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

NO.: TX-1153-S-105-S DATE: June 21, 2006

SOURCE TYPE: Line Source, Ruler Source

MODEL:
BM83-10 - Flexible Line Source
BM83-20 - Flexible Ruler Source
BM83-30 - Rigid Ruler Source
BM83-40 - Rigid Line Source

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

ISOTOPE:

Co-57

MAXIMUM ACTIVITY:

BM83-10	(b)(2)High
BM83-20	
BM83-30	
BM83-40	

LEAK TEST FREQUENCY: 6 Months

PRINCIPAL USE: (X) Medical Reference Sources

CUSTOM DEVICE: _____ YES __X__ NO

B-13

SOURCE TYPE: Line Source, Ruler Source

DESCRIPTION:

These sources are designed by RadQual L.L.C. for manufacture by International Isotopes, Inc. and consist of an epoxy resin containing the radioactive material encased in flexible Tygon® tubing, rigid Acrylic tubing, or stainless steel. The models BM83-10, BM83-20, and BM83-30 are manufactured by drawing a mixture of cobalt-57 chloride and high impact epoxy resin through flexible Tygon® tubing. Model BM83-10 sources are completed by securing plastic end caps over the ends of the tubing with epoxy or structural adhesive. For model BM83-20 and BM83-30 sources, the flexible tubing is cut into 1 cm segments and set into an outer casing in alternating sequence with 1 cm stainless steel or equivalent dowel pins. The outer casing for the model BM83-20 is flexible tubing, while the outer casing for the model BM83-30 is rigid Acrylic. The sources are completed by sealing the ends with plastic end caps set in place with epoxy or structural adhesive. The model BM83-40 rigid line source is manufactured as the BM83-10, but utilizing stainless steel tubing instead of Tygon®. This tubing is then inserted into another stainless steel tube and the ends of the tubes secured with stainless steel set screws.

Model	Active Length	Inner Tube O.D.	Outer Tube O.D.
BM83-10	19.7 in. (50.04 cm)	0.093 in. (2.36 mm)	N/A
BM83-20	18.5 in. (46.99 cm)	0.093 in. (2.36 mm)	0.1875 in. (4.763 mm)
BM83-30	6.7 in. (17.02 cm)	0.093 in. (2.36 mm)	0.25 in. (6.35 mm)
BM83-40	1.0 - 12.0 in. (2.54 - 30.48 cm)	0.1 in. (2.54 mm)	0.25 in. (6.35 mm)

LABELING:

Each source and storage case or shield (if provided to customer) is conspicuously marked with both source data and warning labels. The source data label is 1 ¾ inches long by ¾ of an inch in width and contains information on the radioisotope and source activity in millicuries (mCi) or microcuries (uCi), the source calibration date (MM/YY) and the source model and lot numbers. A warning label 3 ½ inches long and 1 ½ inches wide with a magenta trefoil on a yellow background with the words CAUTION RADIOACTIVE MATERIAL is affixed to the side of the source or storage case/shield opposite the data label. All labels are printed on photo quality paper with an adhesive backing. A clear protective sheet is placed over the labels to help ensure legibility through the working life of the source

DIAGRAM:

Attachment #1. - Source data and warning labels
Attachment #2. - Model BM83-10
Attachment #3. - Model BM83-20
Attachment #4. - Model BM83-30
Attachment #5. - Model BM83-40

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

SOURCE TYPE: Line Source, Ruler Source

CONDITIONS OF NORMAL USE:

These sources are designed for use in a hospital or clinical environment as reference markers, anatomical markers, and reference standards to check the response of radiation detection instruments or nuclear imaging systems. They 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 life of these sources is expected to be approximately two years.

PROTOTYPE TESTING:

One prototype of each model was manufactured with a source loading of approximately 3 μCi per cm of Co-57. Each was subjected to a series of environmental tests as described in ANSI/HPS N43.6-1997 "Sealed Radioactive Sources - Classification" and each achieved a classification of 97C22212.

EXTERNAL RADIATION LEVELS:

Radiation exposure rates for these 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 or R/hr and mSv/hr or Sv/hr.

