 7/9/02

8.0 References

8.1 Drawings: the most current revision is to be used.

8.1.1 Calibration "E" Vial Sources

I⁴


International Isotopes Idaho Inc.
A Subsidiary of International Isotopes Inc.

TITLE:	Number:	Effective Date:
Sealed Source Testing for Dose Calibrators	DC-Test	07/08/02
	Page:	Superseded Date:
	6 of 6	None

Test	Dose Calibrator Testing Data Page			
Low Temp.	Start Time	Stop Time	Swipe Results	Recorded By
	1240	1300	58cpm < MDA	O. Linn 7/9/02
High Temp	Start Time	Stop Time	Swipe Results	Recorded By
	1125	1230	63cpm < MDA	O. Linn 7/9/02
External Pressure	Start Time	Stop Time	Swipe Results	Recorded By
	1105	1120	60cpm < MDA	O. Linn 7/9/02
Impact	Start Time	Stop Time	Swipe Results	Recorded By
	1050	1055	59cpm < MDA	O. Linn 7/9/02
Puncture	Start Time	Stop Time	Swipe Results	Recorded By
	1055	1100	49cpm < MDA	O. Linn 7/9/02

Instrument used is a Ludlum 2000, Serial # 99223.
 Calibration Due Date is 7/31/02.
 Ludlum 2000 efficiency is 22.6%.
 MDA = 137 pCi
 Background = 66 cpm



International Isotopes Idaho Inc.

A Subsidiary of International Isotopes Inc.

September 18, 2002

Mr. James Scott Kee
Medical and Academic Licensing
Division of Licensing, Registration and Standards
Bureau of Radiation Control
Texas Department of Health
1100 West 49th Street
Austin, Texas 78756-3189

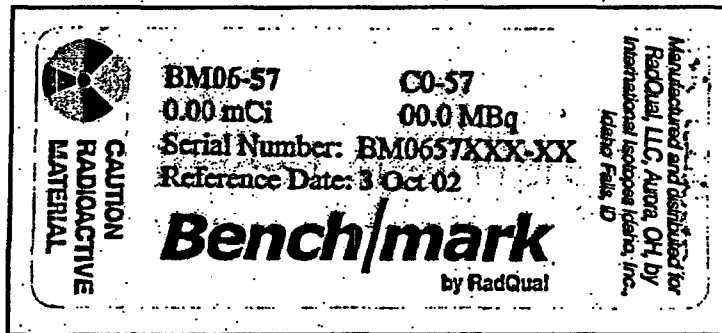
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TDH
SEP 19 2002
BUREAU OF
RADIATION CONTROL

Re: Response to Log No. 2002-08-0002

Dear Mr. Kee:

I have received your letter requesting additional information to support your evaluation of the Application for Safety Review, IntIsolD 071202, which I submitted July 12, 2002. This letter, provided in duplicate, provides the information requested by Log Number 2002-08-0002.

1. Please provide a copy of the label to be placed on the source.



The label above will be used for the sealed sources. The information included on this example has been provided for display purposes only and will vary with model number, isotope and activity.

2. *Please provide the dimensions of the label and identify the materials that go into construction of the label.*

The label on the preceding page is 3.5 inches long and 1.5 inches high. The Label is a Tire Label with TL-11 adhesive and TA Clear Laminate. The Model Number, Serial Number, Isotope, Activity, and Reference Date are printed on a smaller transparent label that is affixed to the primary label.

3. *Identify how the label will be attached to the source and where it will be attached.*

In an effort to minimize worker extremity dose, the primary label will be placed around the body of the vial, approximately centered between the bottom and the neck of the vial before radioactivity is introduced to the source. After the source has been cured, final construction completed and assayed, the smaller transparent label containing the specific source information will be affixed the primary label. A clear laminate will then be placed over the completed label to prevent the label from wearing as a result of use.

4. *Please understand that the label must also contain information on the source model number, serial number, isotope, activity, the name of the manufacturer, and the assay date.*

The label as designed contains the required information.

5. *Please confirm the expected life of the source.*

The useful life of the Co-57 sources will be limited by half-life. It is expected that the source will perform adequately for 3 half-lives or about 2 years. The useful life of the Cs-137 and Ba-133 sources will be limiting by the legibility of the label. Great care has been taken to ensure the label will last as long as possible. It is expected that under normal conditions of use the expected life of these sources will be at least 5 years.

6. *Please identify any factors which may have affected the measurements given in the radiation profile for the prototype source.*

There have been no factors identified which may have affected the measurements provided in the radiation profile. Radiation measurements were obtained in an area of low background utilizing radiation detection instruments that are calibrated annually and performance tested daily. Each source was measured one at a time so that radiation from the other sources would not affect the results of the source being measured.

