REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A SOURCE
(AMENDED IN ITS ENTIRETY)

No.: NR-1235-S-102-S DATED: January 5, 2007
(Supercedes TX-1153-S-102-S)

SEALED SOURCE TYPE: Medical Reference Source

MODEL: BM06**E** Series and **BM06S Series**

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

ISOTOPE:

Cobalt-60
Barium-133
Cesium-137
Sodium-22 (NARM/NORM)
Cobalt-57 (NARM/NORM)
Germanium-68 (NARM/NORM)

MAXIMUM ACTIVITY:

(b)(2)High

High Ex-2

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: Medical Reference Source (X)

CUSTOM SOURCE: ____ Yes __X__ No

B-3

SEALED SOURCE TYPE: Medical Reference Source

DESCRIPTION:

The Model BM06 Series sealed sources are intended for use as reference standards to check the response of dose calibrators used to measure research, diagnostic, and therapeutic radiopharmaceuticals. **The BM06 Series offers these reference standards in two differing geometries. The first of these is the 30 ml vial geometry referred to as the BM06E. The second geometry is the 5 cc syringe geometry referred to as the BM06S. Both the BM06E and BM06S Series** consist of a radioisotope in a chloride or nitrate 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 **either** a 30 ml dose calibrator vial **or a facsimile of a 5 cc syringe.** The **BM06E** 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 (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.

The syringe geometry consists of a body and cap manufactured with a translucent acrylic. The body is filled with a layer of epoxy containing dispersed radioactivity which is sealed beneath a layer of epoxy containing no radioactive material. A screw type acrylic cap, color coded to match the epoxy matrix is chemically welded into the body of the syringe so that disassembly without destruction of the syringe is not possible.

Each source is supplied to the customer in a shielded storage pig.

The BM06 Series consists of **twelve models encompassing two geometries and six isotopes.** The BM06E is approximately 1.25 inches in diameter and 3.5 inches in height. **The BM06S is approximately 0.625 inches in diameter and 2.94 inches in height.**

SEALED SOURCE TYPE: Medical Reference Source

DESCRIPTION (Cont'd):

The following table delineates the isotope differences between the Models of the BM06**E and BM06S Series**:

Model Number	Isotope	Geometry
BM06E-33	Barium-133	30 ml vial
BM06E-37	Cesium-137	30 ml vial
BM06E-60	Cobalt-60	30 ml vial
BM06E-22	Sodium-22	30 ml vial
BM06E-57	Cobalt-57	30 ml vial
BM06E-68	Germanium-68	30 ml vial
BM06S-33	**Barium-133**	**5 cc syringe**
BM06S-37	**Cesium-137**	**5 cc syringe**
BM06S-60	**Cobalt-60**	**5 cc syringe**
BM06S-22	**Sodium-22**	**5 cc syringe**
BM06S-57	**Cobalt-57**	**5 cc syringe**
BM06S-68	**Germanium-68**	**5 cc syringe**

Models of the BM06E and BM06S Series

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 source and will be laminated to prevent wear as a result of use.

DIAGRAM:

See Attachments 1 and 2.

SEALED SOURCE TYPE: Medical Reference Source

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 **vial and syringe** source, containing Co-57, designated as Models BM06**E**-57 **and BM06S-57**, were constructed and tested in accordance with ANSI N43.6-1997 and achieved a sealed source classification of ANSI 97C22312. Only a prototype BM06**E**-57 **and BM06S-57** were tested because the maximum activity of this model was 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 in the BM06**E** Series **and no difference in the construction materials or assembly methods for the different models in the BM06S Series.**

EXTERNAL RADIATION LEVELS:

Maximum radiation levels for these sources are as follows:

Model	Contact Dose	Dose at 5 cm	Dose at 30 cm	Dose at 100 cm
BM06E-33	39	10	1.4	0.1
BM06E-37	45	12	1.6	0.1
BM06E-60	160	30	1.0	0.2
BM06E-22	470	78	6.0	0.6
BM06E-57	293	68	5.9	1.2
BM06E-68	219	37	3.0	0.4

