

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

NO.: NR-0187-S-102-S DATE: January 14, 2003

PAGE 2 OF 4

SOURCE TYPE: Brachytherapy Sources

DESCRIPTION:

The **Model 81-02** gold seeds are manufactured by Engelhard Industries of Canada (Part No. 80-451, Drawing No. 88630041). Each batch of seeds received by **Best Medical International, Inc.** (formerly Best Industries) is certified by the manufacturer as to the contents and sizes.

These seeds are gold (99.99% pure) encapsulated in platinum (99.99% pure, iridium free). Each seed is 2.5 millimeters long and 0.8 millimeters in diameter and contains 8.6 milligrams + 0.6 milligrams of gold. **Best Medical International, Inc.** (formerly Best Industries) has each batch of the seeds irradiated in a nuclear reactor. Following irradiation and when supplied to **Best Medical International, Inc.** customers, each seed may contain up to 33 millicuries of gold-198. The most commonly used activity is 1 millicurie per seed.

LABELING:

The labeling of individual seeds is impractical due to their small size. The shipping container is labeled in accordance with criteria established in Best Industries letter of application dated July 24, 1981.

DIAGRAM:

See Attachments 1 and 2.

CONDITIONS OF NORMAL USE:

These sources are designed for use in hospital and clinical environments for the treatment of cancer under the normal conditions encountered in clinical practice.

PROTOTYPE TESTING:

No additional prototype testing was performed by Best Industries. Best Industries claimed that these gold seeds have been in clinical use without problems with source design. Both metallic gold and iridium-free platinum are insoluble in body fluids.

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

NO.: NR-0187-S-102-S DATE: January 14, 2003

PAGE 3 OF 4

SOURCE TYPE: Brachytherapy Sources

EXTERNAL RADIATION LEVELS:

- For the most common used activity of 1 millicurie/seed the dose rate is 92 mR/hr at 5 cm and 2.55 mR/hr at 30 cm.
- Source container's radiation profile:

Maximum Reading With

<u>Maximum Activity</u>	<u>Best/4 (500mCi)</u>	<u>Best/5 (1 Curie)</u>
Top	50 mR/hr	110 mR/hr
Bottom	60 mR/hr	100 mR/hr
Side	60 mR/hr	100 mR/hr

QUALITY ASSURANCE AND CONTROL:

Each batch of seeds received from the manufacturer, Engelhard Industries is certified as to content and size. Following irradiation, a Capintec isotope calibrator is used for calibrating all gold seeds. The calibrator has been standardized with a standard of known activity by Capintec. The calibrator is double checked with a similar gold seed calibrated in exposure rate. This exposure rate calibration is traceable to the National Institute of Standards and Technology. Each batch of seeds is given a code number for traceability and are grouped so that variation among seeds is not more than $\pm 5\%$ from the stated average activity. Seeds are smear tested for contamination to an acceptable limit of 10^{-6} microcuries. A Certification of Assay (Attachment 2) accompanies each shipment.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

These sources may be distributed to persons specifically licensed pursuant to 10 CFR Part 35, **Subpart F**, or under equivalent regulations of Agreement States.

- Leak testing of this product is not applicable due to the 2.7 day half life of gold-198.
- Handling, storage, use, transfer, and disposal: to be determined by the licensing authority.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(Amended in its Entirety)

NO.: NR-0187-S-102-S DATE: January 14, 2003

PAGE 4 OF 4

SOURCE TYPE: Brachytherapy Sources

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

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

SAFETY ANALYSIS SUMMARY:

Based on our review of the information contained within the references cited below, we continue to conclude that the **Best Medical International, Inc. (formerly Best Industries, Inc.)** Model 81-02 gold-192 seeds are acceptable for licensing purposes. These sources are for use by trained radiotherapists for the interstitial treatment of cancer and have extensive history of successful use for this purpose. Since the high purity of gold encased in platinum is essentially inert, the possibility of contamination from loss of containment is considered minimal. However, the extremely small size of these sources (2.5 mm x 0.8 mm) will require a higher level of accountability during use to prevent source misplacement and loss.

An amendment dated June 20, 1985, increased the maximum activity a user can receive from 11 millicuries to 33 millicuries.

REFERENCES:

The following supportive documents for the **Best Medical International, Inc. (formerly Best Industries, Inc.)** 81-02 gold seeds are hereby incorporated by reference and are made a part of this registration document.

