

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

No.: NR-8147-S-802-S  
(Previously NR-569-S-101-S)

DATE: April 30, 2004

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SOURCE TYPE: Therapeutic Brachytherapy Seeds

MODEL: RSNP-Au

MANUFACTURER/DISTRIBUTOR:

Radiation, Safety & Nuclear  
Products (RSNP)  
3589 West 500 South, Unit 2  
Salt Lake City, UT 84104

ISOTOPE:

Gold-198

MAXIMUM ACTIVITY:

80 mCi (2.96 GBq)

LEAK TEST FREQUENCY:

Not required

PRINCIPAL USE:

(V) General Medical Use  
For use in manual brachytherapy  
in accordance with 10 CFR 35.400  
or equivalent Agreement State  
regulations

CUSTOM SOURCE:

\_\_\_\_\_ YES      \_\_\_\_\_ X      NO

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SOURCE TYPE:      Therapeutic Brachytherapy Seeds

DESCRIPTION:

The "non-irradiated" gold seeds were manufactured by Engelhard Industries of Canada (Part No. 88-63-004-1). Each seed contains  $8.6 \pm 0.6$  milligrams ( $[18.96 \pm 1.32]E-6$  lb) of Gold (99.99 percent pure) which is encased in a platinum, sheath (99.99 percent pure, Iridium free). The manufacturer certified that the seeds are "iridium free" platinum and gold. The seeds are cylindrical and have dimensions of 2.5 mm (0.098") in length and 0.8 mm (0.031") in diameter. The platinum sheath is 0.15 mm (0.006") thick. These were identical to those used by Best Industries and Nuclear Sources & Services, Inc.

RSNP had the seeds irradiated in a reactor. Upon arrival at RSNP, each seed had a maximum activity of 80 mCi (2.96 GBq).

DIAGRAM:

See Attachments 1 through 5.

LABELING:

Due to the small size of the gold seeds, the seeds are not labeled. However, the shipping/storage containers used in the USDOT Type A, 7A package were labeled with the following:

- "Caution-Radioactive Material" stickers/tape;
- The trefoil radiation symbol;
- Isotope contained within the package; and
- Total activity in the package.

Certificate sheet with a decay chart and instructions for handling and storage accompanied each shipment of gold seed. The shipping/storage container were to be labeled in accordance with the requirements of Section 32.74(a)(3) of 10 CFR Part 32.

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SOURCE TYPE:      Therapeutic Brachytherapy Seeds

CONDITIONS OF NORMAL USE:

Seeds were used in hospital/clinical/medical environment for the interstitial treatment of cancer by persons trained and licensed to use therapeutic radiation sources.

Due to the short half-life of Gold-198 (2.7 days), the useful life of the seeds were limited to about 20 days as a maximum.

PROTOTYPE TESTING:

No testing was performed on the seeds. RSNP reported they were identical to seeds previously approved by the NRC and the States of Texas and Utah for licensing purposes. Additionally, the seeds had been in use in the medical community for over 30 years, with no reported significant health and safety problems.

EXTERNAL RADIATION LEVELS:

The specific gamma ray constant for Gold-198 is listed as 2.327 R-cm<sup>2</sup>/hr/mCi. Amersham, the original developer of Gold-198 seeds reported approximately 10% attenuation of the gamma ray intensity due to the platinum sheath. Therefore, the apparent activity from a Gold-198 seed was 90% of the contained activity. For a 30 mCi (1.11 GBq) seed, the calculated radiation levels would be:

62.80 R/hr (628.0 mSv/hr) at 1 cm (0.39")  
2.51 R/hr ( 25.1 mSv/hr) at 5 cm (1.97")  
0.63 R/hr ( 6.3 mSv/hr) at 10 cm (3.94")

There is no beta radiation involved, as the 0.15 mm (0.006") platinum sheath filters out the 0.96 MeV beta particle from the Gold-198.

