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

NO.: NR-0187-S-105-S DATE: May 7, 2012

SOURCE TYPE: Flood Sources

MODEL:	5302 Series (rectangular) 5303 Series (circular)
MANUFACTURER/DISTRIBUTOR:	Best Medical International, Inc. 7643 Fullerton Road Springfield, VA 22153

ISOTOPE:	MAXIMUM ACTIVITY:
Co-57	25 mCi (0.93 GBq)

LEAK TEST FREQUENCY:	6 Months
PRINCIPAL USE:	(X) Medical Reference Source
CUSTOM SOURCE:	_____ Yes __X__ No

SOURCE TYPE: Flood Sources

DESCRIPTION:

The 5302 Series and 5303 Series models consists of Co-57 uniformly dispersed in high impact epoxy resin (active matrix) approximately 0.25" thick. This active matrix is sealed between two halves of a pre-formed durable molded outer housing. The housing is made of ABS plastic (0.06" minimum thickness) and is sized and shaped to completely contain the active matrix. A thin small celled soft packing sheet of foam is used as a spacer to stabilize the active matrix within the housing when the interlocking lips of the two halves are joined.

Each source is supplied with a shielded storage container.

These source series represent a range of source configurations to match the detector size requirements for a particular nuclear medicine (SPECT) gamma imaging camera system. Sources are either rectangular (5302 Series) or circular (5303 Series) in shape. Models in the 5302 Series range from 9"x9" to 18" x 26". Models in the 5303 Series range from 13" to 26" in diameter. The model number identifies the source dimension(s) as shown below.

Source Model Dimensions

Source Model	Dimensions	Shape
5302-XY	$9" \leq X \leq 26"$ $9" \leq Y \leq 18"$	Rectangular
5303-D	$13" \leq D \leq 26"$	Circular

Models in the 5302 Series include 5302-2416, 5302-1814, and 5302-1410.

Models in the 5303 Series include 5303-18.

SOURCE TYPE: Flood Sources

LABELING:

Each source and accompanying shielded lead container is labeled with a durable adhesive backed label identifying the manufacturer. The label includes the model number, isotope, activity level, serial number, reference date, the trefoil, and states "Caution- Radioactive Material." The label also includes the following statement "The U.S. Nuclear Regulatory Commission has approved distribution of this product to NRC and Agreement State Licensees. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited."

The 6.75" x 4.75" label is centered on the upper portion of the source. A second label is centered on the front face of the shielded container supplied with the source.

DIAGRAM:

See Attachments 1 through 3.

CONDITIONS OF NORMAL USE:

The source is designed and manufactured for daily use in nuclear imaging departments under controlled laboratory conditions to provide a uniform field of radiation for evaluation of nuclear medicine gamma camera (SPECT) performance, where possible camera malfunctions could interfere with diagnostic procedures. The sources should be handled by qualified individuals and should not be subjected to extreme temperatures. The upper working temperature is 80° C (176° F). The lower working temperature is -20° C (-4° F).

The estimated working life of the source is approximately 2 years due to radioactive decay.

SOURCE TYPE: Flood Sources

PROTOTYPE TESTING:

Two prototype units (one Model 5302-2416 and one Model 5303-18), each containing 2 millicuries (mCi) of Co-57, were subjected to the tests provided in ANSI N 43.6-2007 and achieved a classification of 07C22314, which exceeds the required level of 07C22212 "Calibration Source Activity >30 µCi."

EXTERNAL RADIATION LEVELS:

The radiation levels below were reported by the manufacturer for source models in the 5302 Series and 5303 Series. Radiation levels for the maximum source activity were calculated based on measurements of a 5 mCi Model 5302-2416. Radiation levels were extrapolated to the maximum source activity with the smallest dimensions.

Table 1 Maximum Radiation Levels (mR/hr)

Co-57 Source			Distance from Source			
Model	Activity		Surface	5 cm	30 cm	100 cm
5302-2416	5 mCi	M	40	30	6	1.5
5302-2416	25 mCi	C	210	140	30	5
5302-0909	25 mCi	E	1025	685	155	25

M – Measured directly
C – Calculated from measurements
E – Extrapolated to smallest source

QUALITY ASSURANCE AND CONTROL:

Best Medical International maintains a quality assurance and control program that conforms to ISO 13485:2003 and 21 CFR Part 820. The Best Medical QA/QC program has been deemed acceptable for licensing purposes by NRC. A copy of the program manual is on file with NRC.

