TEXAS DEPARTMENT OF STATE HEALTH SERVICES

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

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March 31, 2006

U.S. Nuclear Regulatory Commission
Attn: Ms. Traci 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-104-S

Dear Ms. Kime,

Enclosed is the Safety Evaluation of Source sheet TX-1153-S-104-S for International Isotopes Idaho, Inc. This sheet is issued to describe the specifications and applications of the BM03-XXA and BM03-XXL calibration point sources. 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

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

NMSS12

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

NO.: TX-1153-S-104-S DATE: March 31, 2006

SOURCE TYPE: Calibration point source

MODEL: BM03-XXA; BM03-XXL (where XX identifies the isotope)

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

Contact: John J. Miller, CHP
(208) 524-5300

ISOTOPE:	MAXIMUM ACTIVITY:
Na-22	BM03-22L - 0.12 mCi (4.44 MBq) BM03-22A - 0.60 mCi (22.2 MBq)
Co-57	BM03-57L - 1.2 mCi (44.4 MBq) BM03-57A - 12.0 mCi (444 MBq)
Ge-68/Ga-68	BM03-68L - 0.12 mCi (4.44 MBq) BM03-68A - 0.60 mCi (22.2 MBq)

LEAK TEST FREQUENCY: 6 Months

PRINCIPAL USE: (X) Medical Reference Sources

CUSTOM SOURCE: _____ YES __X__ NO

SOURCE TYPE: Calibration point source

DESCRIPTION:

These sources are designed by RadQual, L.L.C. and consist of an epoxy resin containing the radioactive material enclosed in either Lucite or Aluminum, designated by an "A" or "L" in the model number.

The model BM03-XXL sources are constructed by placing an epoxy mixture (Stycast W-19 Parts A and B or equivalent) containing the radioactive material into a cavity centered in a Lucite disk of 0.496 to 0.498 inches (approx. 12.6 to 12.65 mm) in diameter and 0.182 to 0.185 (approx. 4.6 to 4.7 mm) inches in height. The epoxy is cured and assayed and the disk is then set into a cavity in a second Lucite disk of 1.0 inches (25.4 mm) in diameter and 0.25 inches (6.35 mm) in height so that the second disk covers the exposed surface of the epoxy. The two disks are chemically welded at the time of assembly with a solvent glue.

The model BM03-XXA sources are constructed in a similar manner to the "L" sources. The overall dimensions of the disks are the same as the "L" sources but the disks are aluminum, are of a slightly different design than the Lucite disks, and are mechanically bonded using steel set screws with an adhesive thread lock.

LABELING:

Each source and storage pig (if provided) are conspicuously labeled with the isotope, activity, assay date and model number along with a radioactive material warning label (see attachment # 6). Labels are printed on paper disks with an adhesive backing and once applied are then covered with a second clear label to keep the label from becoming worn and illegible through handling of the source or storage pig. Labels are attached to the top and bottom of each source and to the top of the storage pig.

DIAGRAM: See attachments.

CONDITIONS OF NORMAL USE:

These sources are designed for use as point reference markers, anatomical markers, and reference standards to check the response of radiation detection instruments or nuclear imaging systems. They are designed for use in a hospital or clinical environment and are not expected to encounter conditions of handling or use outside of what would normally be encountered in these environments. They should not be exposed to an environment that exceeds their ANSI/HPS N43.6-1997 classification of 97C22212.

The working lives of the models BM03-57 and BM03-68 sources are expected to be 2 years, while the BM03-22 can be expected to have a working life of 5 years.

SOURCE TYPE: Calibration point source

PROTOTYPE TESTING:

One prototype each of a model BM03-57L and a model BM03-57A, containing approximately 120 and 90 uCi respectively of Co-57, were constructed and subjected to environmental tests described in ANSI/HPS N43.6-1997 "Sealed Radioactive Sources - Classification" and achieved a classification of 97C22212.