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SOURCE TYPE: Therapeutic Brachytherapy Seeds

QUALITY ASSURANCE AND CONTROL:

RSNP used two basic types of radiation detection systems in the assay of seed within  $\pm 5\%$  accuracy:

1. A fixed-geometry ion chamber was used for rapid counting and assay of seeds required to fill an order or to batch a shipment of irradiated seeds.
2. A Capintec dose calibrator was used to confirm the readings of, and document the performance of the ion chamber assay system.

To document the performance of the ion chamber, the following tests were performed:

- C Daily constancy check for reproducibility in measuring a Cs-137 tube source, which has been mounted in a plastic rod to assure constant geometry. A log of the results was maintained.
- C Quarterly intercomparison study to compare the measurement capabilities of the ion chamber system and the dose calibrator. Logs of these tests were maintained.

To calibrate dose calibrators, the following tests were performed:

- C Constancy at least once each day prior to assay of seed strengths.
- C Linearity at installation and at least quarterly thereafter.
- C Accuracy at installation and at least annually thereafter.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The sources shall be distributed to persons specifically licensed by the NRC pursuant to 10 CFR 35.13, 35.14, and 35.400 of 10 CFR Part 35 or equivalent provisions of an Agreement State.

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SOURCE TYPE:      Therapeutic Brachytherapy Seeds

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

- Due to the short half-life of the Gold-198, these sources do not have to be leak tested.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.
- The small size of these sources will require a higher level of accountability during use to prevent source misplacement and loss.
- This registration sheet and the information contained within the references shall not be changed or transferred without the written consent of the NRC.
- This product will no longer be commercially distributed but may still be approved for licensing purposes.

SAFETY ANALYSIS SUMMARY:

Based on our review of information contained within the references cited below, that these seeds are identical to seeds previously deemed acceptable for licensing purposes by the NRC and the States of Texas and Utah, that the high purity gold encased in platinum is inert and the 2.7 day half-life of Gold-198, we continue to conclude that the Model RSNP-Au seeds are acceptable for licensing purposes.

Furthermore, we continue to conclude that this source design would be expected to maintain its containment integrity for conditions of use which might occur during uses specified in this certificate.

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REFERENCES :

The following supporting documents for the Model RSNP-Au gold seeds are hereby incorporated by reference and are made a part of this registry document.

- Radiation, Safety and Nuclear Products letters dated August 15, 1983, January 3, 1984, March 20, 1987, February 22, 1999, and April 7, 1999, with enclosures thereto.
- Radiation, Safety and Nuclear Products, Inc. letter dated October 24, 2003, with enclosures thereto.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: \_\_\_\_\_ Reviewer: \_\_\_\_\_  
John P. Jankovich

