REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SOURCE

NO.: **TX-1153-S-802-S** DATE: March 22, 2006 PAGE 1 OF 6
(Supercedes TX-1153-S-102-S)

DEVICE TYPE: Sealed source

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

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 (BM06-68)

MODEL NUMBER	MAXIMUM ACTIVITY
BM06-33, BM06-37, BM06-68 BM06-22	(b)(2)High
BM06-57	
BM06-60	

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: Medical reference source(X)

CUSTOM SOURCE: ____ YES __X__ NO

CUSTOM USER:

B-16

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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.

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.

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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.

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 μSv)
30 cm - 5.9 mrem/hr	(59 μSv)
100 cm - 1.2 mrem/hr	(12 μSv)

Model BM06-37

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

Model BM06-33

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

Model BM06-68

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

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EXTERNAL RADIATION LEVELS (Continued):

Model BM06-22

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

Model BM06-60

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

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.

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

- 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 State Health Services, Radiation Safety Licensing Branch.
- 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.
- **These sources will continue to be manufactured and distributed under the U. S. Nuclear Regulatory Commission (NRC) Sealed Source and Device Evaluation No. NR-1235-S-102-S. The manufacturer will continue to provide customer support services for sources manufactured and shipped prior to issuance of the NRC Sealed Source and Device Evaluation. Services to include return of expended sources to the manufacturer.**

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.

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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.
- **International Isotopes Idaho, Inc. letter dated February 13, 2006.**

ISSUING AGENCY: **Texas Department of State Health Services**
Radiation Safety Licensing Branch

Date: March 22, 2006 Reviewer: J. Scott Kee

Date: March 22, 2006 Concurrence: David Fogle

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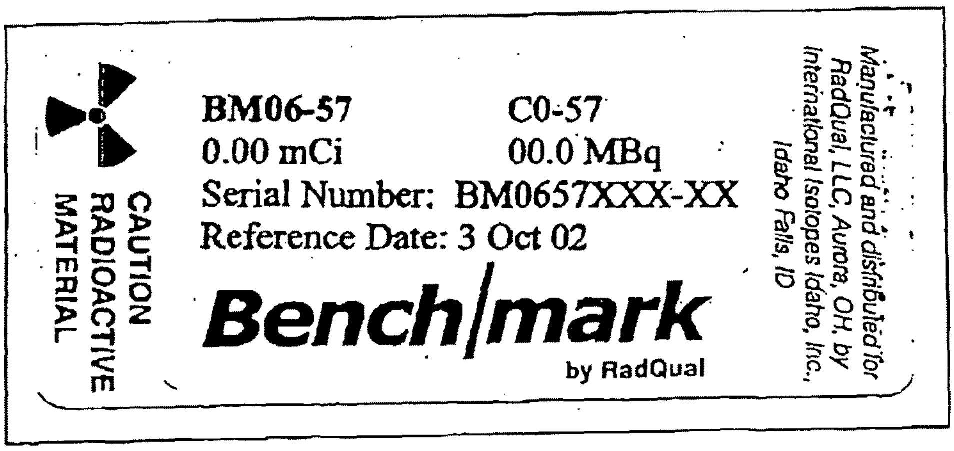
ATTACHMENT 1

SOURCE LABEL



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ATTACHMENT 2

BM06 Series