	BM83-10	BM83-20	BM83-30	BM83-40	BM83-40, L=12 in
	(b)(2)High				(b)(2)High
On-contact	800 mR/hr (8 mSv/hr)	1 R/hr (10 mSv/hr)	5 R/hr (50 mSv/hr)	240 R/hr (2.4 Sv/hr)	12 R/hr (0.12 Sv/hr)
5 cm	75 mR/hr (0.75 mSv/hr)	200 mR/hr (2 mSv/hr)	200 mR/hr (2 mSv/hr)	1.2 R/hr (0.012 Sv/hr)	600 mR/hr (6 mSv/hr)
30 cm	6 mR/hr (0.06 mSv/hr)	7 mR/hr (0.07 mSv/hr)	7 mR/hr (0.07 mSv/hr)	40 mR/hr (0.4 mSv/hr)	35 mR/hr (0.35 mSv/hr)
100 cm	0.6 mR/hr (0.006 mSv/hr)	0.6 mR/hr (0.006 mSv/hr)	0.6 mR/hr (0.006 mSv/hr)	4 mR/hr (0.04 mSv/hr)	4 mR/hr (0.04 mSv/hr)

Note: On-contact dose calculated at 0.5 cm from the surface of the source.

SOURCE TYPE: Line Source, Ruler Source

QUALITY ASSURANCE AND CONTROL:

All manufacturing of the sources described in this sealed source evaluation 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.

A technical data sheet will be provided with each source. Information on this sheet will include Leak Test Results, Recommended Use and Storage, and Radiation Safety Recommendations. A Certificate of Calibration is also provided with each source and gives information on the source model and lot number, the name of the radioisotope, the half-life, source emission data (i.e. energies and intensities of emitted radiations), a physical description of the source, method of calibration and total activity of the source with uncertainty of source loading.

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 level 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, an Agreement State or a Licensing State.

2. Handling, storage, use, transfer and disposal 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 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 0.005 microcurie (185 Bq) of removable contamination.

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

5. Storage/transportation shields will be provided depending upon the maximum activity of the individual source.

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.

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

NO.: TX-1153-S-105-S DATE: June 21, 2006

SOURCE TYPE: Line Source, Ruler Source

SAFETY ANALYSIS SUMMARY:

Based on review of the sources described in this registration sheet, the ANSI classification for the sources, and the information cited below, we conclude that these sources are acceptable for licensing purposes. Furthermore, we conclude that the sources would be expected to maintain their containment integrity for normal conditions of use and most accident conditions which might occur during uses specified in this certificate.

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

REFERENCES:

The following supporting documents for the sources described in this registration sheet are hereby incorporated by reference and are made a part of this document.

- International Isotopes, Inc. application dated February 14, 2006, with enclosures thereto.
- International Isotopes, Inc. facsimile dated April 19, 2006, with associated source diagrams.

ISSUING AGENCY: Bureau of Radiation Control
Texas Department of Health

Date: June 21, 2006 Reviewer: J. Scott Kee

Date: June 21, 2006 Concurrence: David B. Fogle

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

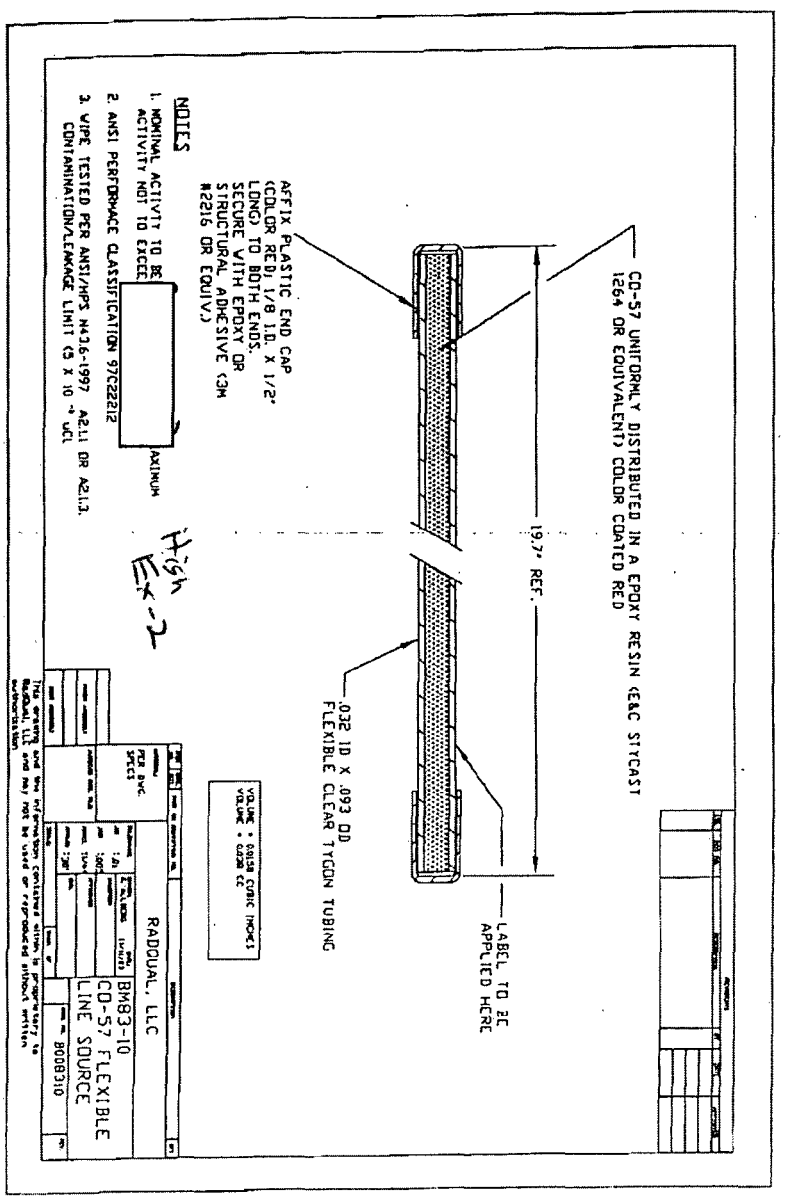
NO.: TX-1153-S-105-S DATE: June 21, 2006 ATTACHMENT 1