7. Please identify what shipping documents will be supplied with the sources.

The following documents will be included with each source:

1. A Certificate of Calibration Sheet which includes:
 - a. Source Model and Serial Number,
 - b. The Radioisotope and its physical properties, i.e. half-life, emission energies and intensities,
 - c. The physical description of the source,
 - d. The method of calibration and total uncertainty,
 - e. Radiation Protection recommendations,
 - f. The wipe test results,
 - g. Recommended leak test method.
2. A Shipper's Declaration of Dangerous Goods will be provided, as necessary in accordance with current Department of Transportation regulations. Experience has shown that 5 millicurie Co-57 evial sources, shipped in their leaded storage shield meet the requirements for excepted packages for limited quantities of Class 7 (radioactive) material in accordance with 49 CFR 173.421.

Sincerely,



John J. Miller, CHP
Radiation Safety Officer

cc: J. J. Miller file (JJM-2002-11)



Texas Department of Health

Eduardo J. Sanchez, M.D., M.P.H.
Commissioner of Health

1100 West 49th Street
Austin, Texas 78756-3189
1-888-963-7111

Radiation Control
(512) 834-6688

Gary R. Bego
Chief Operating Officer

Charles E. Bell, M.D.
Executive Deputy Commissioner

September 9, 2002

INTERNATIONAL ISOTOPES IDAHO INC
ATTN JOHN J MILLER CHP
4137 COMMERCE CIRCLE
IDAHO FALLS ID 83401

RE: Log No. 2002-08-0002

Dear Mr. Miller,

This office is currently reviewing a request dated July 12, 2002, for evaluation of a sealed source. Please note that the following information is necessary so that we may complete the review of this request.

1. Please provide a copy of the label to be placed on the sources.
2. Please provide the dimensions of the label and identify the materials that go into construction of the label.
3. Identify how the label will be attached to the source and where it will be attached.
4. Please understand that the label must also contain information on the source model number, serial number, isotope, activity, the name of the manufacturer, and the assay date.
5. Please confirm the expected life of the source.
6. Please identify any factors which may have affected the measurements given in the radiation profile for the prototype source.
7. Please identify what shipping documents will be supplied with the sources.

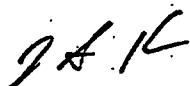
Mr. John J. Miller, CHP

Page 2 ✓

September 9, 2002

Upon receipt of two copies of the information specified above we will resume the processing of the request. Please respond within thirty (30) days of the date of this letter so that we may expedite the completion of this action. Please reference the above mentioned log number in your reply. If you have any questions concerning this transmittal, please contact me at (512) 834-6688 ext. 2212.

Sincerely,


J. Scott Kee, Acting Chief
Medical and Academic Licensing
Division of Licensing, Registration
and Standards
Bureau of Radiation Control

bcc: pending file L05433
JSK:sk

International Isotopes Idaho Inc.

A Subsidiary of International Isotopes Inc.

July 12, 2002

Mr. James Scott Kee
Medical and Academic Licensing
Division of Licensing, Registration and Standards
Bureau of Radiation Control
Texas Department of Health
1100 West 49th Street
Austin, Texas 78756-3189

RE: An Application for Safety Review, IntIsold 071202

Dear Mr. Kee:

Please accept this letter as a request for evaluation of three sealed sources for a single certificate in the Registry of Sealed Sources and Devices. Each is designed for use as a medical reference source and will contain up to 15 mCi (55 MBq) of cobalt-57 or 0.5 mCi (18.5 MBq) of cesium-137 or barium-133. Construction methods will be identical, except that matrix containing the radioisotope and the screw top caps for the polyethylene vials will be color coded so that the Source Models can be visually distinguished amongst one another.

An Application for Safety Review, prepared in accordance with Texas Department of Health Regulatory Guide 2.2, *Guide for Applications for Evaluation of Sealed Sources of Radioactive Material*, is enclosed, as is a check for the evaluation fee of \$3,614. Should you have any questions please contact me by email at jjmiller@intisoid.com or by phone at 208-524-5300. Thank you for your prompt attention to our request.