SOURCE TYPE: Flood Sources

QUALITY ASSURANCE AND CONTROL (Cont'd):

All manufacturing of the 5302 Series and 5303 Series source models 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 Best Medical International.

1. Leak Testing: The sources are leak tested in accordance with procedure WI 09.91.400(1), "Wipe (Smear) Test" prior to transfer.

2. Activity Level: Activity levels of each source manufactured shall be kept to within +/- 5% of the stated activity value, not to exceed the maximum activity.

3. Radiopurity: Isotopes used for manufacturing shall have a radiopurity of 99% or better with respect to other nuclides (except associated daughters), as determined by gamma spectroscopy of the batch used, prior to production.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The source shall be distributed to persons specifically licensed by the NRC or an Agreement State.

- Handling, storage, use, transfer and disposal: To be determined by the licensing authority.

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

SOURCE TYPE: Flood Sources

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (Cont'd):

- The source shall not exceed the stated maximum activity level or maximum radiation levels.
- The source shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 185 Bq (0.005 µCi) of removable contamination.
- The source shall not be subjected to conditions that exceed its ANSI N43.6-2007 classification, 07C22314.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

FDA APPROVAL SUMMARY

This source was determined by the U.S. Food and Drug Administration to be a Class 1 medical device and exempt from premarket notification procedures per 21 CFR 892.1380.

SAFETY ANALYSIS SUMMARY:

Based on review of the 5302 Series and 5303 Series sealed source models, their ANSI classification, and the information and test data cited below, we conclude that these sources are acceptable for licensing purposes.

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

SOURCE TYPE: Flood Sources

REFERENCES:

The following supporting documents for the 5302 Series and 5303 Series sealed source models are hereby incorporated by reference and are made a part of this registry document.

- Best Medical International Corporation's application dated April 18, 2011, with enclosures thereto.
- Best Medical International Corporation's letters dated August 26, 2011, December 9, 2011, and February 20, 2012, with enclosures thereto.
- Best Medical International Corporation's electronic mail dated March 28, 2012.

ISSUING AGENCY:

