REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
**(AMENDED IN ITS ENTIRETY)**

NO.: NR-0187-S-103-S DATE: January 14, 2003 

SOURCE TYPE: Therapeutic Brachytherapy Seed Sources

MODEL: 2300 Series (see description for approved models)

MANUFACTURER/DISTRIBUTOR: **Best Medical International, Inc.**
(**Formerly** Best Industries, Inc.)
7643 Fullerton Rd.
Springfield, VA 22153

| ISOTOPE: | MAXIMUM ACTIVITY: |
|---|---|
| Iodine-125 | 110 millicuries (4.07 GBq) |
| Cesium-131 | 110 millicuries (4.07 GBq) |
| Palladium-103 | 110 millicuries (4.07 GBq) |
| Samarium-145 | 110 millicuries (4.07 GBq) |

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: (V) **For use in accordance with 10 CFR 35.400 through 35.491 (Subpart F) or the equivalent state regulations**

CUSTOM SOURCE: _____YES ____X___NO

SOURCE TYPE: Therapeutic Brachytherapy Seed Sources

DESCRIPTION:

The Model 2300 Series (2301-2345) therapeutic seed sealed sources consist of the radioisotope either in liquid form and adsorbed onto various substrate material or as solid samarium-145, singly encapsulated in a cylindrical double-walled titanium capsule, and sealed by laser weld. Liquid radioisotopes may be iodine-125, cesium-131, or palladium-103. The different model numbers refer to different substrates. The substrates for iodine sources may be rods or balls of carbon1 polytyrosine, or anion exchange resin and may contain an x-ray marker in their center. Substrates for all isotopes are chosen for their affinity to the isotope with which they are used.

Substrate material, with adsorbed radioactive material in suitable quantities to provide the desired activity, or solid Sa-145 of the desired activity, is placed into an ASTM B265, Grade 2, titanium capsule with one end open. Another titanium capsule with a slightly larger diameter and open at one end is placed over the first tube and welded in place, completing the encapsulation. Each of the capsules cylindrical walls is 0.0016" (0.04 mm) thick for a total thickness of 0.0031" (0.08 mm). Each of the capsule ends is 0.08 mm thick. The approved model numbers and isotopes within the series are shown below with the capsules nominal external dimensions:

| Model Numbers | Isotope | Nominal Dimensions |
|---|---|---|
| 2301-2308 | I-125 | 0.03" X 0.20" (0.80 X 5.00 mm) |
| 2309-2316 | I-125 | 0.028" X 0.19" (0.70 X 4.70 mm) |
| 2321-2325 | Cs-131 | 0.03" X 0.20" (0.80 X 5.00 mm) |
| 2331-2335 | Pd-103 | 0.03" X 0.20" (0.80 X 5.00 mm) |
| 2341-2345 | Sm-145 | 0.03" X 0.20" (0.80 X 5.00 mm) |

Nominal activity of the sources varies from 0.1 mCi to 100.0 mCi (0.0037 GBq to 3.7 GBq) with an accuracy of ±10%. Each source is calibrated as part of a batch of sources with common nominal activity. Calibrated batches of sources are stored or shipped in one of the following containers: small glass vials, Royal Marsden cartridges, Mick magazines, Best magazines or cartridges, nylon ribbons, absorbable vicryl sutures or absorbable tubes.

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LABELING:

Due to their small size, individual sources are not labeled, but rather are the storage and shipping containers are labeled. The sources are supplied as a group with total activity within a stated range as of the assay date. The storage/shipping containers are labeled with the isotope, number of sources, average activity per source, total activity, date of assay, manufacturer's logo, the words "Caution-Radioactive Material" and the trefoil radiation symbol. The labels comply with the provisions of 10 CFR 32.74, 20.1901, and 20.1904. For shipment, these containers are additional placed in an outer cardboard or metal container and accompanied by an invoice that indicates the model and batch number for the sources.

DIAGRAM:

See Attachments 1 and 2.

CONDITIONS OF NORMAL USE:

The sources are to be used in the permanent or temporary interstitial treatment of cancerous tumors and are expected to be subjected to only mildly acidic or alkaline conditions within the human body. In addition, the sources are designed to be sterilized using ethylene oxide or by autoclave at temperatures and pressures up to 275°F (135°C) and 30 psi (206.9 kPa). Dry heat sterilization methods shall not be employed. Due to the high dose rates from the sources, appropriate handling equipment, such as forceps, must be used. Ruptured or damaged sources should never be used.