Sincerely,



John J. Miller, CHP
Radiation Safety Officer

Enclosures

cc: J. J. Miller file (JJM-2002-09)

70775/120
5067162
\$3614.00
7-26-02

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JUL 23 2002
BUREAU OF
RADIATION CONTROL

70775.120

Application for Safety Review
IntIsold 071202

SUMMARY DATA

Date: July 12, 2002

Sealed Source Type: Dose Calibrator, Gamma Emitting

Models: BM06-33
BM06-37
BM06-57

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

Other Company Involved:

RadQual, LLC
114 Barrington Town Square #124
Aurora, OH 44202
(Engineering/Design)

For further information, contact
Keith Allberg
President
(603) 224-3556

Isotope and Maximum Activity:

Model Number	Isotope	Nominal Activity	Maximum Activity
BM06-33	Ba-133	0.2 millicuries (7.4 Mbq)	0.5 millicuries (18.5 Mbq)
BM06-37	Cs-137	0.2 millicuries (7.4 Mbq)	0.5 millicuries (18.5 Mbq)
BM06-57	Co-57	5 millicuries (185 Mbq)	15 millicuries (555 Mbq)

Leak Test Frequency: 6 Months

Principal Use: W (Medical Reference Source)

Custom Source: No

DESCRIPTIVE DATA

Description:

These sources consist of the radioisotope in a chloride complex uniformly dispersed in high impact epoxy casting resin (Emerson & Cuming Stycast 1264 or equivalent, color coded to visually differentiate the radioisotopes), which is then cured in a 30 ml dose calibrator vial. The epoxy containing the dispersed radioactivity is sandwiched between a bottom and top layer of epoxy, which does not contain radioactivity. A rubber septum or equivalent is chemically welded into the neck of the vial and a color-coded (to visually differentiate the radioisotopes) screw top cap is chemically welded onto the vial so that disassembly without destruction of the vial is not possible. Each source is supplied in a shielded storage pig. Each source is approximately 1.25 inches in diameter and 3 inches in height.

Labeling:

Each source and storage pig is conspicuously labeled with the isotope and activity and bears the warning "CAUTION: RADIOACTIVE MATERIAL" as well as the trefoil radiation symbol in magenta on a yellow background along with the designer's name and logo. Safe handling instructions are included with the source. The radioactive content, in millicuries or microcuries and the date of manufacture, is shown, as well as model number and serial number.

Drawings:

Refer to Attachment 1.

Conditions Of Normal Use:

The sources are used as reference standards to check the response of radioisotope calibrators used to measure research, diagnostic, and therapeutic radioactive agents.

Limitations And/Or Other Considerations Of Use:

1. The sources shall be distributed to persons specifically licensed by the NRC, an Agreement State or a Licensing State.
2. Handling, storage, use, transfer and disposal to be determined by the licensing authority but should be, at a minimum, in accordance with the product information pamphlet provided by the distributor.
3. 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.
4. The sources shall not be subjected to conditions that exceed its ANSI/HPS N43.6-1997 classification, 97C22312.
5. The probable effect of severe environmental conditions, such as accidents and fire, would be minimal release of radioactivity since the radioisotope is incorporated into the cured epoxy matrix. Although the polyethylene container, even as it commenced to melt, would prevent dispersion of radioactivity, temperatures exceeding 200 degrees C would result in combustion of the resin in which the radioisotope is dispersed, as well as the plastic, which constitutes the vial.
6. This registration sheet and the information contained within the references shall not be changed without the written consent of the Texas Department of Health Bureau of Radiation Control.

Supporting Detail:

Refer to Attachment 2, I⁴ Procedure (Draft), I4-OP-041, *Manufacture of E-vials* for information pertaining to the method of manufacture.

HEALTH AND SAFETY DATA

Safety Analysis Summary:

Based on review of Models BM06-57, BM06-33, and BM06-37 and the information and test data cited below, we conclude that the sources are acceptable for licensing purposes. Furthermore, we conclude that all of the Models in the BM06 series would be expected to maintain their containment integrity for normal conditions of use and accidental conditions, which might occur during uses specified in this application.

Manufacturer's Safety Analysis of Sealed Source Review:

A prototype of one source (BM06-57, containing 15.38 mCi of Co-57) was constructed and subjected to four environmental tests as provided in ANSI/HPS N43.6-1997, Table 1

Classification of sealed-source performance tests, and achieved a classification of 97C22312 (Calibration Source). It should be noted that a prototype of Model BM06-57 was selected over the other Models because the maximum activity of the BM06-57 is significantly greater than that of the other models and therefore a failure would be more readily detected. Prototypes of Models BM06-37 and BM06-33 were not constructed and tested because the only difference between each source is the radioisotope and the color of the screw top cap and epoxy, differences that would not affect the results of the performance tests.

Maximum external radiation levels, reported in mrem/hr are as follows:

	Co-57 ⁽¹⁾ (15 mCi)	Cs-137 ⁽²⁾ (0.5 mCi)	Be-133 ⁽²⁾ (0.5 mCi)
On Contact	292.6	45.2	38.8
@ 5 cm	68.3	11.8	10.3
@ 30 cm	5.9	1.6	1.4
@ 100 cm	1.2	0.13	0.09
Notes: (1)	Dose rates measured on prototype source manufactured by I ⁴ corrected to 15 mCi		
(2)	Dose rates measured on NIST traceable sources of similar construction and geometry of nominal activity then corrected to maximum activity.		