SEALED SOURCE TYPE: Medical Reference Source

EXTERNAL RADIATION LEVELS (Cont'd):

Model	Contact Dose	Dose at 5 cm	Dose at 30 cm	Dose at 100 cm
BM06S-33	456	49	1.7	0.2
BM06S-37	558	60	2.1	0.2
BM06S-60	352	38	1.4	0.1
BM06S-22	891	95	3.4	0.3
BM06S-57	1382	158	12	2.4
BM06S-68	377	40	1.4	0.1

External Radiation Levels in mrem/hr

Note: Dose rates for Models BM06**E**-57, BM06**E**-68, and **BM06S-57** were measured on prototype sources manufactured by International Isotopes Idaho, Inc., and corrected to the maximum activities for these sources. Dose rates for Models BM06**E**-33, 37, 22, and 60 measured on NIST traceable sources of similar construction and geometry and corrected to the maximum activities for these sources. **Dose rates for Models BM06S-33, 37, 60, 22, and 68 were calculated using MicroShield.**

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 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.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A SOURCE
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SEALED SOURCE TYPE: Medical Reference Source

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (Cont'd):

- 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 U.S. Nuclear Regulatory Commission.

- 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.

- Reviewer's Note: the sources had been previously registered by the State of Texas under registration No. TX-1153-S-102-S, which also included the following sources with NARM/NORM materials: BM06-22 (Sodium-22 (b)(2)High BM06-57 (Cobalt-57, (b)(2)High and BM06-68 (Germanium-68 (b)(2)High Registration No. TX-1153-S-102-S was reissued by NRC as NR-1235-S-102-S under the licensee's address in Idaho. High Exa

SEALED SOURCE TYPE: Medical Reference Source

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (Cont'd):

The Energy Policy Act of 2005 gave authority to the NRC to regulate NARM/NORM. However, a waiver from the requirements of the Energy Policy Act of 2005, issued by the NRC in Federal Register, Vol. 70, No. 168, Wednesday, August 31, 2005, was granted to all States, and will expire on August 7, 2006. The State of Idaho does not have a state licensing program nor regulations for NARM or NORM materials. Therefore the NRC has included NARM/NORM on this certificate, accepting the review performed by the State of Texas under Registration No. TX-1153-S-102-S for the NARM/NORM sources.

SAFETY ANALYSIS SUMMARY:

The BM06**E and BM06S** Series sources are intended for use as quality control and reference sources for dose calibrators and are expected to maintain their integrity for normal conditions of use and likely accidental conditions. 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 20° 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**E and BM06S** Series sources and the references cited below, we conclude the these sources are acceptable for licensing purposes as described within this certificate.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
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SEALED SOURCE TYPE: Medical Reference Source

REFERENCES:

The following supporting documents for International Isotopes Idaho, Inc. Model BM06**E and BM06S** Series reference sources are hereby incorporated by reference and are made a part of this registry document.

- International Isotopes application dated July 12, 2002, sent to Texas Department of Health, with enclosures thereto.
- International Isotopes letters dated September 18, 2002, October 16, 2002, August 20, 2003, and November 27, 2003, sent to Texas Department of Health, with enclosures thereto.
- International Isotopes letter dated March 31, 2005, to Texas Department of Health, requesting transfer of certificate to NRC.
- Texas Department of Health letter dated April 27, 2005, transferring International Isotopes Model BM-06 Series file to NRC.
- Texas Department of Health email dated June 13, 2005.
- State of Idaho, INL Oversight and Radiation Control Division, email dated October 28, 2005.
- **International Isotopes letters dated November 16, 2006, and January 3, 2007, with enclosures thereto.**

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: January 5, 2007 Reviewer: **/RA/**
Nima Ashkeboussi

