

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

NO.: TX-1153-S-101-S
(Supercedes TX-1068-S-102-S)

DATE: August 26, 2004

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DEVICE TYPE: Sealed source

MODEL: BM01 Series (BM01-10, BM01-15, BM01-20, BM01-99)
BM02 Series (BM02-05, BM02-10, BM02-15) -----
BM04 Series (BM04-10, BM04-15, BM04-99)
BM05 Series (BM05-10, BM05-05)
BM09 Series (BM09-10, BM09-75, BM09-99)

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

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

ISOTOPE: Co-57

<u>MODEL NUMBER</u>	<u>MAXIMUM ACTIVITY</u>
BM01 Series	25 millicuries (925 MBq)
BM02 Series	25 millicuries (925 MBq)
BM04 Series	15 millicuries (555 MBq)
BM05 Series	15 millicuries (555 MBq)
BM09 Series	15 millicuries (555 MBq)

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: Medical reference source

CUSTOM SOURCE: — YES —X— NO

CUSTOM USER: No

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DESCRIPTION:

These sources consist of Co-57 as cobaltous chloride uniformly dispersed in high impact epoxy casting resin (E & C Stycast 1264 or equivalent) which is cured and placed in a 1/8 inch thick ABS encapsulation. Dimensions are given below. The encapsulation consists of two formed halves that interlock upon assembly and are chemically welded so that disassembly without destruction of the encapsulation is not possible. Each source is supplied in a shielded storage case.

Model Number	Physical Dimensions
BM01 Series	25.28 in. (64.21 cm) X 17.89 in. (45.44 cm) X 0.7 in. (1.78 cm)
BM02 Series	20.28 in. (51.51 cm) X 0.7 in. (1.78 cm)
BM04 Series	19.62 in. (49.83 cm) X 15.56 in. (39.52 cm) X 0.71 in. (1.8 cm)
BM05 Series	10 in. (25.4 cm) X 10 in. (25.4 cm) X 0.71 in. (1.8 cm)
BM09 Series	16.42 in. (41.71 cm) X 10.87 in. (27.61 cm) X 0.71 in. (1.8 cm)

LABELING:

Each source and storage case is conspicuously labeled "Co-57 Flood Source" and bears the warning "CAUTION: RADIOACTIVE MATERIAL" as well as the trefoil radiation symbol in magenta on a yellow background, the manufacturer's name and logo, and the instruction "See Use and Handling Instructions". The radioactive content, in millicuries, and the date manufacture is shown, as well as model number and serial number.

DIAGRAM:

See Attachments 1 - 6. Attachment 1 contains the drawings for Models BM01-10, BM01-15, BM01-20 and BM01-99. Attachment 2 contains the drawings for Models BM02-05, BM02-10 and BM02-99. Attachment 3 is the label to be affixed to each source. Attachment 4 is a drawing for Models BM04-10, BM04-15 and BM04-99. Attachment 5 is a drawing for Models BM05-10 and BM05-99. Attachment 6 is a drawing for Models BM09-10, BM09-75, and BM09-99.

CONDITIONS OF NORMAL USE:

The sources are designed for use in a medical environment and are not expected to experience extreme environmental factors. The flood sources provide a uniform field of radiation for evaluation of nuclear medicine gamma camera performance, allowing detection and correction of any camera malfunction prior to diagnostic use. The useful life of the flood sources is approximately 2 years.

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PROTOTYPE TESTING:

The BM01 and BM02 Series sources were tested in accordance with ANSI N542-1977 "Sealed Radiation Sources, Classification" and achieved a sealed source classification of ANSI 77C22312. The BM04 and BM05 Series sources were tested in accordance with ANSI N43.6-1997 "Sealed Radioactive Source - Classification" and achieved a sealed source classification of ANSI 97C22312. Leak testing of prototypes for models BM01 through BM05 was performed in accordance with ISO 9978. No prototype testing was performed for the model BM09 Series. The ANSI classification of 97C22312 was assigned to this Series by the manufacturer based on the similarity of the construction materials and methods with sources previously tested and currently in production. The manufacturer has also elected not to perform leak testing of prototype sources in this Series for the same reasons of similarity of materials and construction to existing sources.