PROTOTYPE TESTING:

Prototypes of the source capsules containing carbon ball substrates without radioactive material were subjected to tests to demonstrate that the sources will maintain their integrity under normal use and accident conditions that may occur. These tests included percussion, compression, forceps use simulation, autoclave temperatures and pressures, and impact tests.

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PROTOTYPE TESTING (cont'd):

The tests performed closely followed the recommendations of ANSI N44.1-1973. The only deviations from the recommended ANSI procedures were for the high temperature and impact tests. Results show that the sources retain their integrity up to temperatures of 482°F (250°C) for the high temperature test. The capsules lost their integrity and ruptured at temperatures above 1022°F (550°C). The capsules are not to be subjected to autoclave temperatures in excess of 275°F (135°C). Impact testing results showed that the capsules maintained their integrity when dropped from a height of 8' (2.44 m). A drop test of greater than 8' was not conducted since the sources are not likely to be dropped from a height greater than normal table height of 4 feet (1.22 m).

The manufacturer indicates the sources passed each of these tests.

EXTERNAL RADIATION LEVELS:

External radiation levels from a 100 mCi iodine-125 source were determined by in-air planer and vertical dosimetry measurements to be as follows:

| Distance from source | Radiation levels mrem/hr (μSv/hr) |
|---|---|
| 1.97" (5 cm) | 2500 (25000) |
| 11.8" (30 cm) | 53.0 (530) |

The following are the maximum external radiation levels for the Pd-103, Cs-131, and Sa-145 sources containing 100 mCi of each isotope, as estimated by the manufacturer:

| Distance from the source | Radiation levels - mrem/hr (μSv/hr) Pd-103 | Sa-145 | Cs-131 |
|---|---|---|---|
| 1.97" (5 cm) | 59.2 (592) | 31.0 (310) | 32.0 (320) |
| 11.8"(30 cm) | 1.64 (16.4) | 0.86 (8.6) | 0.89 (8.9) |
| 39.4"(100 cm) | 0.148 (1.48) | 0.078 (0.78) | 0.08 (0.80) |

SOURCE TYPE: Therapeutic Brachytherapy Seed Sources

QUALITY ASSURANCE AND CONTROL:

**Best Medical International, Inc.** (**formerly** Best Industries) maintains a quality control (QC) program that has been deemed acceptable for licensing purposes by the NRC. A copy of the program is on file with the NRC. The QC program for the 2300 Series brachytherapy seeds includes ensuring the identity of incoming titanium capsules and radioisotopes, conducting material and dimensional checks, initial leak tests, autoclave and second leak test, visual micro-inspection of capsule assembly and welding, and assay for activity of each lot of capsules and substrates. Any seed found with more than 0.005 $\mu$Ci (185 Bq) of removable contamination is rejected.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The 2300 Series sources may be distributed only to persons specifically licensed by the NRC or an Agreement State.
- The sources shall not be exposed to concentrated acids or alkaline fluids or sterilized by dry heat methods.
- The sources shall not be exposed to temperatures in excess of 275°F (135°C) and pressures in excess of 30 psi (206.9 kPa).
- The sources shall not be autoclaved in plastic tubing or plastic containers. Only autoclave suitable materials such as stainless steel, glass, nylon, teflon, lead or tin should be used.
- The sources shall be leak tested at intervals not to exceed six months using techniques capable of detecting the 0.005 microcurie (185 Bq) of removable contamination.
- REVIEWER NOTE: Please ensure the safety procedures outlined in 10 CFR Part 35, **Subpart F** are adhered to, especially as they pertain to the handling of the sources.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority. The sources shall be

SOURCE TYPE: Therapeutic Brachytherapy Seed Sources

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

handled only with appropriate: equipment (due to the high activity of the sources forceps are recommended).

- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

Based on our review of the information and test data cited below and the past history of similar source designs, we continue to conclude that **Best Medical International, Inc. (formerly** Best Industries) 2300 Series sealed sources are acceptable for licensing purposes.

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

REFERENCES:

The following supporting documents for **Best Medical International, Inc. (formerly** Best Industries) 2300 Series therapeutic sealed sources are hereby incorporated by reference and are made a part of this registry document.

- Best Industries' application dated April 30, 1991.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
**(AMENDED IN ITS ENTIRETY)**



DEVICE TYPE: Therapeutic Brachytherapy Seed Sources

REFERENCES (cont'd):

- Best Industries' letters dated July 13, 1994, June 10, 1994, October 27, 1993, October 6, 1993, August 3, 1993, July 9, 1993, May 4, 1993, December 4, 1991, October 30, 1991, October 7, 1991, August 14, 1991, July 17, 1991, May 30, 1991, and May 15, 1991, with enclosures thereto.