Date: January 5, 2007 Concurrence: **/RA/**
John P. Jankovich

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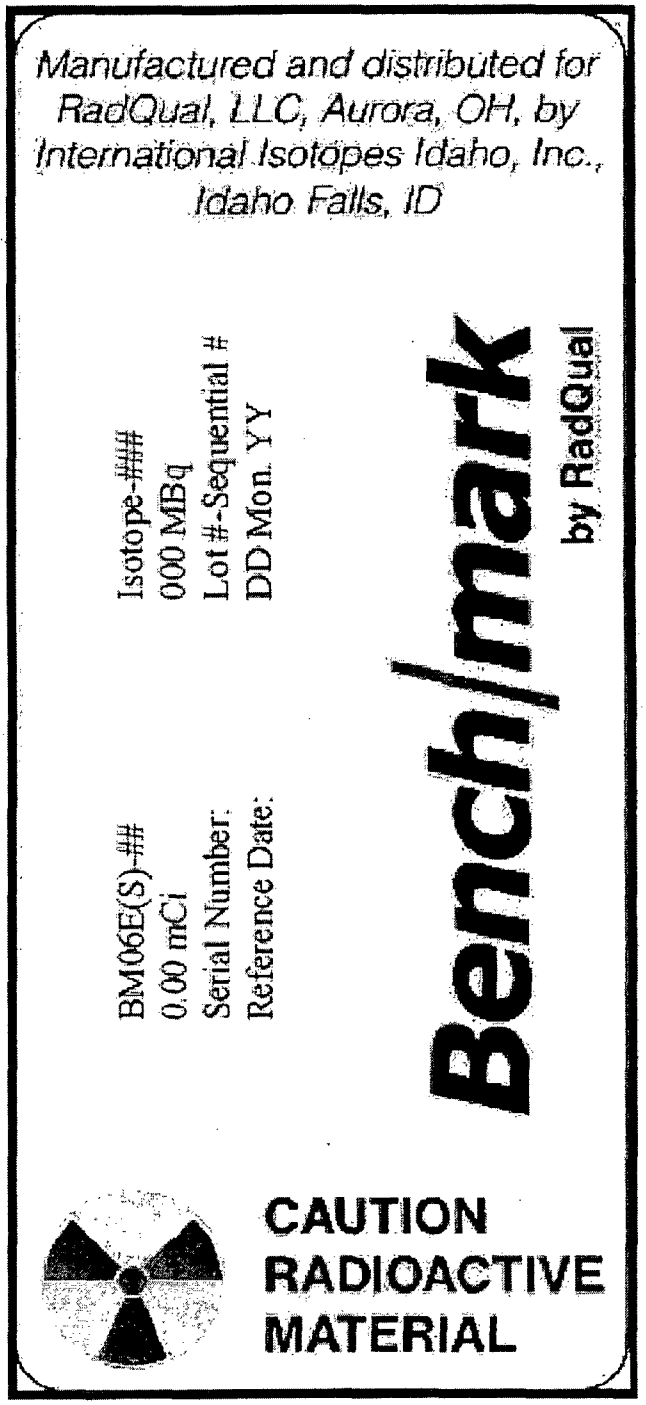
No.: NR-1235-S-102-S DATED: January 5, 2007 Attachment 1
(Supercedes TX-1153-S-102-S)