EXTERNAL RADIATION LEVELS:

Radiation exposure rates for theses sources were modeled by the manufacturer using information available in Microshield 6.0, and are shown below. Calculated dose rates are shown in units of mR/hr / uSv/hr.

	BM03-22L 0.12 mCi (4.44 MBq)	BM03-57L 1.2 mCi (44.4 MBq)	BM03-68L 0.12 mCi (4.44 MBq)
On Contact	3,000 / 300	1,550 / 155	1,420 / 142
5 cm	49.5 / 4.95	24.1 / 2.41	22.8 / 2.28
30 cm	1.6 / 0.16	0.8 / 0.08	0.7 / 0.07
100 cm	0.14 / 0.014	0.07 / 0.007	0.07 / 0.007

	BM03-22A 0.6 mCi (22.2 MBq)	BM03-57A 12.0 mCi (444 MBq)	BM03-68A 0.6 mCi (22.2 MBq)
On Contact	15,300 / 1,530	15,300 / 1,530	7,000 / 700
5 cm	247 / 24.7	239 / 23.9	114 / 11.4
30 cm	7.8 / 0.78	7.6 / 0.76	3.4 / 0.34
100 cm	0.7 / 0.07	0.68 / 0.068	0.33 / 0.033

QUALITY ASSURANCE AND CONTROL:

All manufacturing of the Model BM03-XXA and BM03-XXL sources and related operations are to be carried out in manufacturing processes consistent with the current Good Manufacturing Practices Final Rule, Quality System Regulation, 21 CFR Part 820, under the supervision of the Quality Assurance group at International Isotopes Inc.

SOURCE TYPE: Calibration point source

QUALITY ASSURANCE AND CONTROL (Cont.):

A Technical Data Sheet will be provided with each source. Information provided on this sheet will include Leak Test Results, recommendations for source use and storage, radiation safety recommendations, source model and lot number. A Certificate of Calibration will also be provided with each source and will include information on the radioisotope and it's physical properties (i.e., half-life, emission energies and intensities), a physical description of the source, method of calibration and uncertainty.

International Isotopes, Inc. provides for procurement control, process quality control, and final quality assurance for the manufacture of these sources.

Licensed entities possessing sources that have decayed below a useful activity may contact the manufacturer/distributor for instructions regarding return of the sources.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

1. These sources shall be distributed to persons specifically licensed by the NRC or an Agreement State.

2. Handling, storage, use, and transfer: To be determined by the licensing authority. In view that these sources can exhibit high dose rates on contact, the sources should be handled by experienced licensed personnel using adequate handling equipment and procedures.

3. The sources shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 185 Bq (0.005 μCi) of removable contamination.

4. Storage/transportation shields will be provided depending upon the radioisotope and total activity of the individual source.

5. The sources shall not be subjected to conditions that exceed the ANSI/HPS N43.6-1997 classification of 97C22212.

6. 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.

SAFETY ANALYSIS SUMMARY:

Based on review of the model BM03-XXA and BM03-XXL sources, the ANSI classification for the sources, and the information cited below, we conclude that these sources are acceptable for licensing purposes.

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SOURCE TYPE: Calibration point source

SAFETY ANALYSIS SUMMARY (Cont.):

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

Note that exposure of these sources to fire could result in the release of radioactive material.

REFERENCES:

The following supporting documents for the Models BM03-XXA and BM03-XXL sources are hereby incorporated by reference and are made a part of this registry document.

- International Isotopes, Inc. application dated November 16, 2005, with enclosures thereto.
- International Isotopes, Inc. letter dated February 13, 2006, with enclosures thereto.
- International Isotopes, Inc. letter dated March 14, 2006.