Refer to Attachment 3, Radiation Profile Data Sheet.

These sources should be leak tested at intervals not to exceed 6 months when in use.

A Technical Data Sheet will be included with each source. This sheet will include Leak Test Results, Recommended Use and Storage, and Radiation Safety Recommendations. In addition, a Certificate of Calibration will be included that includes the Source Model and Serial Number, the Radioisotope and its physical properties, i.e. half-life, emission energies and intensities, the physical description of the source, method of calibration and total uncertainty.

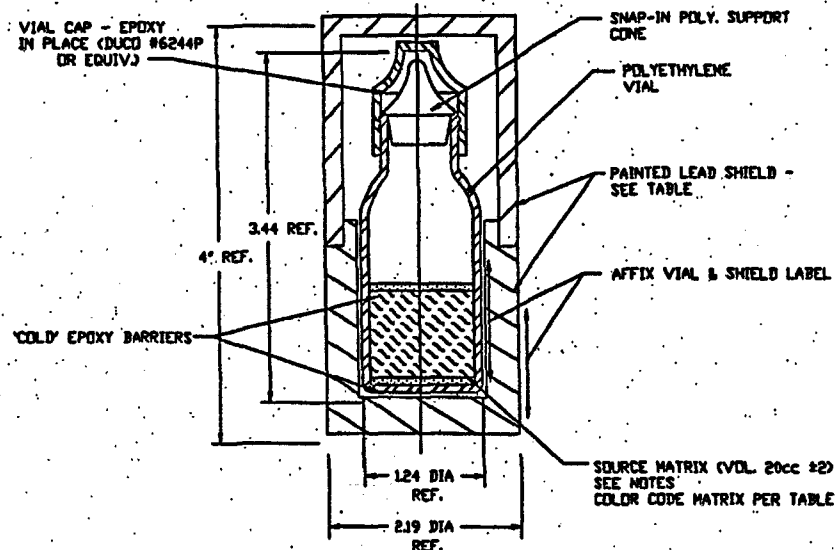
Manufacturing and Distribution Controls:

International Isotopes Idaho Inc (I⁴) provides for design control, procurement control, process quality control, and final quality assurance.

I⁴ maintains a quality assurance and quality control program, which has been deemed acceptable for licensing purposes by the Nuclear Regulatory Commission. Periodic audits by I⁴ Quality Assurance staff will ensure that the program continues to perform as intended.

Each source will be assayed at I⁴ using a dose calibrator that has been calibrated to a NIST traceable standard. No source will be distributed by I⁴ if it has not passed leak testing performed in accordance with 25 TAC 289.201(g) and ANSI/HPS N43.6-1997. Sources will only be transferred to authorized recipients.

Licensees in possession of sources that have decayed below their useful range of activities may contact the distributor for instructions regarding return to the manufacturer. In most cases this will be as limited quantity of radioactive material as specified in 49 CFR 173.421.



STANDARD MODEL TABLE			
ASSY. P/N	MODEL NO.	NUCLIDE	COLOR CODE
-01	BM06-57	Co-57	RED
-02	BM06-33	BA-133	BLACK
-03	BM06-37	CS-137	GREEN

REVISIONS				
REV.	REV. NO.	DESCRIPTION	BY	DATE

NOTES

1. SOURCE ACTIVITY CONSISTS OF RADIONUCLIDE DISPERSED UNIFORMLY IN A HIGH IMPACT EPOXY RESIN. RESIN MAYBE COLOR CODED PER TABLE USING EPOXY COLOR PASTE FOR STYCAST EPOXY OR EQUIV.
2. PRODUCT NOMINAL ACTIVITY SHALL BE REFERENCED TO LABEL DATE. NOMINAL ACTIVITY TOLERANCE SHALL NOT BE $\pm 20\%$ NOR $\pm 10\%$ AT TIME OF SHIPMENT.
3. NUCLIDE CALIBRATION SHALL BE RADIOACTIVITY CONTENT DETERMINED BY IONIZATION CHAMBER MEASUREMENT, WITH RANDOM ERRORS COMPUTED AT THE 95% CONFIDENCE LEVEL. OVERALL ERRORS OF CALIBRATION SHALL BE $\pm 5\%$. MAXIMUM MEASUREMENT SYSTEM STANDARDIZATION SHALL BE N.I.S.T. TRACEABLE.
4. RADIPURITY TO MEET RADIONUCLIDE SPECIFICATIONS AT TIME OF CALIBRATION. PARTICULARLY CO-57 $\leq 99.9\%$ CO-57 EXCLUSIVE OF (0.3% CO-56, CO-58).
5. REPORT THE ACTIVITY CALIBRATIONS USING THE FORMAT REQUIRED FOR EACH MODEL AS REQUIRED IN MFG. SDP XXXXXXXXXXXXXXXX.
6. CONTAMINATION/LEAKAGE TESTING OF EACH SOURCE SHALL BE PER PROCEDURE FOR CONTAM/LEAK TEST OF REF. SOURCES. LIMIT 5×10^{-4} uCi.
7. CERTIFICATES, INSERTS & LABELING PER SDP XXXXXXXXXXXXXXXX.
8. SOURCE SET NO. BM06-127 CONSISTS OF ONE EACH OF BM06-57 (CO-57), BM06-37 (CS-137) AND BM06-33 (BA-133).
9. THE PRODUCTS SHOWN IN THIS DRAWING ARE CLASS I MEDICAL AND MEET THE ANSI N436-1997 PERFORMANCE CLASSIFICATION OF C2212 FOR CALIBRATION SOURCES.