Source Label Example



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A SOURCE
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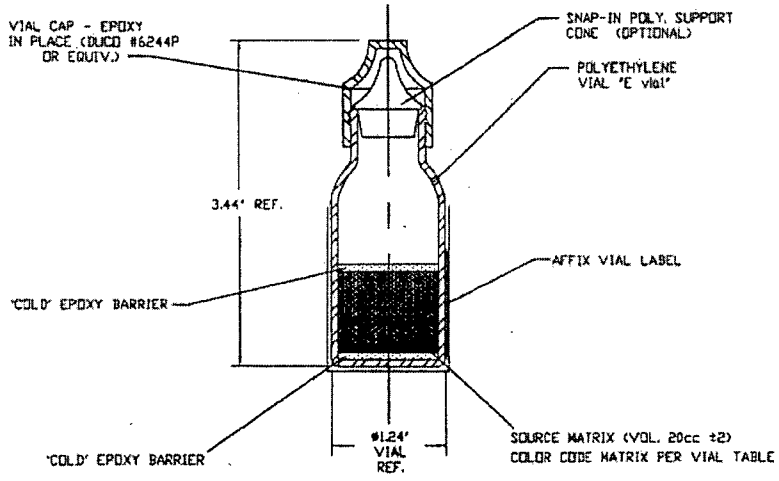
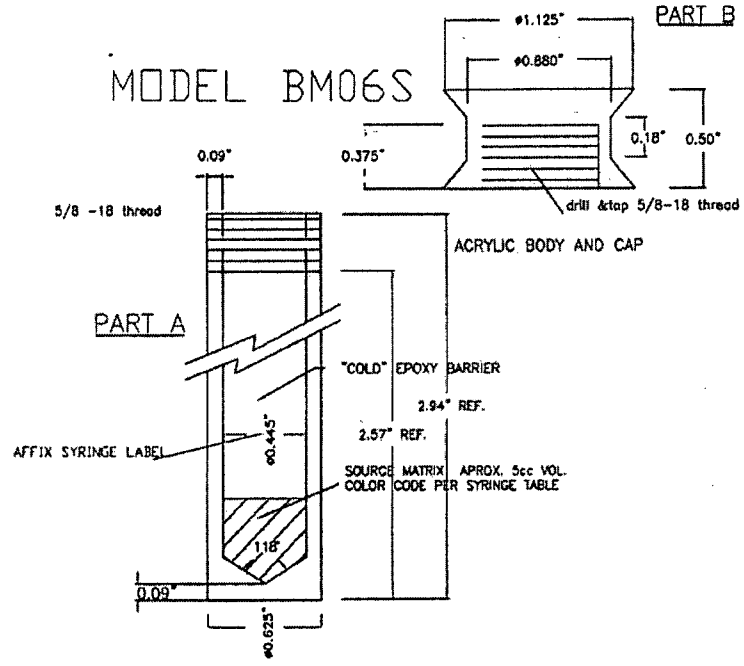
No.: NR-1235-S-102-S DATED: January 5, 2007 Attachment 2
(Supercedes TX-1153-S-102-S)

MODEL BM06E



MODEL BM06S



VIAL STANDARD MODEL TABLE				
ASS'Y. P/N	MODEL NO.	NUCLIDE	MAXIMUM ACTIVITY	COLOR CODE
-01	BM06E-22	Na-22	(b)(2)High	YELLOW
-02	BM06E-60	Co-60		BLUE
-03	BM06E-37	Cs-137		GREEN
-04	BM06E-33	Ba-133		BLK/GRY
-05	BM06E-57	Co-57		RED
-06	BM06E-68	Ge-68		WHITE

High Ex-2

NOTES

1. SOURCE ACTIVITY CONSISTS OF RADIONUCLIDE DISPERSED UNIFORMLY IN A HIGH IMPACT EPOXY RESIN. RESIN MAYBE COLOR CODED PER TABLE USING EPOXY COLORING APPROPRIATE FOR STYCAST EPOXY (OR EQUIV).
2. PRODUCT ACTIVITY SHALL BE REFERENCED TO LABEL DATE. PRODUCT ACTIVITY TOLERANCE SHALL NOT BE > +20% NOR < -10% AT TIME OF SHIPMENT.
3. CONTAMINATION/LEAKAGE TESTING OF EACH SOURCE SHALL BE PER PROCEDURE FOR CONTAM./LEAK. TEST OF REF. SOURCES'. LIMIT 5 X 10^{-3} uCi.
4. ANSI N43.6-1997 PERFORMANCE CLASSIFICATION OF 96C22212 FOR CALIBRATION SOURCES

SYRINGE STANDARD MODEL TABLE				
ASS'Y. P/N	MODEL NO.	NUCLIDE	MAXIMUM ACTIVITY	COLOR CODE
-01	BM06S-22	Na-22	(b)(2)High	YELLOW
-02	BM06S-60	Co-60		BLUE
-03	BM06S-37	Cs-137		GREEN
-04	BM06S-33	Ba-133		BLK/GRY
-05	BM06S-57	Co-57		RED
-06	BM06S-68	Ge-68		WHITE

High Ex-2