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

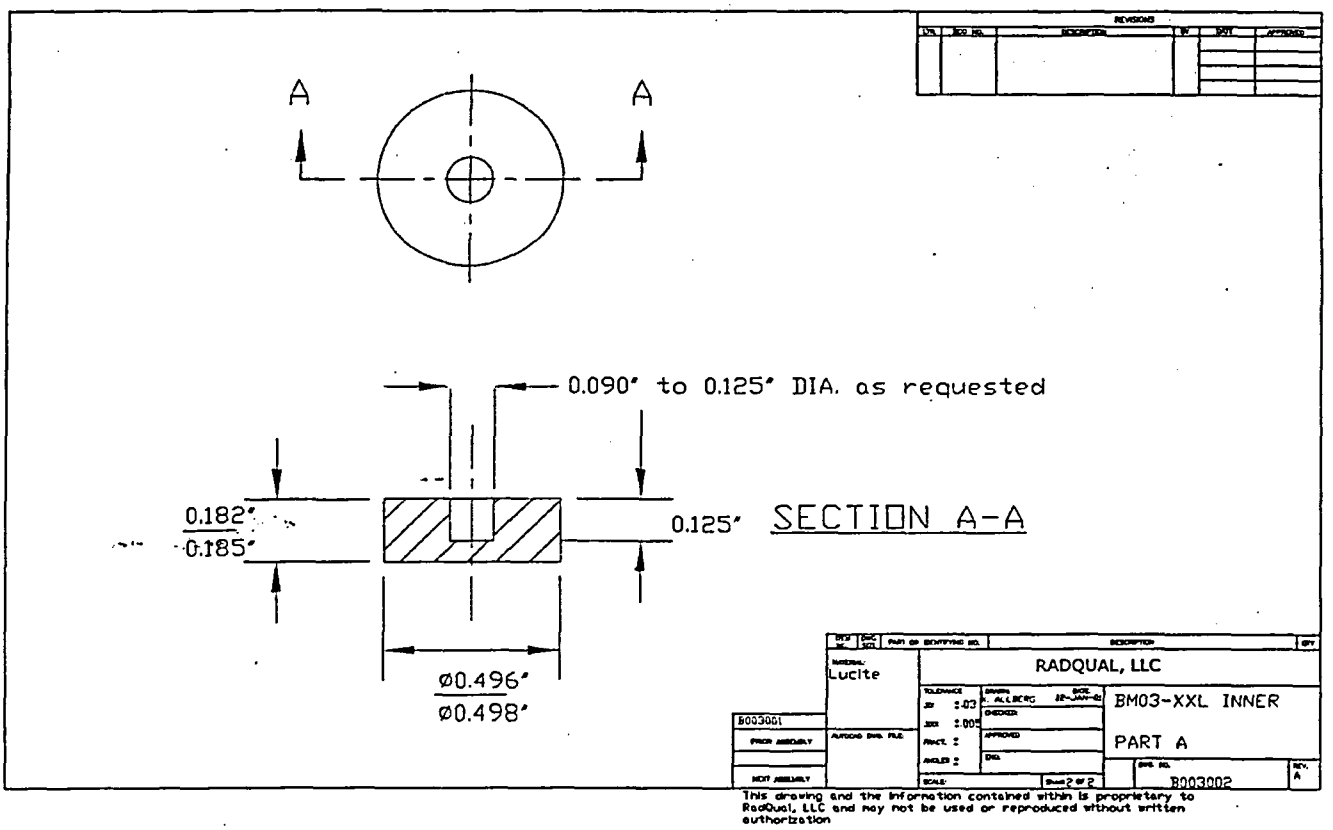
Date: March 31, 2006 Reviewer: J. Scott Kee

Date: March 31, 2006 Concurrence: David B. Fogle

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: TX-1153-S-104-S DATE: March 31, 2006 ATTACHMENT 1