FILE NO.	REV. NO.	DATE OF SHIPMENT	DESCRIPTION	BY

INTERNAL: FOR REVIEW AND SIGNATURE		RADQUAL, LLC	
TOLERANCE JEL 2.0% JEL 2 PART 2.1% PART 2 PART 1 = 0	DATE DATE & SIGNATURE CHECKED APPROVED DATE	CALIBRATION "E" VIAL SOURCES BM06-33 (BA-133), BM06-37 (CS-137), BM06-57 (Co-57)	
PART 1 = 0 PART 1 OF 1	PART 1 OF 1	VIAL NO. 8004001	REL

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Manufacture of E-vials		I4-OP-041	DRAFT
PRI:		Page:	Superceded Date:
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PRI Signature and Date:	Document Control Signature and Date:	Quality Assurance Signature and Date:	

Nuclide	Lot Number	Nominal Activity	Manufacture Date

1.0 Purpose

1.1 To provide a standardized method of manufacturing NIST traceable E-Vial Gamma Reference Sources.

2.0 Potential Hazards

2.1 The potential of radiation exposure and/or contamination exists during the performance of this procedure. Dosimetry, safety glasses, gloves, and lab coats should be worn and caution exercised while performing this procedure. This procedure is to be performed under a radiological work permit by trained operators who must take appropriate steps to minimize radiation exposure to themselves and surrounding personnel and must follow all radiation and safety procedures.

2.2 Fumes from the epoxy used in this procedure may be irritating to the upper respiratory tract. Personnel should exercise caution and use appropriate ventilation to minimize exposure to these fumes

3.0 Applicability and Limitations

3.1 This manufacturing record is a complete, accurate, legible and current copy of the Master Manufacturing Record.

Reviewed and Issued By: _____ Date: _____
Quality Control

3.2 This procedure applies to the manufacture of NIST traceable E-Vial Gamma Reference Sources only. Any other source requires an approved procedure for manufacture.

3.3 Waste that is contaminated with Co-57 MUST be clearly labeled as "Contaminated with Co-57" and segregated from all other radioactive wastes.

3.4 Signatures of Qualified Operators

Signatures of Qualified Operators	Date

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4.0 Definitions

4.1 E-vial – A 20 ml polyethylene screw-top vial.

4.2 Pig – A lead shield designed to hold and store a finished E-Vial.

4.3 Target Source Reference Date – Projected date at which a source will be available for sale. Used to calculate the amount of activity added to each lot.

5.0 Responsibilities

5.1 I4 Quality – Verify this procedure is the current revision for manufacture of E-Vials. Review final inspection records and approve sources for shipment.

5.2 I4 Technician – Perform the steps of this procedure.

6.0 Equipment and Materials

6.1 Stycast #1264 Epoxy

Part A

Part B

6.2 Polyethylene Screw-Top Vial (containing cold pour)

6.3 Vial Screw Cap and plug

6.4 E-Vial Storage Pig

6.5 Radionuclide

Cobalt-57 as $^{57}\text{CoCl}_2$ in 0.1N HCl

Cesium-137 as $^{137}\text{CsCl}_2$ in 0.1N HCl

Barium-133 as $^{133}\text{BaCl}_2$ in 0.1N HCl

6.6 DUCO #6244 or equivalent

6.7 Epoxy Dye per Step 7.2.8

6.8 Krylon Crystal Clear or equivalent

6.9 Detection equipment calibrated to National Institute of Standards and Technology traceable sources appropriate for detecting 0.005 microcuries (185 Bq) of the radiation of concern.

