

Application for Safety Review
INIS 022309 - BMNT & BMCY

SUMMARY DATA

Date: February 23, 2009

Sealed Source Type: Cylindrical Phantom, Photon Emitting

Models: BMCY68-DDHH-YY
BMNT57- YY
DD equals cylinder diameter in centimeters
HH equals cylinder height in centimeters
YY equals activity in millicuries

Manufacturer/distributor

International Isotopes 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) 513-1221

Isotope and Maximum Activity:

Model Number	Isotope	Nominal Activity	Maximum Activity
BMCY68	Ge-68	0.05-5 millicuries (2MBq-185 MBq)	12 millicuries (444 MBq)
BMNT57	Co-57	0.05-6 millicuries (2 MBq -222 MBq)	12 millicuries (444 MBq)

Leak Test Frequency: 6 Months

Principal Use: Medical Reference Source

Custom Source: No

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DESCRIPTIVE DATA

Description:

These sources consist of a Cobalt-57 or Ge-68 uniformly dispersed in high impact epoxy casting resin (Emerson & Cuming Stycast 1264 or equivalent). The epoxy containing the dispersed radioactivity is poured into a cylindrical plastic (HDPE or equivalent) housing that contains a thin layer of cured non-radioactive epoxy to seal the bottom and provide a non-radioactive barrier. After the radioactive epoxy resin cures, it is capped with a thin layer of non-radioactive epoxy to seal the top and provide a non-radioactive barrier. After the top non-radioactive epoxy layer cures, a plastic disc (HDPE or equivalent) is attached to the cylinder with nylon (or equivalent) allen screws. A thread adhesive is applied to the allen screws prior to attaching the top and bottom discs to the cylinder walls. After the source has been completely assembled a clear epoxy resin is used to backfill the allen heads so that disassembly without destruction of the source is not possible. The BMNT design has a maximum diameter of 7.5 inches (active matrix maximum diameter of 4.0 inches) and a maximum height of 5.0 inches (active matrix maximum height of 4.0 inches), Refer to Attachment 2, DWG B900101 for further detail. The BMCY design has a maximum diameter of 8.4 inches (active matrix maximum diameter of 7.4 inches) and a maximum height of 8.4 inches (active matrix maximum height of 7.4 inches) (Each source design is supplied in a shield container for transport and/or storage.) Refer to Attachment 1, DWG RAD020309-1 for further detail. BMCY cylinder sources with a active matrix of less than 2.6 inches in diameter are limited to a maximum of 5 millicuries activity.

Labeling:

Each source and storage shield is conspicuously labeled with the radioisotope, activity content in millicuries (MBq), reference date, model and serial number 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.

Drawings:

Refer to attachment 1 and attachment 2.

Conditions Of Normal Use:

The sources are used as reference standards to check the response of nuclear imaging systems used in diagnostic and therapeutic treatments utilizing radioactive agents.

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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 resin matrix, even as it commenced to melt, would prevent dispersion of radioactivity, temperatures exceeding 200 C° would result in combustion of the resin in which the radioisotope is dispersed, as well as the Acrylic, which constitutes the shell.
6. This registration sheet and the information contained within the references shall not be changed without the written consent of the Nuclear Regulatory Commission (NRC).

HEALTH AND SAFETY DATA

Safety Analysis Summary:

Based on review of Model BMNT and BMCY and the information and test data cited below, we conclude that this source model would be expected to maintain its containment integrity for normal conditions of use and accidental conditions, which might occur during uses specified in this application and therefore is acceptable for licensing purposes.

Manufacturer's Safety Analysis of Sealed Source Review:

A prototype of a BMNT, containing 1 (one) mCi of Co-57 was constructed and subjected to four environmental tests as stipulated in ANSI/HPS N43.6-1997, Table 1 *Classification of sealed-source performance tests*, and achieved a classification of 97C22312 (Calibration Source), because of the similarity between the BMNT and BMCY design, an engineering review was done for the BMCY.

Exposure rate measurements for the BMNT57 were obtained using direct measurements of contact readings of manufactured sources, (1 mCi and 4 mCi sizes), reporting the highest recorded level (side of cylinder). Based on those readings the data for maximum activity was modeled using Microshield 7.0. Exposure rate measurements for the BMCY68 were obtained

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using direct measurements of contact readings of manufactured sources, (2 mCi), reporting the highest recorded level (top of cylinder). Based on these readings the data for maximum activity was modeled using Microshield 7.0. Radiation levels are reported in mrem/hr (uSv/hr).