DIAGRAM: Source Data and Warning Labels

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: TX-1153-S-105-S DATE: June 21, 2006 ATTACHMENT 2

DIAGRAM: Model BM83-10

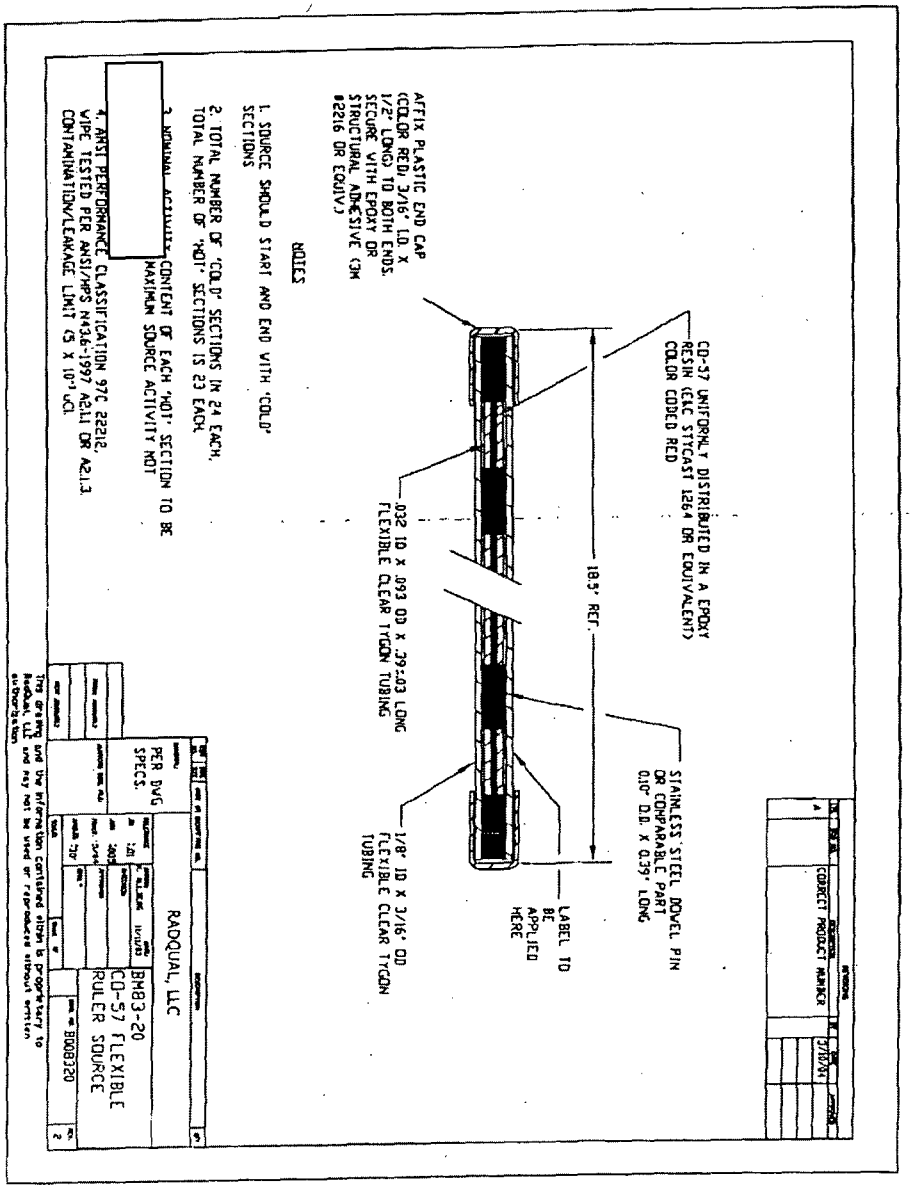


REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: TX-1153-S-105-S DATE: June 21, 2006 ATTACHMENT 3

DIAGRAM: Model BM83-20