EXTERNAL RADIATION LEVELS:

Measured radiation dose rates for a nominal 10 mCi source are as follows:

BM01 Series

Contact - 35 mrem/hr (350 μ Sv/hr)
5 cm - 35 mrem/hr (350 μ Sv/hr)
30 cm - 6 mrem/hr (60 μ Sv/hr)
100 cm - 1.1 mrem/hr (11 μ Sv/hr)

BM02 Series

Contact - 45 mrem/hr (450 μ Sv/hr)
5 cm - 30 mrem/hr (300 μ Sv/hr)
30 cm - 6 mrem/hr (60 μ Sv/hr)
100 cm - 1.1 mrem/hr (11 μ Sv/hr)

BM04 Series

Contact - 45 mrem/hr (450 μ Sv/hr)
5 cm - 36 mrem/hr (360 μ Sv/hr)
30 cm - 6 mrem/hr (60 μ Sv/hr)
100 cm - 0.1 mrem/hr (1 μ Sv/hr)

BM05 Series

Contact - 90 mrem/hr (900 μ Sv/hr)
5 cm - 60 mrem/hr (600 μ Sv/hr)
30 cm - 8 mrem/hr (80 μ Sv/hr)
100 cm - 0.2 mrem/hr (2 μ Sv/hr)

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EXTERNAL RADIATION LEVELS:

(Continued)

Calculated radiation dose rates for sources in the BM09 Series are as follows:

BM09-75 (7.5 mCi max.)

Contact - 54 mrem/hr (540 μ Sv/hr)
5 cm - 36 mrem/hr (360 μ Sv/hr)
30 cm - 4.8 mrem/hr (48 μ Sv/hr)
100 cm - 0.2 mrem/hr (2 μ Sv/hr)

BM09-10 (10 mCi max.)

Contact - 72 mrem/hr (720 μ Sv/hr)
5 cm - 48 mrem/hr (480 μ Sv/hr)
30 cm - 6.4 mrem/hr (64 μ Sv/hr)
100 cm - 0.2 mrem/hr (2 μ Sv/hr)

BM09-99 (15 mCi max.)

Contact - 108 mrem/hr (1.08 mSv/hr)
~~5 cm - 72 mrem/hr (720 μ Sv/hr)~~
30 cm - 9.6 mrem/hr (96 μ Sv/hr)
100 cm - 0.3 mrem/hr (3 μ Sv/hr)

QUALITY ASSURANCE AND CONTROL:

International Isotopes, Inc. and/or RadQual, LLC quality assurance staff will monitor the product quality by performing periodic quality assurance audits of the manufacturer.

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 N542-1977 or ANSI N43.6-1997 classifications of ANSI 77C22312 or ANSI 97C22312.

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LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

(Continued)

- The probable effect of severe environmental conditions, such as accidents and fire, would be minimal release of radioactivity since the Cobalt-57 is incorporated into the cured epoxy matrix. Although the ABS encapsulation, 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 Cobalt-57 is dispersed, as well as the plastic encapsulation.
- Care should be taken to avoid contact with organic solvents, hot surfaces, and excessive mechanical stress.
- The sources shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting the presence of 0.005 microcurie (185 Bq) of removable contamination.
- 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.

SAFETY ANALYSIS SUMMARY:

The BM01, BM02, BM04, BM05 and BM09 Series sources are intended for use as quality control and reference sources for medical imaging devices 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 still not reasonably be expected to allow dispersion of radioactive material due to the epoxy matrix with which the radioactive material is mixed.

Based on review of the information and test data submitted for the BM01, BM02, BM04 and BM05 Series sources, the references cited below, and the assurance of International Isotopes Idaho, Incorporated concerning the manufacturing processes for the BM09 Series, we conclude 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.

