

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

NO.: NR-0187-S-106-S DATE: May 7, 2012

PAGE 1 of 6

SOURCE TYPE: Spot Marker

MODEL: 5304

MANUFACTURER/DISTRIBUTOR: Best Medical International, Inc.
7643 Fullerton Road
Springfield, VA 22153

ISOTOPE: MAXIMUM ACTIVITY:

Co-57 200 µCi (7.4 MBq)

LEAK TEST FREQUENCY: 6 Months

PRINCIPAL USE: (X) Medical Reference Source

CUSTOM SOURCE: Yes X No

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

NO.: NR-0187-S-106-S DATE: May 7, 2012

PAGE 2 of 6

SOURCE TYPE: Spot Marker

DESCRIPTION:

The Model 5304 is a 1" acrylic disc, approximately 0.25" thick with a hole bored approximately 0.125" diameter by 0.125" deep. The radioactive material is deposited in the hole and allowed to dry. The radioactive material is sealed beneath two layers of epoxy. The first epoxy layer is allowed to dry before the second layer is applied.

LABELING:

Each source and accompanying shielded lead container is labeled with a durable adhesive backed label. The source label is 15/16" in diameter centered on the face of the source to cover the epoxy seals. The source label includes the model number, isotope, activity level, serial number, reference date, the trefoil, and states "Caution- Radioactive Material."

The hinged storage case allows for a 2" x 2" label centered on the front face of the case. In addition to the information on the source label this label includes company contact information and 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."

DIAGRAM:

See Attachments 1 and 2

CONDITIONS OF NORMAL USE:

The source is designed and manufactured for daily use in nuclear imaging departments under controlled laboratory conditions for image reference and orientation relative to patient positioning. The sources should be handled by qualified individuals and should not be subjected to extreme temperatures. The upper working temperature is 90° C (194° F). The lower working temperature is -60° C (-76° F).

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

NO.: NR-0187-S-106-S DATE: May 7, 2012

PAGE 3 of 6

SOURCE TYPE: Spot Marker

CONDITIONS OF NORMAL USE (Cont'd):

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

PROTOTYPE TESTING:

Two prototype units of the Model 5304 source containing 100 microcuries (μCi) 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 $>30 \mu\text{Ci}$."

EXTERNAL RADIATION LEVELS:

The calculated radiation levels below were reported by the manufacturer for Model 5304 sources containing the maximum source activity (200 μCi), based on the radiation level measurements of the 100 μCi prototypes also shown below.

Table 1 Maximum Radiation Levels (mR/hr)

<u>Source</u>		<u>Distance from Source</u>			
<u>Isotope</u>	<u>Activity</u>	<u>Surface</u>	<u>5 cm</u>	<u>30 cm</u>	<u>100 cm</u>
Co-57	100 μCi	30	6	0.2	Bkg ¹
Co-57	200 μCi	60	12	0.4	Bkg ¹

¹Bkg - Indistinguishable from natural background radiation levels

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

NO.: NR-0187-S-106-S DATE: May 7, 2012

PAGE 4 of 6

SOURCE TYPE: Spot Marker

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.

All manufacturing of the Model 5304 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 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.

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

NO.: NR-0187-S-106-S DATE: May 7, 2012

PAGE 5 of 6

SOURCE TYPE: Spot Marker

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. The source should be handled by experienced licensed personnel using adequate handling equipment and procedures.
- 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 μ Ci) 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 892.1100.

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

NO.: NR-0187-S-106-S DATE: May 7, 2012

PAGE 6 of 6

SOURCE TYPE: Spot Marker

SAFETY ANALYSIS SUMMARY:

Based on review of the Model 5304 sealed source, its ANSI classification, and the information and test data cited below, we conclude that the source is acceptable for licensing purposes. Furthermore, we conclude that the source would be expected to maintain its containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REFERENCES:

The following supporting documents for the Model 5304 sealed source 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

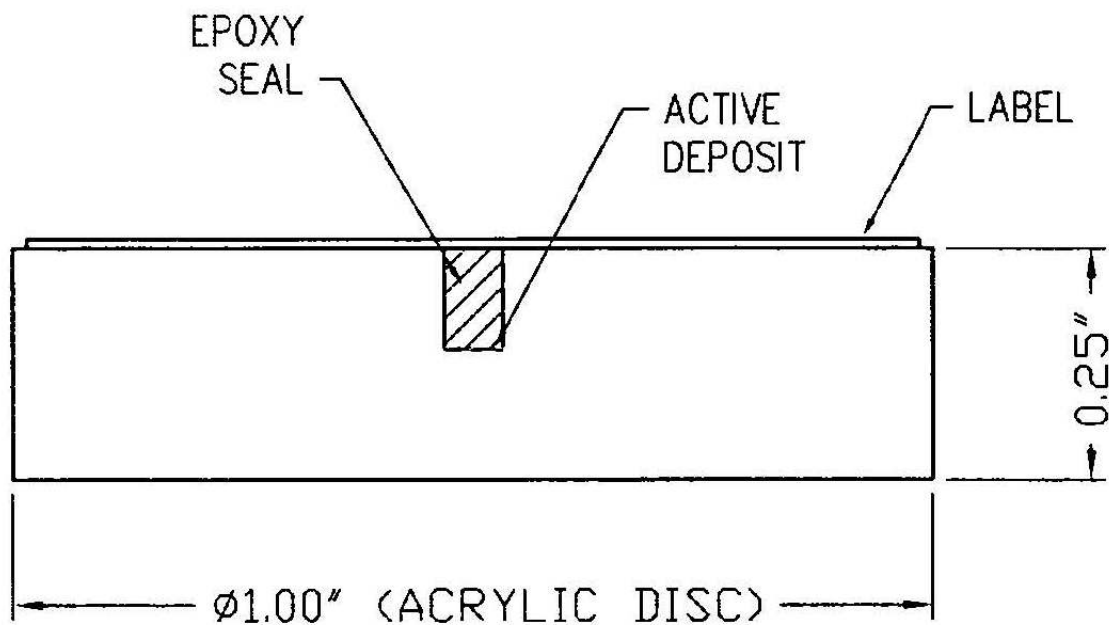
Reviewer: /RA/
John O'Donnell

Date: May 7, 2012

Concurrence: /RA/
Lymari Sepulveda

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

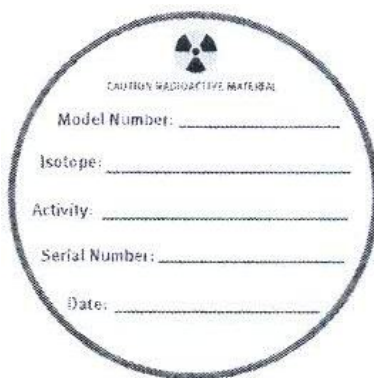
NO.: NR-0187-S-106-S DATE: May 7, 2012 ATTACHMENT 1 OF 2



Model 5304
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REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO.: NR-0187-S-106-S DATE: May 7, 2012 ATTACHMENT 2 OF 2



Model 5304 Label
(15/16" diameter)