Date: \_\_\_\_\_ Concurrence: \_\_\_\_\_  
Ujagar S. Bhachu

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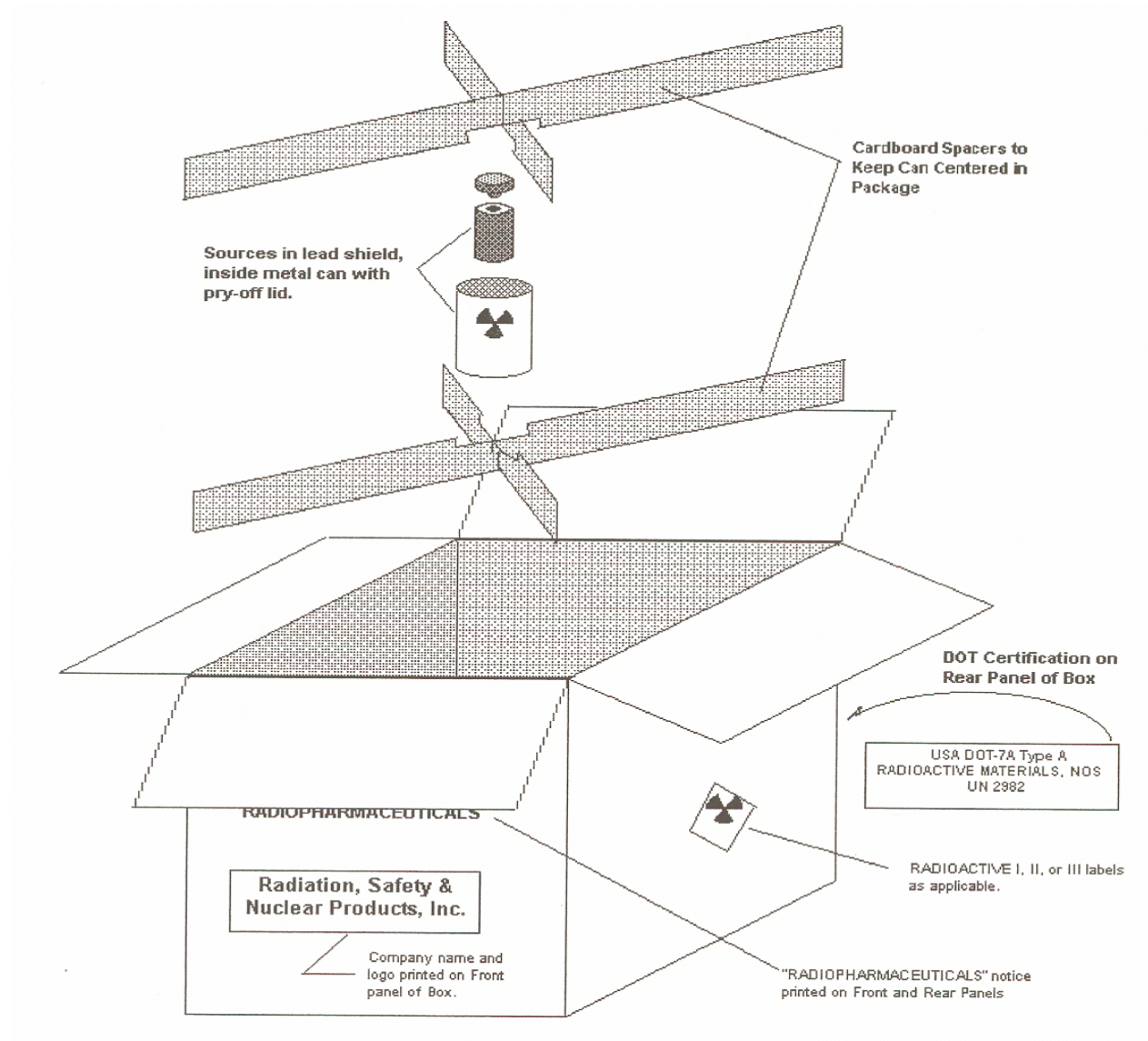
ATTACHMENT 1

(Previously NR-569-S-101-S)

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Shipping Package - Gold-198 Seeds