MANUFACTURING AND DISTRIBUTION CONTROLS:

International Isotopes Idaho, Inc. provides for design control, procurement control, process quality control, and final quality assurance with oversight by International Isotopes, Inc. and/or RadQual, LLC. Distribution will be by drop shipment directly from the manufacturer to the customer.

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MANUFACTURING AND DISTRIBUTION CONTROLS:

----- (Continued) -----

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.

MANUFACTURER'S SAFETY ANALYSIS OF SEALED SOURCE REVIEW:

Prototype sources for models BM01 and BM02 were constructed and subjected to environmental testing as provided in ANSI N542-1977, Table 1, and achieved a classification of 77C22312. Prototype sources for models BM04 and BM05 were constructed and subjected to environmental testing as provided in ANSI N43.6-1997 and achieved a classification of 97C22312. No environmental testing was performed on prototype sources of the BM09 Series. The manufacturer has judged the BM09 Series sources to have an ANSI-classification of 97C2212 based on the similarity of materials and construction methods with sources already in production from this same manufacturer.

Maximum external radiation levels for the BM01 through BM09 Series sources are as previously identified in this certificate.

REFERENCES:

The following supporting documents for the Series BM01 through BM09 flood sources are hereby incorporated by reference and are made a part of this registry document.

- International Isotopes, Inc. application dated December 19, 2000, signed by Bruce Sanza, CHP, Radiation Safety Officer, with enclosures thereto.
- International Isotopes, Inc. letter dated March 13, 2001, signed by Bruce Sanza, CHP, Radiation Safety Officer, with enclosures thereto.
- International Isotopes, Inc. letters dated April 13, 2001, April 18, 2001, with enclosures thereto.
- International Isotopes Idaho, Inc. Quality Assurance Manual, dated October 1, 1999, received April 16, 2001.
- International Isotopes, Inc. letter dated June 21, 2001, signed by Bruce Sanza, CHP, Radiation Safety Officer.

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REFERENCES:

(Continued)

- International Isotopes, Inc. letter dated October 25, 2001, signed by Bruce Sanza, CHP, Radiation Safety Officer.
- NRX Acquisition Corp. letter dated October 25, 2001, signed by Bruce Sanza, CHP, Radiation Safety Officer.
- International Isotopes, Inc. letter dated November 13, 2001, signed by Bruce Sanza, CHP, Radiation Safety Officer.
- International Isotopes Idaho, Inc. letters dated January 8, 2002 and January 22, 2002, signed by John J. Miller, CHP, Radiation Safety Officer.
- International Isotopes Idaho, Inc. letters dated March 29, 2002 and April 11, 2002, signed by John J. Miller, CHP, Radiation Safety Officer.
- International Isotopes Idaho, Inc. letter dated February 25, 2003, signed by John J. Miller, CHP, Radiation Safety Officer and RadQual letter Dated August 5, 2003, signed by Keith C. Allberg.
- International Isotopes Idaho, Inc. letter dated June 3, 2004, signed by John J. Miller, CHP, Radiation Safety Officer and RadQual letter Dated June 29, 2004, signed by Keith C. Allberg.