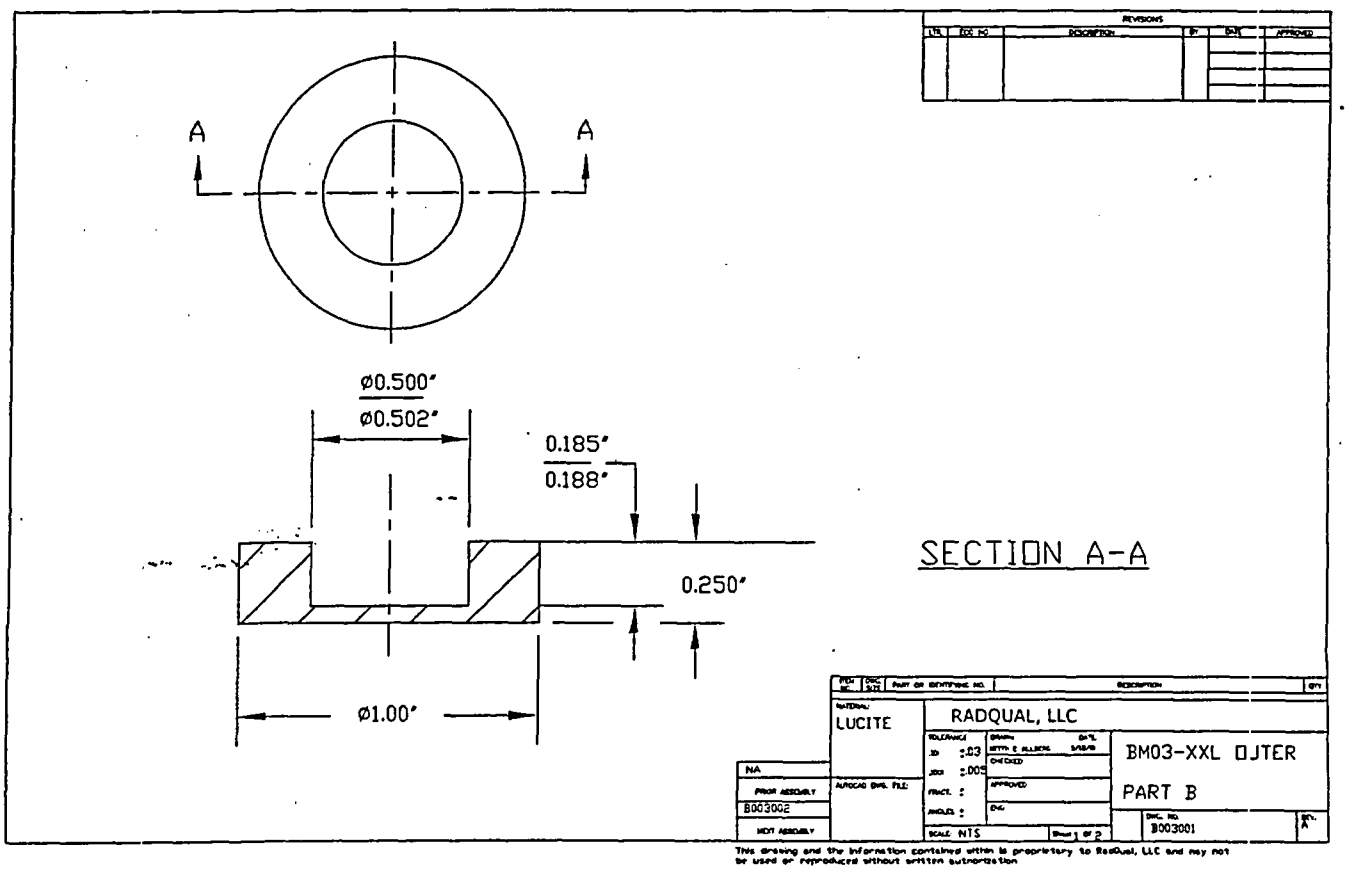
DIAGRAM: Model BM03-XXL Outer Disk



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: TX-1153-S-104-S DATE: March 31, 2006 ATTACHMENT 2