High Ex-2



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

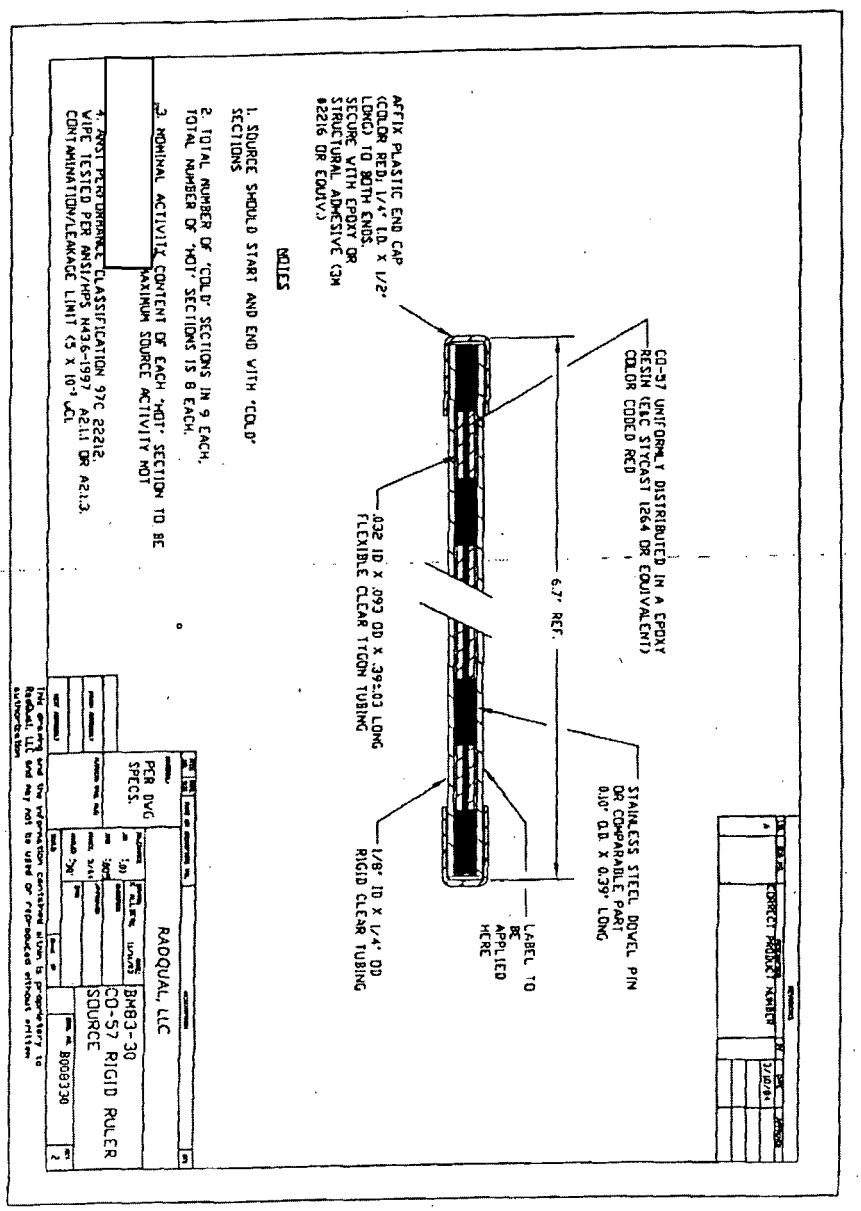
NO.: TX-1153-S-105-S

DATE: June 21, 2006

ATTACHMENT 4

DIAGRAM: Model BM83-30

High
Ex2



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: TX-1153-S-105-S DATE: June 21, 2006 ATTACHMENT 5

DIAGRAM: Model BM83-40

High
Ex-2