ISSUING AGENCY: Texas Department of Health
Bureau of Radiation Control

Date: August 26, 2004

Reviewer: J. Scott Kee
J. Scott Kee

Date: August 26, 2004

Concurrence: William Stringfellow
William Stringfellow

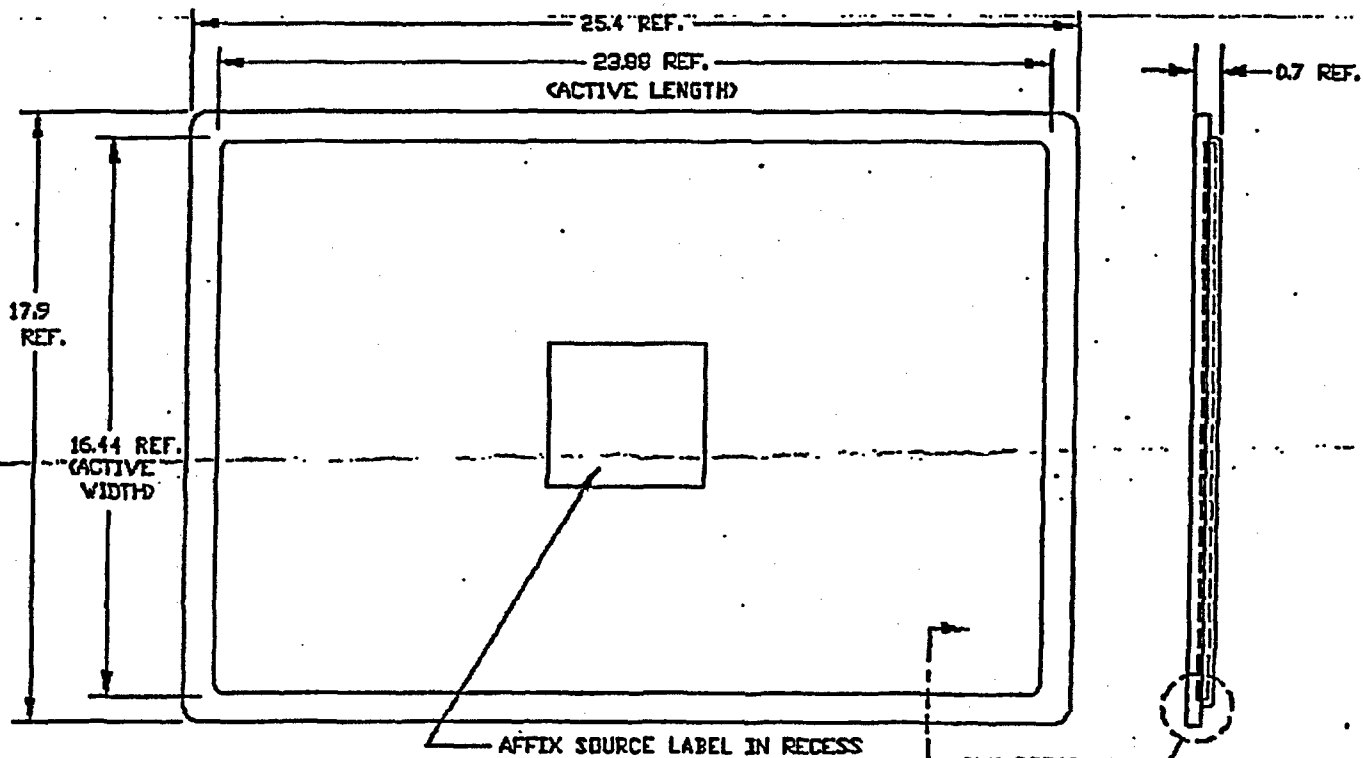
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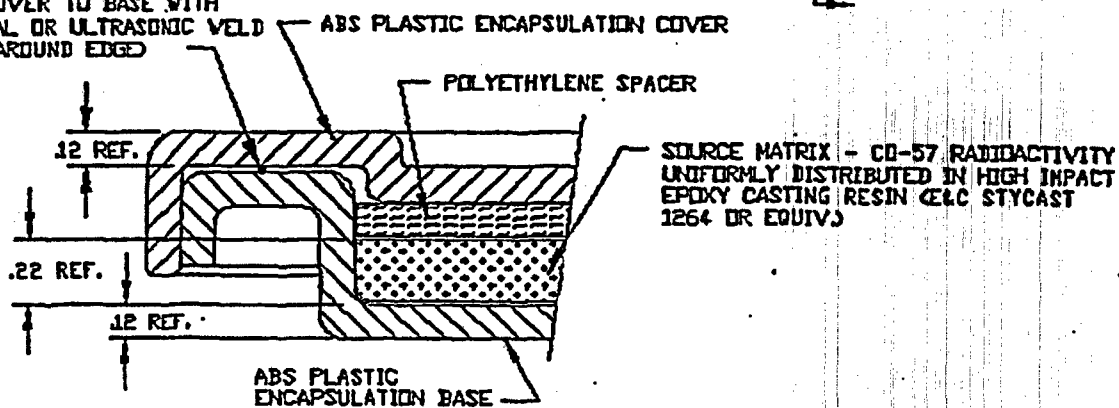
DATE: August 26, 2004