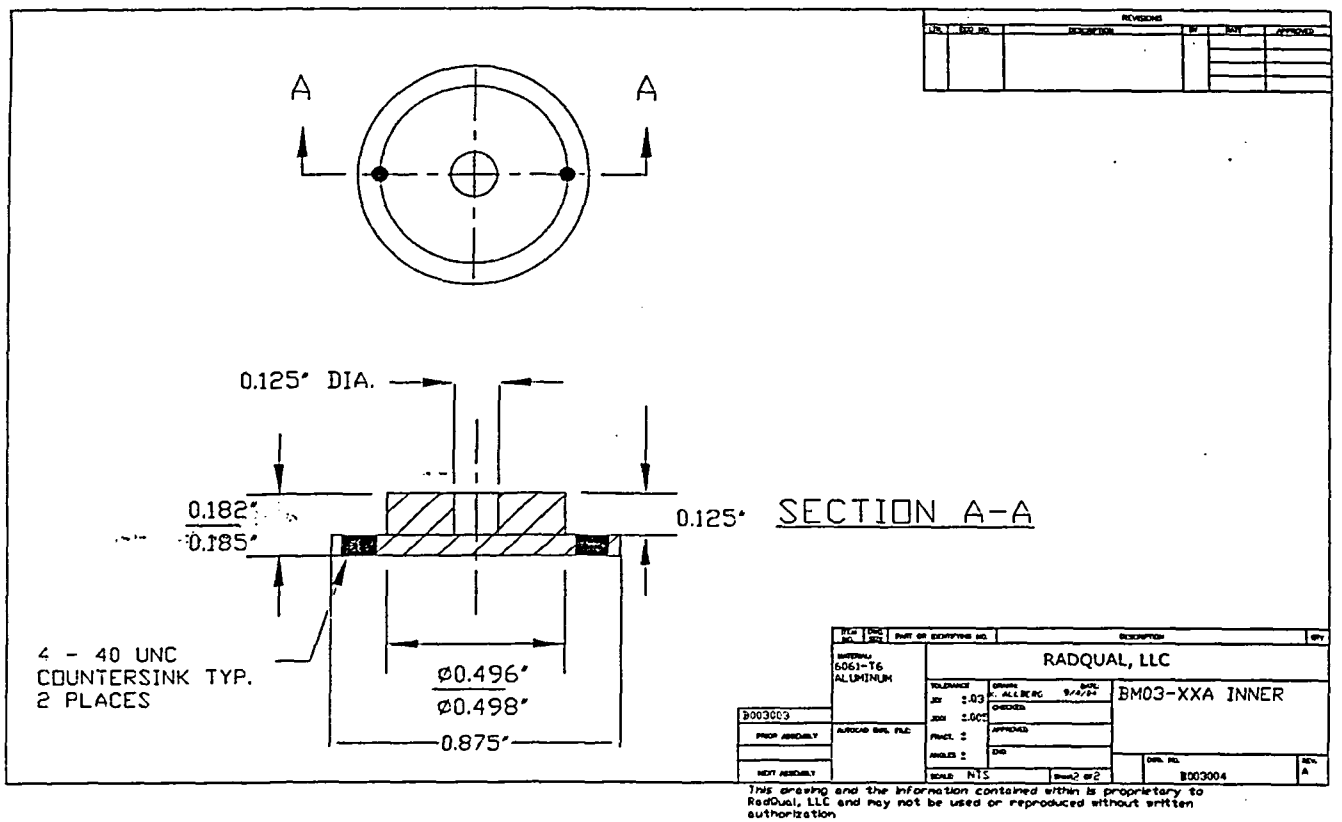
DIAGRAM: Model BM03-XXL Inner Disk



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: TX-1153-S-104-S DATE: March 31, 2006 ATTACHMENT 3