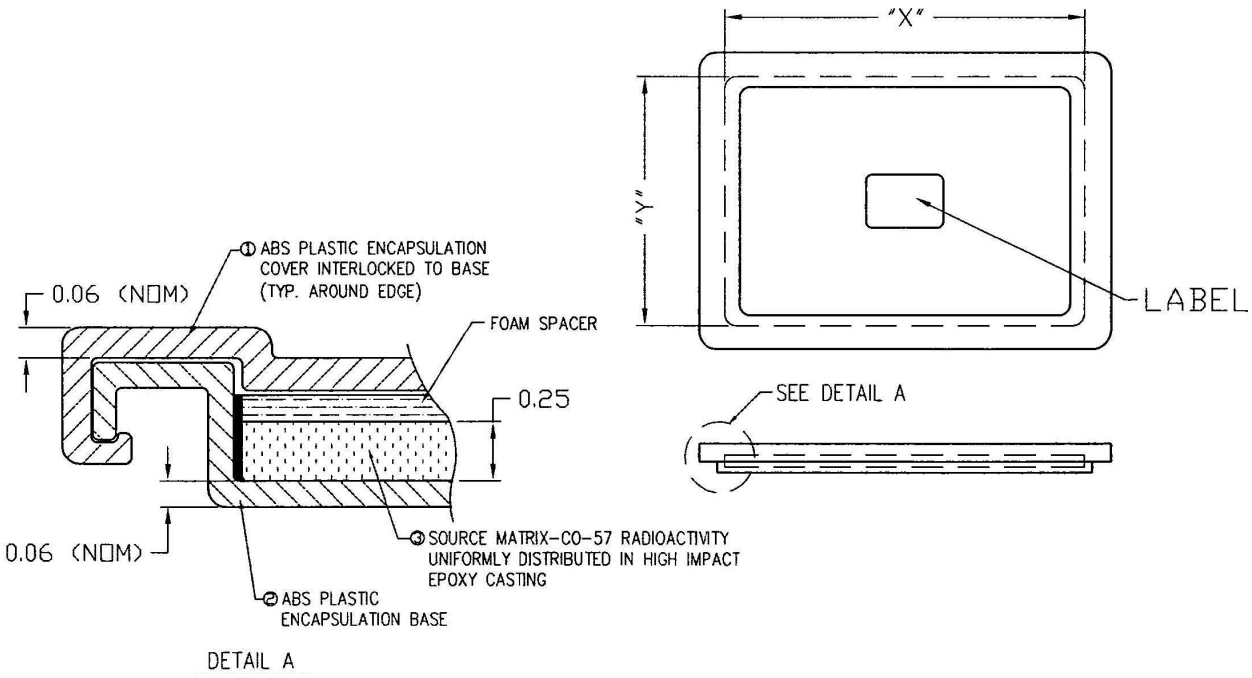
U.S. Nuclear Regulatory Commission

Date: May 7, 2012 Reviewer: **/RA/**
John O'Donnell

Date: May 7, 2012 Concurrence: **/RA/**
Lymari Sepulveda

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

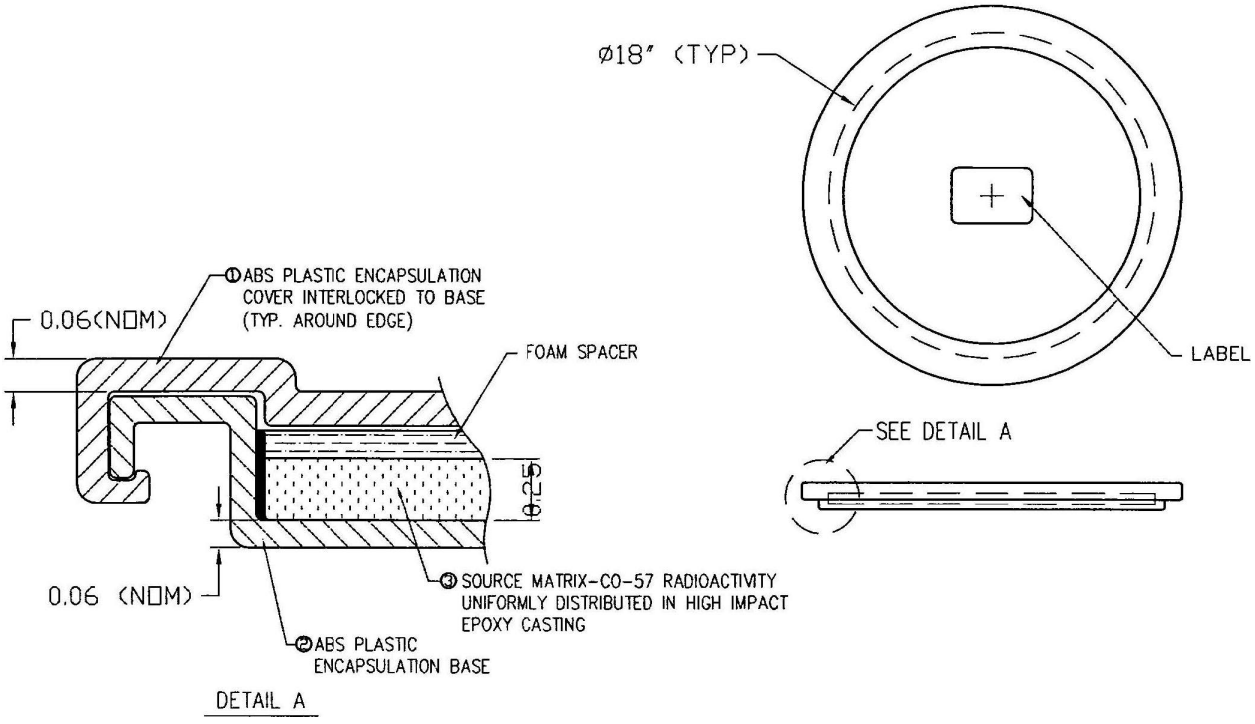
NO.: NR-0187-S-105-S DATE: May 7, 2012 ATTACHMENT 1 OF 3