ATTACHMENT 1

BM01 Series (Rectangular)



BOND COVER TO BASE WITH
 CHEMICAL OR ULTRASONIC WELD
 (TYP. AROUND EDGE)



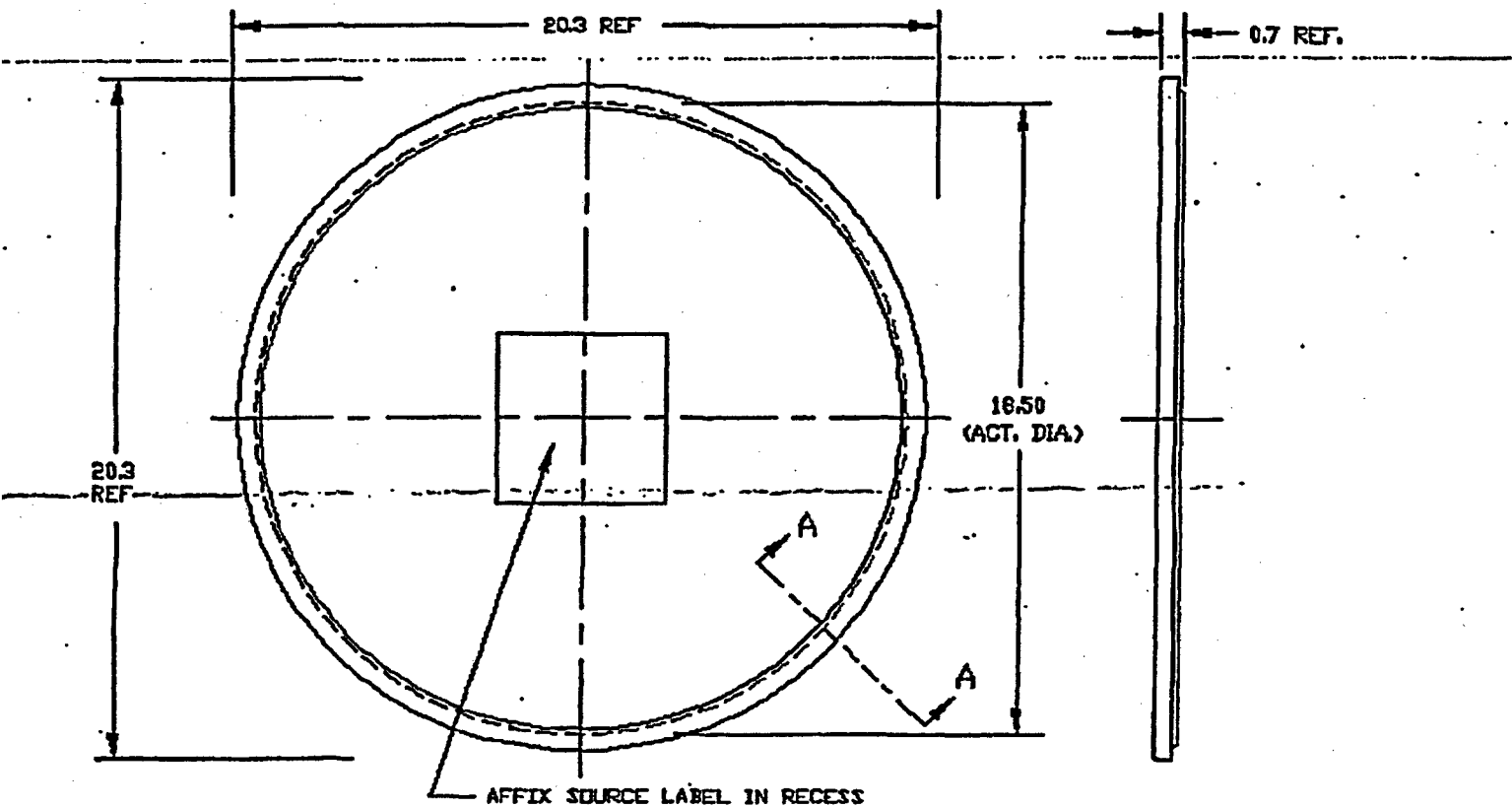
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ATTACHMENT 2