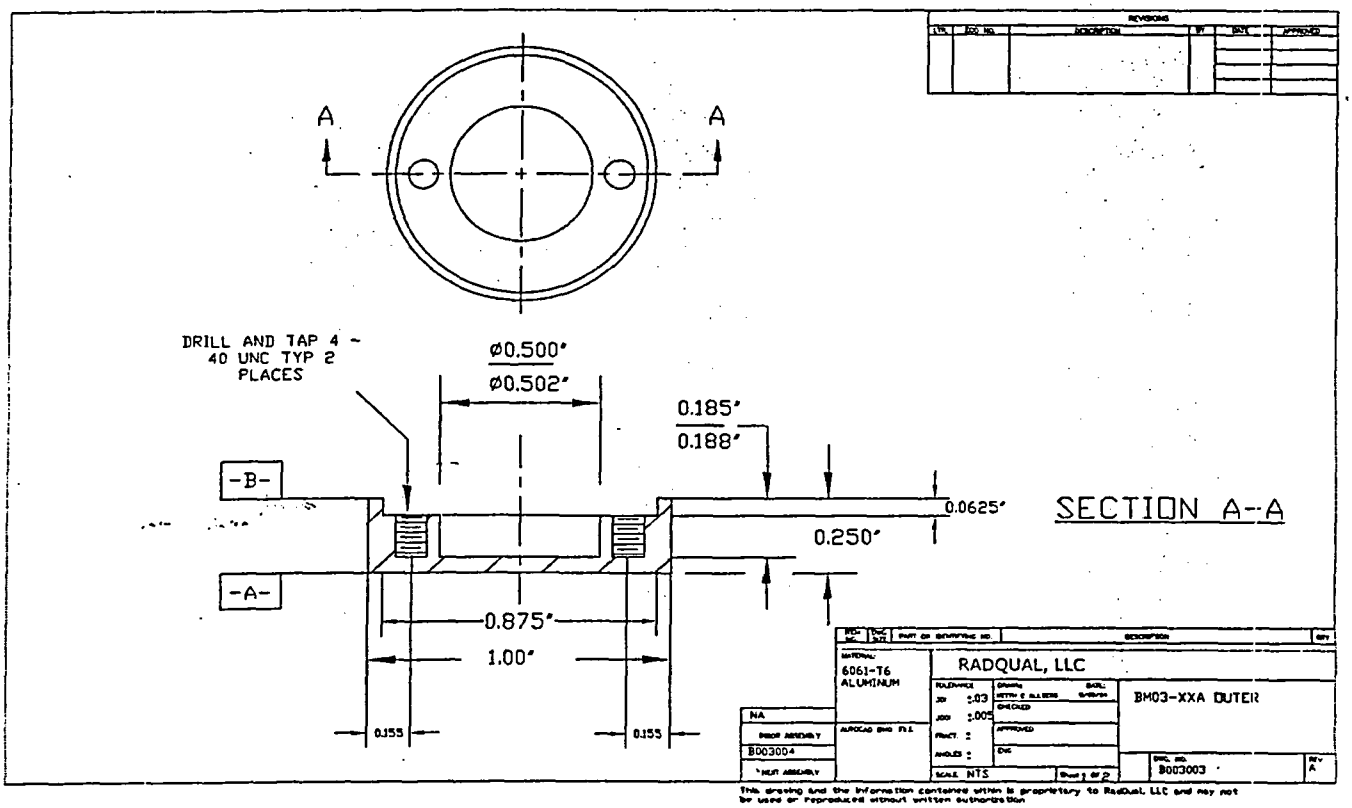
DIAGRAM: Model BM03-XXA Inner Disk



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: TX-1153-S-104-S DATE: March 31, 2006 ATTACHMENT 4