BMNT57-YY	Co-57 1 mCi (37 MBq)	Co-57 4 mCi (148 MBq)	Co-57 12 mCi (444 MBq)
On Contact	8 (0.8)	37 (3.7)	104 (10.4)
@ 5 cm	4 (0.45)	22 (2.2)	62 (6.02)
@ 30 cm	0.4 (0.02)	2.5 (0.25)	6 (0.6)
@ 100 cm	0.03 (0.003)	0.2 (0.02)	1 (0.1)

BMCY68-0606-02	Ge-68 2 mCi (74 MBq)	Ge-68 12 mCi (444 MBq)
On Contact	245 (24.5)	1458 (145.8)
@ 5 cm	52 (5.2)	316 (31.6)
@ 30 cm	3.2 (0.32)	19.3 (1.9)
@ 100 cm	0.4(0.04)	2.6 (0.26)

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 Inc. (INIS) provides for design control, procurement control, process quality control, and final quality assurance.

The INIS Quality Assurance program is a management system established to ensure INIS products are safe and reliable and that those products and INIS services meet or exceed customer requirements.. Quality related activities shall be controlled and conducted using documented procedures including instructions drawings, process diagrams, or other appropriate documents. Quality records are prepared, stored, preserved and kept safe in appropriate facilities so to be retrievable. Periodic audits by INIS Quality Assurance staff will ensure that the program continues to perform as intended.

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INIS actively participates in the National Institute of Standards (NIST) Radioactivity Measurement Assurance Program and Technology. Source activity will be determined by assay of the manufacturing batch solution utilizing a dose calibrator that has been calibrated with radioactive standards directly traceable to NIST.

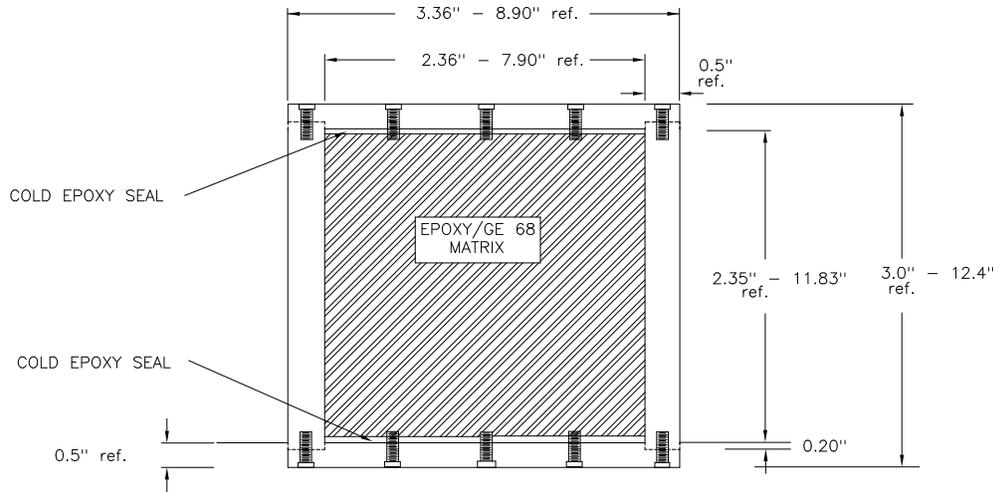
No source will be distributed by INIS if it has not passed leak testing performed in accordance with ANSI/HPS N43.6-1997. Sources will only be transferred to authorized recipients.

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.

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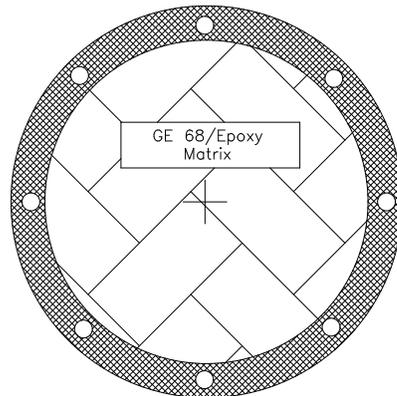
Attachment 1 BMCY-68 Phantom Drawing