BM02 Series (Circular)

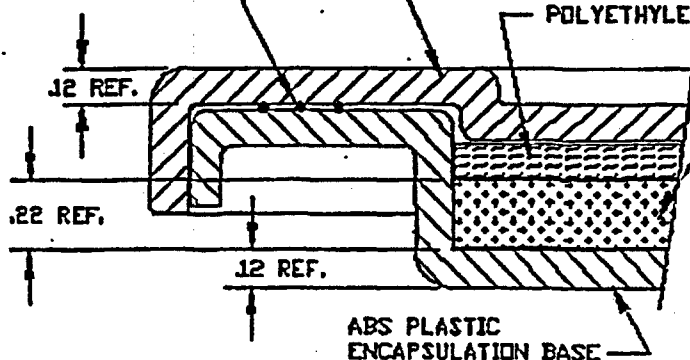


BOND COVER TO BASE WITH
 CHEMICAL OR ULTRASONIC WELD
 (TYP. AROUND EDGE)

ABS PLASTIC ENCAPSULATION COVER

POLYETHYLENE SPACER

SOURCE MATRIX - CO-57 RADIOACTIVITY
 UNIFORMLY DISTRIBUTED IN HIGH IMPACT
 EPOXY CASTING RESIN (E&C STYCAST
 1264 OR EQUIV.)



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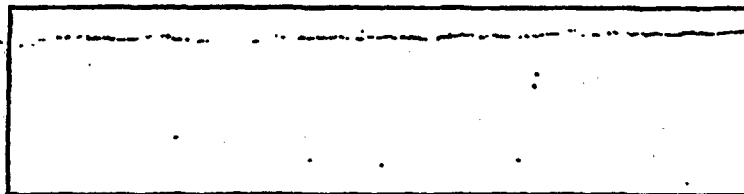
DATE: August 26, 2004

ATTACHMENT 3

SOURCE LABEL

Bench/mark
by RadQual

Cobalt-57 Flood Source



**CAUTION
RADIOACTIVE
MATERIAL**

The Bureau of Radiation Control, Texas Department of Health, has approved this sealed source for distribution to persons licensed pursuant to 25 TAC 289.252 or under equivalent licenses of the USNRC, Agreement State, Licensing State, and outside the United States, to persons authorized by the appropriate authority.

See Use and Handling Instructions

*Manufactured and distributed for RadQual, LLC, Aurora, OH, by International
Isotopes Idaho, Inc., Idaho Falls, ID*