6.10 Smear element. (filter paper, cotton swabs, etc.)

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7.0 Procedure

7.1 Preparation and Staging for manufacture of E-Vials

7.1.1 Area Clearance

7.1.2 Prior to proceeding with manufacturing operations, inspect the work area and equipment per I4-OP-27.

Area Cleared by _____ Date _____

7.1.3 Determine the quantity of E-Vial to be manufactured:

Total _____

7.1.4 Determine the total amount of epoxy required to manufacture the lot using the following calculation method:

Stycast #1264 Epoxy Requirements Formula:

(# of E-vials) X (20 ml Epoxy/E-vial) X (1.1 g/ml) X (% excess) = Total Epoxy Required
 (_____) X (22 g/E-vial) X 1.05 = _____ grams total

NOTE: Stycast #1264 is to be mixed 69% Part A (resin) by weight and 31% Part B (hardener) by weight.

Determine the amount of each part needed:

Part A (resin) needed = _____ grams total X 0.69 = _____ grams

Part B (hardener) needed = _____ grams total X 0.31 = _____ grams

Calculations performed by _____

7.2 Radioactive Epoxy Manufacturing

7.2.1 Determine Required Activity

7.2.1.1 Determine the Decay Factor.

Target Source Reference Date		Nuclide	λ (days ⁻¹)
- Target Source Manufacture Date		Co-57	0.00255
= Delta time (Δt) (in days)		Cs-137	6.315E-5
Decay Factor =	$e^{(-\lambda \times \Delta t)}$	Ba-133	1.803E-4
Decay Factor =			

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7.2.1.2 The activity required is determined by the quantity of sources being produced, the activity per source, the decay factor, additional activity for the 5% excess epoxy and a net 5% excess above the nominal activity level as follows:

(Total No. of Sources) X (Activity Per Source) X (Total Excess) = Total Activity (mCi)

Decay Factor

() X () mCi/source X 1.10 = _____ mCi
 ()

Calculations performed by _____

7.2.2 Verify the concentration (mCi/mL) of the nuclide stock material using the dose calibrator or equivalent instrument. Record Concentration value in step 7.2.3

Concentration Verified and recorded by _____

7.2.3 Using appropriate contamination control containment, dispense required activity into a clean 1 dram vial.

Activity Lot No. _____ Concentration _____ mCi/mL

Volume Dispensed _____ mL Activity _____ mCi

Performed by _____

7.2.4 Assay the activity in the ion chamber (or equivalent), standardized per I4-OP-030. Record any adjustments below.

NOTE: Record all activity transactions in the working inventory.

Instrument: _____ Serial No.: _____

	Adjustments
Calibration factor used	_____
Background	_____
Ion chamber value	_____ mCi
Net activity dispensed	_____ mCi

NOTE: If the activity is not within $\pm 5\%$ of the calculated value, recheck the pot setting on the ion chamber and re-submit a sample for impurity determination before adjusting to a new concentration.

New concentration = Ion chamber Value / Volume Dispensed.

Final (Net) Activity Content _____ mCi Date _____

Performed by _____

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7.2.5 Place an empty mixing vat on the balance and tare to zero

7.2.6 Place the calculated amount of epoxy components into the mixing beaker. Record below.

Part A (resin) +5g (from Step 7.1.4) _____ grams
Part B (hardener) +5g (from Step 7.1.4) _____ grams

Performed By _____

7.2.7 Using the mixing paddle identified for the specific nuclide epoxy, stir the epoxy mixture on the electric lab mixer for at least 5 minutes.

CAUTION: INCREASE MIXER SPEED CAREFULLY TO AVOID SPILLAGE

Time Started _____ Time Ended _____ Elapsed Time _____

Performed By _____

7.2.8 Add the appropriate dye to the epoxy in accordance with the table below:

Nuclide	Color	Dye Product ID
Co-57	Blue	Shepherd Blue 385 (or equivalent)
Cs-137	Green	Shepherd Green 223 (or equivalent)
Ba-133	Black	Shepherd Black 1G (or equivalent)

CAUTION: DO NOT USE MORE THAN 0.05 ML OF LIQUID PER GRAM OF EPOXY

7.2.9 Assay the vial. If the residual activity is greater than 2% of the activity from step 7.2.3, repeat the rinse with 0.5 mL of methanol and transfer the solution to the vat. Continue rinsing until residual value is less than 2% of the activity from step 7.2.3. Continue mixing for 20-25 min. Reduce the mixer setting to its minimum speed for the last five minutes of the mixing cycle to release air.

Time started _____ Time ended _____ Time elapsed _____

Operator _____

NOTE: Vials may be weighed ahead of time so long as tare weight is recorded and maintained with the vial. Vials are tared without the caps.

7.2.10 Tare a Polyethylene Screw-Top Vial (without screw top cap) to zero on the balance.

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7.2.11 Transfer sufficient epoxy mixture to the vial to obtain a weight of approximately 22.00 grams.