- **Best Medical International, Inc. letter dated November 26, 2002, and electronic mail dated January 10, 2003.**

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: January 14, 2003 Reviewer: John P. Jankovich

Date: January 14, 2003 Concurrence: Ujagar S. Bhachu

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
**(Amended in its entirety)**

NO.: NR-0187-S-103-S DATE: January 14, 2003 ATTACHMENT 1

DEVICE TYPE: Therapeutic Brachytherapy Seed Sources

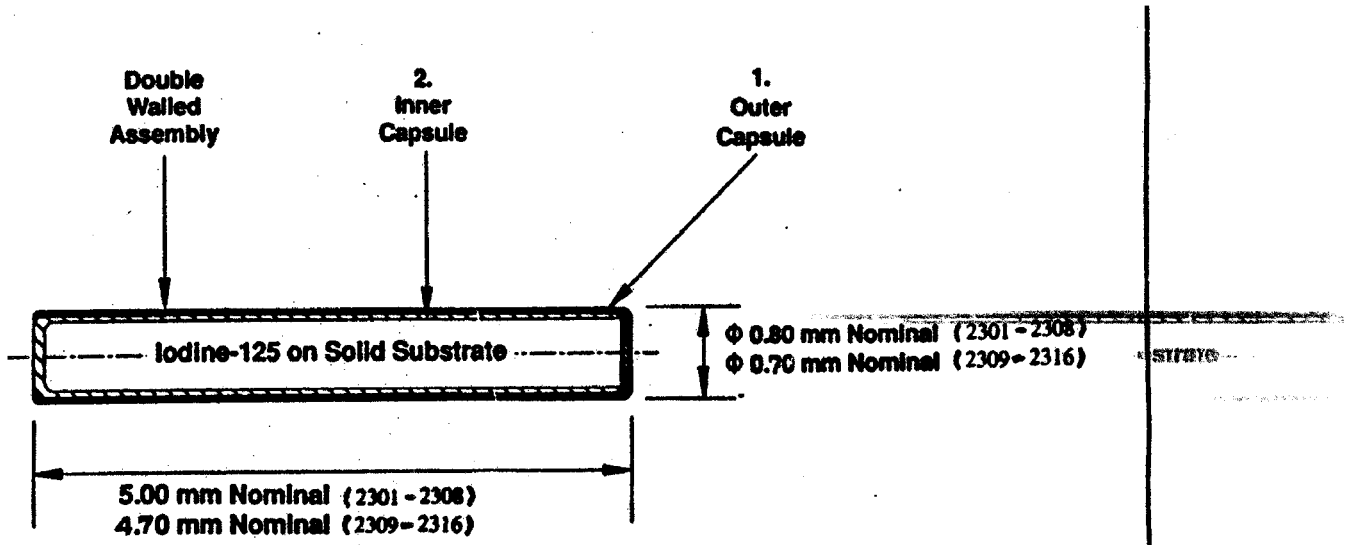
**DESCRIPTION OF BEST INDUSTRIES DOUBLE WALL IODINE-125 SOURCES – 2300 SERIES**

| Model No. | Overall Nominal Dimensions | Solid Substrate for I-125 Adsorption |
|---|---|---|
| 2301 | Dia. 0.8mm Length 5mm | Carbon with tungsten marker |
| 2302 | " | Carbon fibre |
| 2303 | " | Carbon balls |
| 2304 | " | Carbon balls with tungsten marker |
| 2305 | " | Poly-tyrosine with tungsten marker |
| 2306 | " | Poly-tyrosine balls |
| 2307 | " | Poly-tyrosine balls with tungsten marker |
| 2308 | " | Resin balls |
| 2309 | Dia. 0.7mm Length 4.7mm | Carbon with tungsten marker |
| 2310 | " | Carbon fibre |
| 2311 | " | Carbon balls |
| 2312 | " | Carbon balls with tungsten marker |
| 2313 | " | Poly-tyrosine with tungsten marker |
| 2314 | " | Poly-tyrosine balls |
| 2315 | " | Poly-tyrosine balls with tungsten marker |
| 2316 | " | Resin balls |

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
**(Amended in its entirety)**

NO.: NR-0187-S-103-S DATE: January 14, 2003 ATTACHMENT 2

DEVICE TYPE: Therapeutic Brachytherapy Seed Sources




| NO. | DESCRIPTION | MATERIAL |
|---|---|---|
| 2 | Inner Capsule | Titanium |
| 1 | Outer Capsule | Titanium |