FL0001-1201

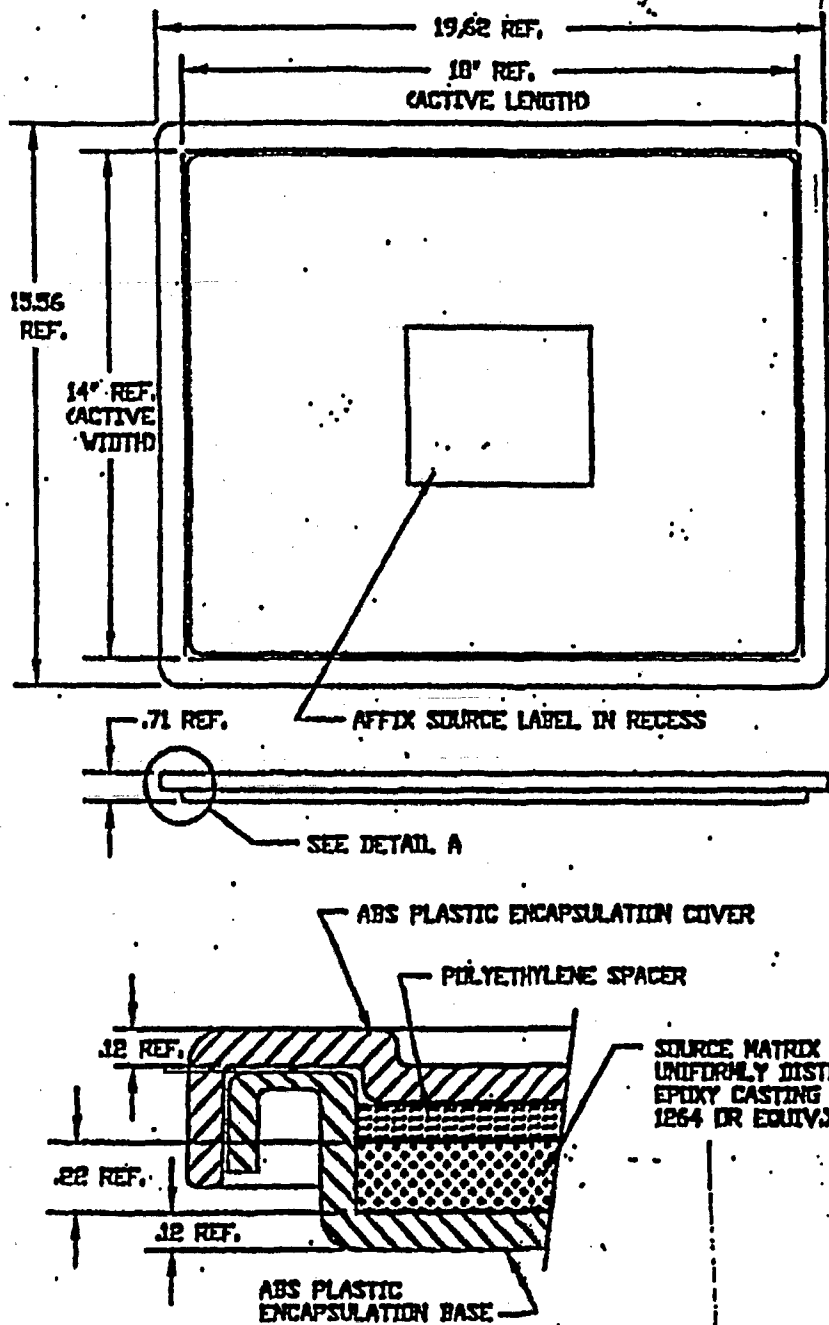
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ATTACHMENT 4

BM04 Series (Rectangular)