REVISIONS					
LTR.	ECO NO.	DESCRIPTION	BY	DATE	APPROVED



Notes

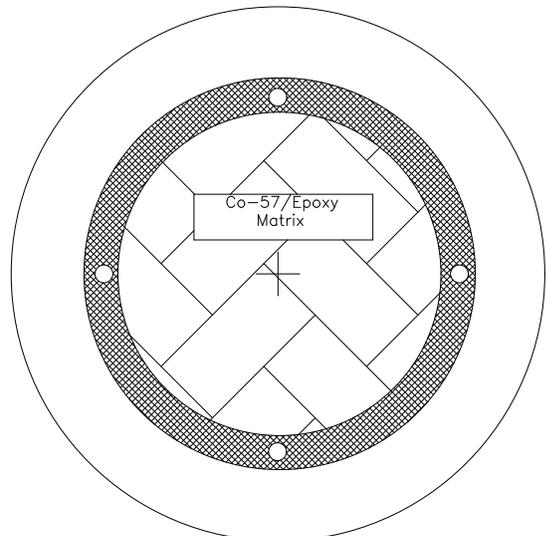
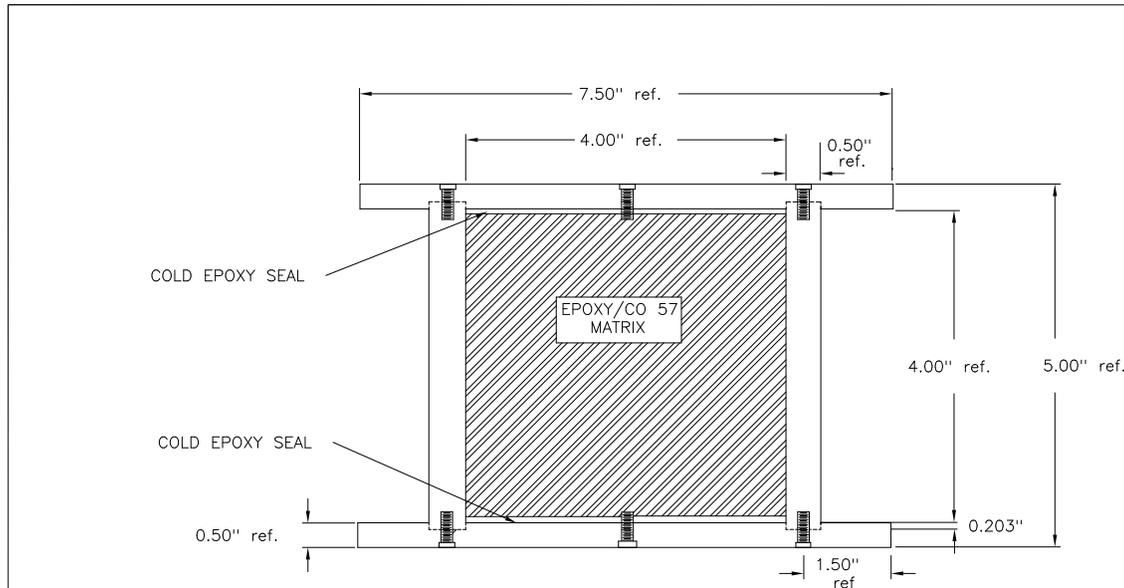
- 1) Nominal activity 2.0 mCi of Ge68/Ga68 uniformly dispersed throughout epoxy matrix (Stycast 1264 or equiv.). Both ends sealed with approx. 0.3 cm (9cc) of cold epoxy.
- 2) Final assembly consists of a source in a shielded container with labeling and inserts.
- 3) Wipe test of entire surface to yield less than 0.005 microcuries
- 4) All screws are to be inserted and backfilled on top plate.



ITEM NO.	DWG. SIZE	PART OR IDENTIFYING NO.	DESCRIPTION	QTY
			RADQUAL, LLC	
			BMCY68-DDHH-YY	
			CYLINDER PHANTOM	
			GE-68/GA-68	
			DWG. NO. RAD020309-1	REV.

MATERIAL: HDPE or EQUIV.	TOLERANCE JXX ±.01 JXX ±.005	FRACT. 1/64	ANGLES ± 30'	SCALE: NTS
AUTOCAD DWG. FILE:	DRAWN: K. Allberg 07/15/08	CHECKED:	APPROVED:	ENG:
PRIOR ASSEMBLY	NEXT ASSEMBLY	Sheet	OF	

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REVISIONS					
LTR.	ECO NO.	DESCRIPTION	BY	DATE	APPROVED

Notes

- 1) Nominal activity 5.0 mCi of Co-57. Maximum 12.0 mCi of Co-57 uniformly dispersed throughout epoxy matrix (Stycast 1264 or equiv.). Both ends sealed with approx. 0.3 cm (25cc) of cold epoxy.
- 2) Final assembly consists of a source in a shielded container with labeling and inserts.
- 3) Wipe test of entire surface to yield less than 0.005 microcuries
- 4) Total Co-56/Co-58 content to be less than 0.08% at reference date of source.
- 5) Cylinder volume is approx. 823cc total. Hot matrix equal to approx. 773cc of epoxy.
- 6) ANSI N43.6-1997 performance classification 97C22312.
- 7) Cylinder is labeled BMNT-57-YY where YY denotes the requested nominal activity level by the customer.

ITEM NO.	DWG. SIZE	PART OR IDENTIFYING NO.	DESCRIPTION	QTY
			RADQUAL, LLC	
			CYLINDER PHANTOM	
			CO-57	
			BMNT-57	
			DWG. NO. B900101	REV. B

MATERIAL: HDPE or EQUIV.	TOLERANCE JXX ±.01 JXX ±.005	DRAWN: K. Allberg	DATE: 10/12/04
AUTOCAD DWG. FILE:	FRACT. ±1/64	CHECKED:	APPROVED:
PRIOR ASSEMBLY	ANGLES ±.30'	ENG:	
NEXT ASSEMBLY	SCALE: NTS	Sheet	OF

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