7.2.12 Record the Source ID number and the epoxy weight on Attachment 9.1, *E-vial Record Table*. Place a green dot sticker on the source and number the sticker to coincide with the source number listed on the *E-vial Record Table*.

7.2.13 Place the E-vial on the shielded curing cart.

7.2.14 For all subsequent sources, repeat steps 7.2.11 and 7.2.13.

7.3 Final Curing and Testing

7.3.1 Purity Test:

7.3.1.1 Tare a 1 dram vial.

7.3.1.2 Transfer approximately 1/2 gram of epoxy mixture from the mixing vat into a one-dram vial. Label the vial with the date, lot number and initials of the technician performing the step.

7.3.1.3 Assay the vial contents for radionuclide purity via gamma spectroscopy. Attach Purity test results to this procedure.

7.3.1.4 Record the activity per weight in uCi/g or mCi/g on Attachment 9.1 *E-vial Record Table*.

7.3.1.5 Calculate the activity of each E-vial base on the weight of the epoxy and the radiopurity results.

7.3.2 Cure:

7.3.2.1 Keep E-vials on the shielded storage cart during the curing period.

7.3.2.2 Allow E-vials to cure for 36 hours at room temperature. Record Date/Time Start and Stop and technician signature below:

Date/Time Start _____ / _____ Date/Time Stop _____ / _____

Performed By _____

7.3.3 After the epoxy has cured prepare a second batch of epoxy for the cold pour.

NOTE: The amount of Epoxy used for the top cold pour should be approximately 1/2 the amount used for the hot pour.

7.3.3.1 Place the calculated amount of epoxy components into the mixing beaker. Record below.

Part A (resin) $\pm 5g$ ($\frac{1}{2}$ the quantity from Step 7.1.4) _____ grams
 Part B (hardener) $\pm 5g$ ($\frac{1}{2}$ the quantity from Step 7.1.4) _____ grams

Performed By _____

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7.3.3.2 Using the mixing paddle identified for the specific nuclide epoxy, stir the epoxy mixture on the electric lab mixer for at least 5 minutes.

CAUTION: INCREASE MIXER SPEED CAREFULLY TO AVOID SPILLAGE

Time Started _____ Time Ended _____ Elapsed Time _____

Performed By: _____

7.3.4 Allow E-vials to cure for 36 hours at room temperature. Record Date/Time Start and Stop and technician signature below:

Date/Time Start _____ / _____ Date/Time Stop _____ / _____

Performed By: _____

7.3.5 Insert plug into throat of E-vial and seal weld the color-coded screw cap onto the cured E-vial using DUCO #6244 or equivalent.

7.3.6 Assay the sources in accordance with instrument technical manual and record results on Table 9.1, *E-vial Record Table*.

7.3.7 Acceptance criteria:

7.3.7.1 Calculated activity and measured activity agree within +/- 5%.

$$\% \text{ Error} = \{1 - (\text{calculated activity} / \text{measured activity})\} * 100$$

7.4 Wipe Testing

7.4.1 Use a smear element(s) to smear the sealed source. Survey the entire surface of the encapsulated source.

7.4.2 Verify that the counting equipment to be used for the analysis of the smears is appropriate as described in section 6.7 and that the calibration is current.

7.4.3 Analyze the smear and record the results and survey instrument data in Table 9.2, *Wipe Test record Sheet*.

Note: To PASS smear results must be less than 0.005 microcuries (185 becquerels) (If results are below the instrument's minimum detectable activity (MDA) then record results as < MDA.

7.4.4 If leakage greater than 0.005 microcuries (185 becquerels) of removable contamination is detected, mark the source as failed, take appropriate measures to prevent the spread of contamination and contact the I⁴ RSO and QA.

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7.5 Final Assembly and Labeling

NOTE: All labels and data sheets must be checked for accuracy and appearance before use. Any unacceptable material must be destroyed and replacements issued.

- 7.5.1** Enter calibration data into the computer to produce a Dose Calibrator Summary Worksheet (Calculates percent deviation from first to second calibration).
- 7.5.2** Prepare labels per the current labeling Bill of Materials (B.O.M.) with the proper information from the assay worksheet. Spray labels with Krylon Crystal Clear or equivalent in order to protect the laser printing. Proofread for accuracy and printing defects before applying.
- 7.5.3** Prepare all certificates, instructions/handling and wipe test certificate sheets for the lot of sources per the current labeling B.O.M. referring to the batch record, test and assay data, and results. There must be a complete and specific set of documentation for each stock unit manufactured.

Performed by: _____

- 7.5.4** Apply labels, matching serial number of label to serial number marked on top of lead shields. Refer to drawing BO04001 for proper placement on the vial and shield.
- 7.5.5** Tape together the top and bottom portions of the shield assembly.
- 7.5.6** Place each set of certificates in a Zip-Loc bag and attach the bag to its respective vial with a rubber band. Clear the work area of any extra labeling materials and/or labeling materials that may be left over from previous operations.