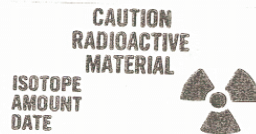


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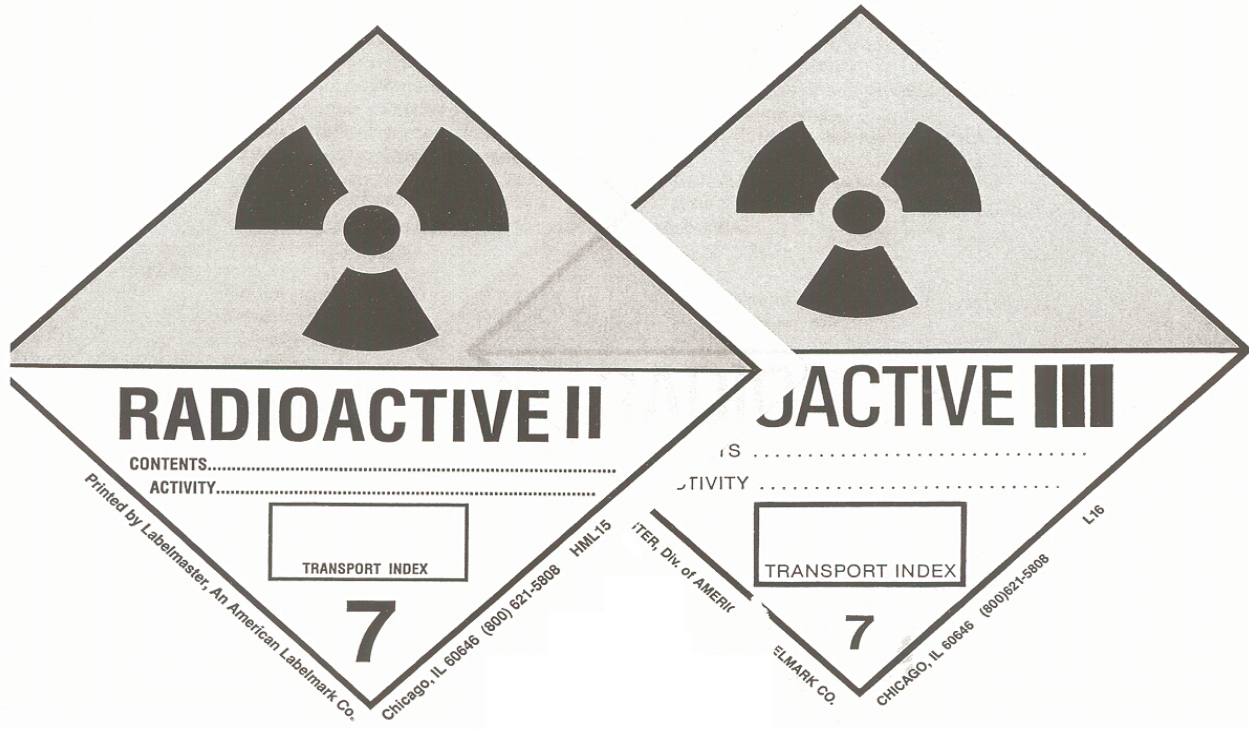
"CAUTION RADIOACTIVE MATERIAL" tape used to identify contents of inner package components:



"Security Seal" / tape to notify package recipient if package has been illicitly opened:

**IF SEAL  
IS BROKEN**  
**CHECK CONTENTS  
BEFORE ACCEPTING**

RADIOACTIVE Yellow II and Yellow III labels for compliance with USDOT/IATA regulations:



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ATTACHMENT 4

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**CUSTOMER:**

**LICENSE:**

**GOLD-198 SEED ASSAY CERTIFICATION**

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ATTACHMENT 5

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**GOLD-198 DECAY FACTORS**

Per NCRP Report 58, 2<sup>nd</sup> Edition (1984) Half-life for Gold-198 = 64.73 Hours.

HOURS	DECAY FACTOR	DAYS	DECAY FACTOR
0	1.0000	0	1.0000
1	0.9893	1	0.7734
2	0.9788	2	0.5981
3	0.9684	3	0.4626
4	0.9584	4	0.3577
5	0.9479	5	0.2767
6	0.9378	6	0.2140
7	0.9278	7	0.1655
8	0.9179	8	0.1280
9	0.9081	9	0.0990
10	0.8985	10	0.0765
11	0.8889	11	0.0592
12	0.8794	12	0.0458
13	0.8700	13	0.0354
14	0.8608	14	0.0274
15	0.8516	15	0.0212
16	0.8425	16	0.0164
17	0.8336	17	0.0127
18	0.8247	18	0.0098
19	0.8159	19	0.0076
20	0.8072	20	0.0059
21	0.7986	21	0.0045
22	0.7901	22	0.0035
23	0.7817	23	0.0027
24	0.7734	24	0.0021

**NOTE:**

To calculate the activity of a Gold-198 seed or source on any day up to 30 days after calibration, multiply the original activity by the appropriate decay factor for that day.

**EXAMPLE:**

You want to calculate the activity of a Gold-198 seed on the 5<sup>th</sup> day after calibration.

Original activity = 10.00 mCi      Decayed activity =  $10.00 \times 0.2767 = 2.767$  mCi