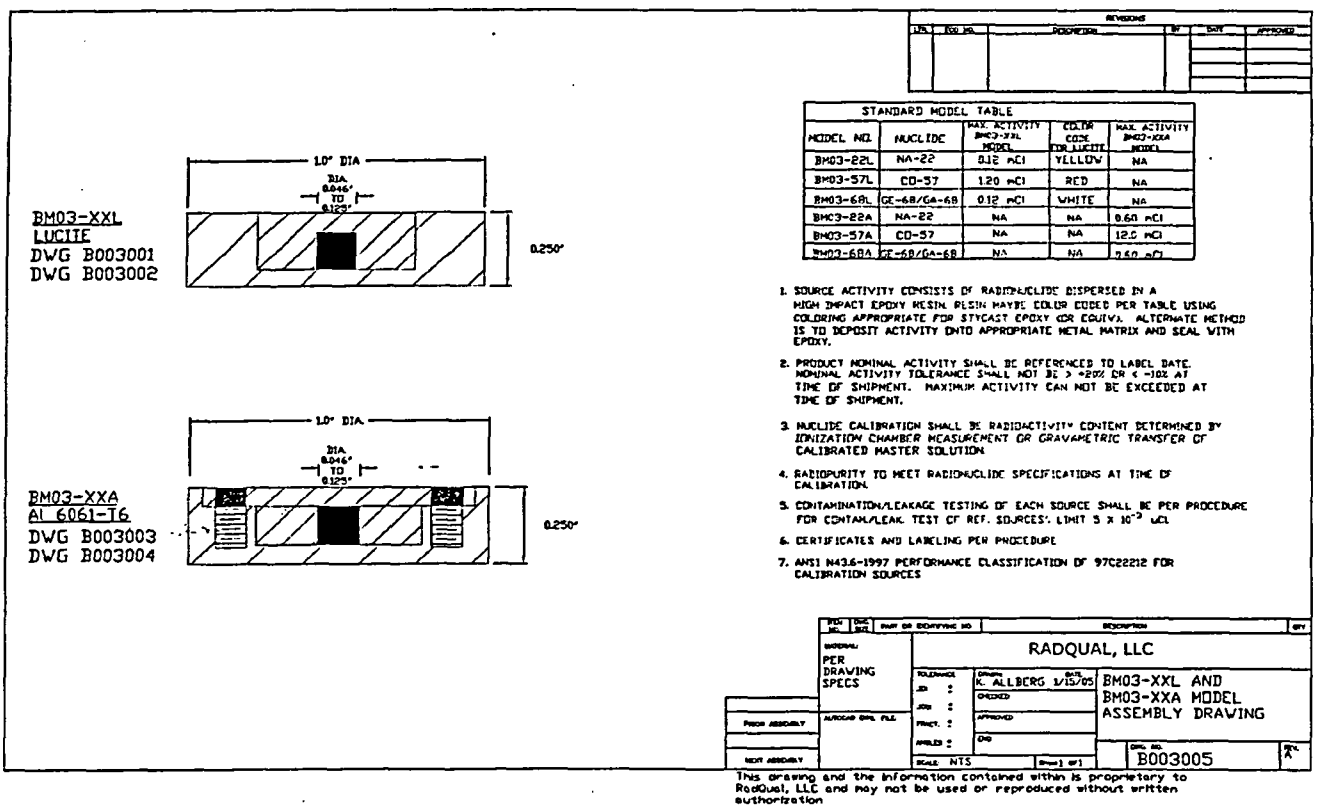
DIAGRAM: Model BM03-XXA Outer Disk



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: TX-1153-S-104-S DATE: March 31, 2006 ATTACHMENT 5

DIAGRAM: Model BM03-XXA and BM03-XXL Assembly Drawing



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: TX-1153-S-104-S DATE: March 31, 2006 ATTACHMENT 6

Source Data Label and Warning Label

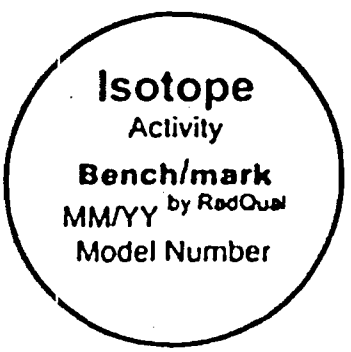


Figure 1: Source Data Label

Figure 2: Warning Label