Area cleared by: _____

7.6 Source Packaging

- 7.6.1** Perform a pre-use inspection of the shipping can and shield pig. Clean or repair as needed.
- 7.6.2** Verify serial numbers on labeling and printed materials are correct.
Performed By _____
- 7.6.3** Stage the sources final inspection and release.

Performed By _____

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7.6.4 Perform final review and release per I4-OP-029

I⁴ QA Representative _____

NOTE: Mark the outside of the tin can with the source ID Number prior to sealing the source in the tin can.

7.6.5 Place each assembled source into its shield pig, wrap with packing material and seal in shipping tin can. Include the proper inserts as needed (see Source QA Data Package Checklist).

Performed By _____

7.6.6 Dispose of rejected sources per I4-OP-026

Performed By _____

7.7 Documentation

7.7.1 File this manufacturing data package and all supporting documentation in the lot history file.

Supervisor (or designee): _____ **Date:** _____

8.0 References

8.1 Drawings: the most current revision is to be used.

8.1.1 BO04001

8.1.2 BO04002

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9.2 Wipe Test Record Sheet

Leak Check Instrument Data and Results				
Source Serial Number	Instrument ID / Serial Number	Instrument MDA	Smear Count Results	PASS/FAIL
Performed by:			Date:	

Radiation Profile Data Sheet

Instrument #1	Model: Eberline RO-20	Serial Number: 1569	Cal Due: 8/15/2002
Instrument #2	Model: Bicron MicroRem	Serial Number: B346V	Cal Due: 7/21/2002

Ba-133 Activity	8.955E+06	Bq	Model Number: MED3550
Assay Date	01/01/01		Serial Number: 5042
Measurement Date	07/09/02		Delta T 554.00 days
Decay Corrected Activity	2.190E+02	uCi	Ba-133 t1/2 3843.45 days
Measured			
	Dose Rate	Dose Rate (mrem/hr)	Notes
	(mrem/hr)	Corrected to 500 uCi	
Distance			
On-Contact	17	38.81	
5 cm (2 in)	4.5	10.27	
30 cm (2 in)	0.6	1.37	Measured using Instrument #2
100 cm (39 in)	0.04	0.09	Measured using Instrument #2

Cs-137 Activity	7.623E+06	Bq	Model Number: MED3550
Assay Date	01/01/01		Serial Number: 4808
Measurement Date	07/09/02		Delta T 554.00 days
Decay Corrected Activity	1.989E+02	uCi	Cs-137 t1/2 10975.55 days
Measured			
	Dose Rate	Dose Rate (mrem/hr)	Notes
	(mrem/hr)	Corrected to 500 uCi	
Distance			
On-Contact	18	45.24	
5 cm (2 in)	4.7	11.81	
30 cm (12 in)	0.65	1.63	Measured using Instrument #2
100cm (39 in)	0.05	0.13	Measured using Instrument #2

Co-57 Activity	5.691E+08	Bq	Model Number: Prototype
Assay Date	07/09/02		Serial Number: Prototype
Measurement Date	07/09/02		Delta T 0.00 days
Decay Corrected Activity	1.538E+01	mCi	Co-57 t1/2 271.8 days
Measured			
	Dose Rate	Dose Rate (mrem/hr)	Notes
	(mrem/hr)	Corrected to 15 mCi	
Distance			
On-Contact	300	292.59	
5 cm (2 in)	70	68.27	
30 cm (12 in)	6	5.85	Measured using Instrument #1
100 cm (39 in)	1.2	1.17	Measured using Instrument #1

Performed By:


John J. Miller

7/9/2002
Date



ONE TIME FEE ASSESSMENTS

License No: L5433 Name: NRX Acquisition (International) Inc.

25 Texas Administrative Code (TAC) §289.204(g) requires Fees for Evaluation of a Sealed Source and/or Device.

Type of Evaluation	Number of Sources/Devices	Fee Amount	Amount Paid
<input checked="" type="checkbox"/> Sealed Source	<u>1</u>	<u>\$ 3,614.⁰⁰</u>	<u>\$ 3,614.⁰⁰</u>
<input type="checkbox"/> Device	<u> </u>	<u>\$ </u>	<u>\$ </u>
TOTAL AMOUNT DUE \$ <u>-01</u>			

No request for evaluation will be processed prior to payment of the full amount specified.

Sealed Source (A) for an initial evaluation, a fee of \$3,614.00 or
(B) for an amendment requiring re-evaluation, a fee of \$1,804.00

Device (A) for an initial evaluation, a fee of \$7,233.00 or
(B) for an amendment requiring re-evaluation, a fee of \$3,619.00