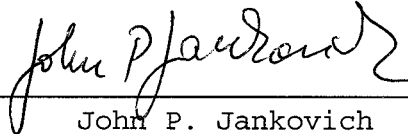
- Best Industries letters dated July 24, 1981, September 2, 1981, September 3, 1981, July 26, 1984, with enclosures thereto.
- Best Medical International, Inc. letter dated November 26, 2002, and electronic mail dated January 10, 2003.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

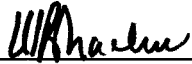
Date: January 14, 2003

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-102-S

DATE: January 14, 2003

ATTACHMENT 1

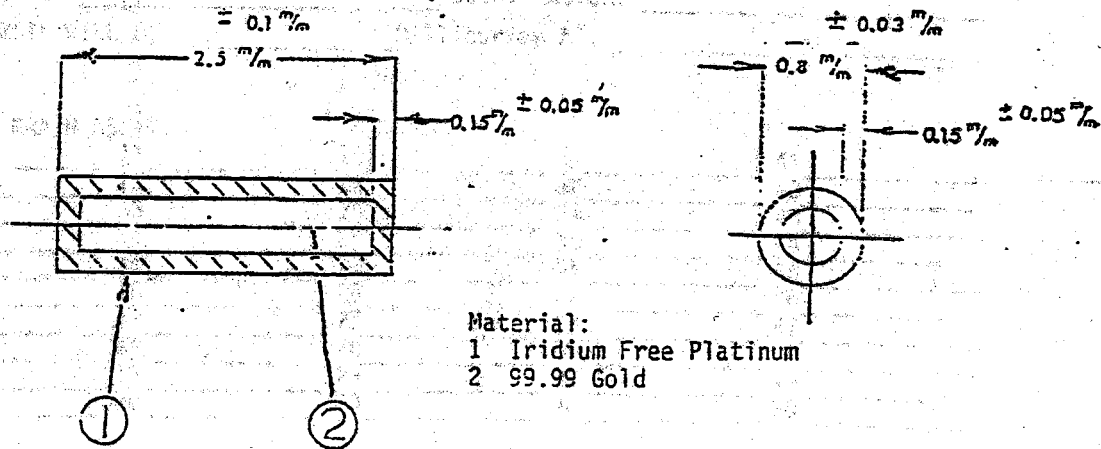
DEVICE TYPE: Brachytherapy Sources

DIAGRAM:

Platinum sheathed gold seed.

ACTUAL SIZE

Weight of gold cylinder $8.6 \text{ mg.} \pm 0.6 \text{ mg.}$
Nominal size of gold cylinder $0.5 \text{ mm Dia} \times 2.2 \text{ mm long}$



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

NO.: NR-0187-S-102-S

DATE: January 14, 2003

ATTACHMENT 2

DEVICE TYPE: Brachytherapy Sources

GOLD-198 GRAIN
CERTIFICATION OF ASSAY

CUSTOMER: _____

DATE: _____ INVOICE NO. _____

LOT NUMBER: _____ GRAINS: _____

TIME OF ASSAY: _____ DATE OF ASSAY: _____

AVERAGE NET ION CURRENT PER GRAIN: _____ AMP.

FACTOR: _____ Amp/mCi (Net Ion Current - Factor)

EACH GRAIN IS: _____ Millicuries AT: _____ ON: _____

DECAY TIME: _____ DECAY FACTOR: _____

EACH GRAIN WILL BE: _____ Millicuries AT: _____ ON: _____

SINGLE GRAIN ASSAY:

1	11	21	31	41
2	12	22	32	42
3	13	23	33	43
4	14	24	34	44
5	15	25	35	45
6	16	26	36	46
7	17	27	37	47
8	18	28	38	48
9	19	29	39	49
10	20	30	40	50

AVERAGE: _____ VARIATION: ± _____

PRODUCT PREPARED BY: _____ PRODUCT CHECKED BY: _____

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

NO.: NR-0187-S-102-S

DATE: January 14, 2003

ATTACHMENT 3

DEVICE TYPE: Brachytherapy Sources

<u>HOURS</u>	<u>DECAY FACTOR</u>	<u>HOURS</u>	<u>DECAY FACTOR</u>	<u>HOURS</u>	<u>DECAY FACTOR</u>
1	0.9894	22	0.7902	120	0.2767
4	0.9581	24	0.7734	144	0.2140
7	0.9278	36	0.6802	168	0.1655
10	0.8985	48	0.5982	192	0.1280
13	0.8701	60	0.5260	216	0.0990
16	0.8426	72	0.4626	240	0.0766
19	0.8159	96	0.3578	360	0.0212

SHIPMENT DATE: _____ TOTAL ACTIVITY AT SHIPMENT: _____ mCi
 CARRIER: _____ WAYBILL: _____

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- A. These sources may be distributed to persons specifically licensed pursuant to §§ 35.13, 35.14, and 35.100 Group VI, 10 CFR 35, or under equivalent regulations of Agreement States.
- B. Leak Test Frequency: Not applicable due to 2.7 day half-life of Gold-198.
- C. Handling, Storage, Use, Transfer, and Disposal: To be determined by the licensing authority.