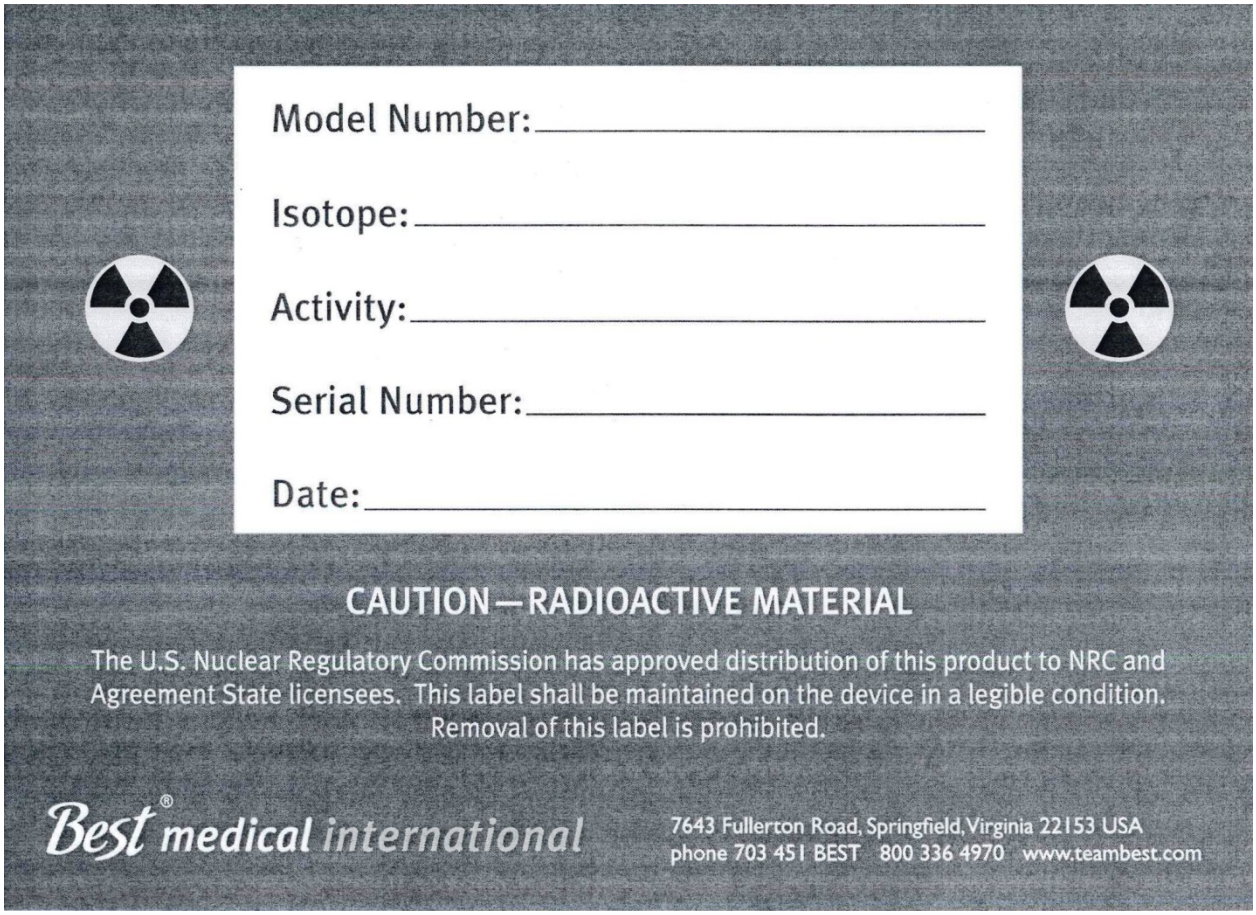
5302 Series
Flood Source

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

NO.: NR-0187-S-105-S DATE: May 7, 2012 ATTACHMENT 2 OF 3



5303 Series
Flood Source



5302 Series and 5303 Series Label
For Source and Container
(Actual size is 6.75" x 4.75")