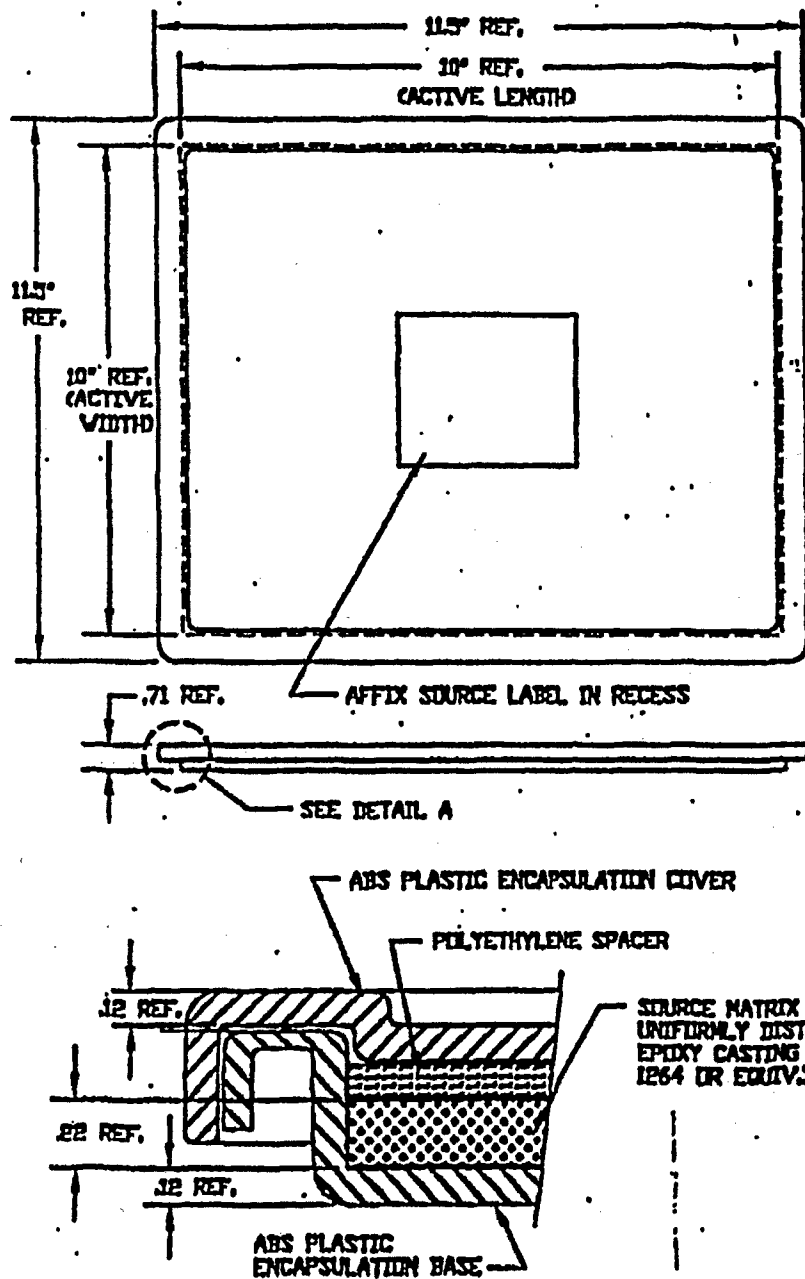
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ATTACHMENT 5

BM05 Series (Square)



Amended in Entirety

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NOMINAL ACTIVITY		10 PCI		75		SEE NOTE 8	
<p align="center">NOTES</p> <p>1. SOURCE ACTIVITY TOLERANCE TO BE $\pm 10\%$, $\pm 1\sigma$ REFERENCED TO LABEL DATE.</p> <p>2. RADIATION EMISSION UNIFORMITY TO BE MEASURED PER PROCEDURE.</p> <p>3. FINAL ASSEMBLY CONSISTS OF A SOURCE IN A RADHEIMEL WITH LABELLING AND INSERTS PER PROCEDURE.</p> <p>4. TOTAL CO-57 CONTENT TO BE LESS THAN 50% OF CO-57 CONTENT REFERENCED TO LABEL DATE.</p> <p>5. MOST 1975-1977 PERFORMANCE CLASSIFICATION 9700000.</p> <p>6. SWEEP TEST OF ENTIRE SURFACE OF FLOOD SOURCE TO YIELD 4.5×10^{-4} uCi.</p> <p>7. PERCENT OF INSPECTION PER PROCEDURE.</p> <p>8. NOMINAL ACTIVITY TO BE SPECIFIED ON PURCHASE ORDER FOR SOURCES MAY/NOV NOMINAL ACTIVITIES OTHER THAN THOSE IN TABLE. MAXIMUM ACTIVITY TO BE 15 uCi.</p>							

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