

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

NO.: NR-460-S-926-S

DATE: February 16, 1996

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SEALED SOURCE TYPE: Therapeutic Seed Source

MODEL: 6711

MANUFACTURER/DISTRIBUTOR:

3M Health Physics Services
3M Center, Building 224-2E-06
St. Paul, MN 55144-1000

ISOTOPE:

Iodine-125

MAXIMUM ACTIVITY:

100.0 millicuries (3.700 GBq)

LEAK TEST FREQUENCY: 6 Months

PRINCIPAL USE: (V) General Medical Use

CUSTOM SOURCE: _____ YES _____ X _____ NO

9610160330 960216
PDR RC *
SSD PDR

9610160330

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DESCRIPTION:

The Model 6711 is an interstitial brachytherapy seed. Iodine-125 (I-125) is adsorbed onto a 0.020 in. (0.050 cm) diameter, 0.118 in. (0.300 cm) long silver rod which is coated with silver chloride. The rod is encased in a 0.032 in. (0.080 cm) outer diameter titanium tube with 0.002 in. (0.005 cm) thick walls. The tube is plasma-arc welded shut at both ends, creating a hermetic seal to retain the radioactive silver rod inside.

Plasma-arc welding allows for higher welding speeds with greater energy concentration and deeper and narrower welds. During Plasma-arc welding the molten metal reforms behind the advancing arc allowing for a solid weld joint.

Before implantation, the Model 6711 seeds are stored in a 1 dram glass vial with a screw-on cap. That vial is kept either in a 2.500 in. (6.350 cm) tall, 1.320 in. (3.353 cm) outer diameter container with 0.125 in. (0.318 cm) thick walls which is capable of holding one vial or in a 6.000 in. (15.24 cm) tall, 4.750 in. (12.07 cm) outer diameter, foam lined container with 0.125 in. (0.318 cm) minimum thickness walls which is capable of holding 10 vials. The container is made from lead alloyed with 6 percent antimony to make it hard. The lead container is placed in a cardboard box lined with Styrofoam for shipping.

DIAGRAM:

See Attachment 1

LABELING:

Because of their small size, individual seeds are not labeled. Model 6711 seeds are supplied as a group of seeds having an activity within a stated range on a given assay date. The seeds come packaged in a 1 dram vial, onto which is affixed a label with the words, "Caution-Radioactive Material," Iodine-125, activity range, total activity, assay date, manufacturer's logo, and the trefoil radiation symbol.

The lead storage container has a label attached to it which

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includes the words, "Caution-Radioactive Material," and "I-125 Seeds," the activity range, number of seeds in the vial, lot number for the seeds, total contained activity, assay date, manufacturer's logo, and the trefoil radiation symbol.

The labels bear the Medi+Physics, Inc. logo instead of 3M's. Under an agreement between 3M and Medi+Physics, Inc., 3M manufactured and distributed source Model 6711 for Medi+Physics, Inc. under 3M's distribution license.

CONDITIONS OF NORMAL USE:

The 3M Model 6711 sealed source (therapeutic seed) is designed for use in the interstitial treatment of cancerous tumors. The placement of I-125 seeds in tissue is a surgical procedure which is facilitated by the use of one of several commercially-available implant tools. These implant tools are used solely for source placement and are not designed to either store or hold I-125 seeds, as is the case with conventional applicators and cesium-137 sources. The seeds are designed to withstand normal autoclave temperature and pressure variations from 249.8°F (121°C) at 15.00 psi (103.4 kPa) to 280.4°F (138°C) at 35.00 psi (241.3 kPa).

PROTOTYPE TESTING:

Prototypes of 3M Health Physics Services' I-125 seeds were subjected to the four tests described below to demonstrate that they maintain their integrity under conditions likely to be encountered in normal use and foreseeable accident conditions. The tests were designed to be similar to those in ANSI N542-1977, Appendix C, and in ANSI N44.1-1973.

1. Autoclave Test: Each tested seed was placed into a 1 dram vial with a screw cap loosely placed on its top. The vial was autoclaved at 249.8°F (121°C) and 15.00 psi (103.4 kPa) for 30 minutes, then allowed to cool to room temperature. After at least 12 hours in the soak solution following this test, no seed showed greater than 2×10^{-6} μCi (0.074 Bq) of removable contamination.

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PROTOTYPE TESTING: (Continued)

2. Impact Test: Each tested seed was dropped through a 30.00 ft. (9.144 m) length of 0.625 in. (1.588 cm) diameter electrical conduit onto a 0.512 in. (1.301 cm) thick steel plate. Each seed was visually inspected for damage after it was dropped. After at least 12 hours in the soak solution following this test, no seed showed greater than 7.7×10^{-6} μCi (0.285 Bq) of removable contamination.
3. Percussion Test: Each tested seed was placed on a 0.591 in. (1.500 cm) thick lead plate supported by an aluminum plate. A 0.984 in. (2.500 cm) diameter steel rod weighing 3.131 lb (1.420 kg) was dropped on the seed from a height of 39.37 in. (1.000 m). The visual inspection showed that each Model 6711 seed tested was flattened evenly throughout the middle portion of its length, but bulged somewhat at its end welds. After at least 12 hours in the soak solution following this test, no seed showed greater than 5.8×10^{-6} μCi (0.215 Bq) of removable contamination.
4. Bend Test: One-half of the length of each tested seed was gripped in the jaws of 4.000 in. (10.16 cm) long needle-nose pliers specially altered to hold the seeds. The other half of the seed was gripped with a similar pair of needle-nose pliers. Each tested seed was bent using the pliers to about 45°. After at least 12 hours in the soak solution following this test, no seed showed greater than 9.9×10^{-6} μCi (0.366 Bq) of removable contamination.

Following each of these prototype tests, the seeds were subjected to a soak test in a 0.101 oz (3 ml) wash solution containing 0.1 M NaI, 0.1 M NaOH, and liquid detergent at room temperature for 12 to 20 hours. The maximum allowable amount of removable contamination to pass the soak test was 0.005 μCi (185.0 Bq).

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EXTERNAL RADIATION LEVELS:

The following average radiation levels for Model 6711 seeds were determined by 3M Company's use of film badges (specified accuracy $\pm 15\%$):

<u>Distance From Source</u>		<u>Average Dose Rate</u>	
<u>inches</u>	<u>(cm)</u>	<u>mr/hr·mCi</u>	<u>(μSv/hr·MBq)</u>
1.969	(5.0)	25	(6.757)
11.81	(30.0)	0.53	(0.143)

QUALITY ASSURANCE AND CONTROL:

The following quality control procedures were followed during production of this source:

1. Completed seeds were visually inspected for uniform welds, the absence of holes, seed length between 0.165 in. and 0.193 in. (4.200 mm and 4.900 mm), and seed diameter between 0.031 in. and 0.038 in. (0.775 mm and 0.960 mm).
2. Completed seeds were leak tested by the vial (the contents of one vial ≤ 50 seeds). Each vial was filled with cleaning solution and placed into an ultrasonic bath for 15-30 minutes. Any vial showing more than 0.005 μ Ci (185.0 Bq) of removable contamination had each seed in it tested separately, using the same procedure as the full vial leak test. At this stage, any individual seed showing in excess of 0.005 μ Ci (185.0 Bq) of removable contamination was rejected.
3. Seeds were soak tested again as in Procedure 2, above. Seeds showing more than 0.005 μ Ci (185.0 Bq) of removable contamination were rejected.
4. Seeds were autoclaved in vials containing from 100-200 seeds at 260°F-280°F (126.7°C-137.8°C) for 15-20 minutes while immersed in cleaning solution.

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QUALITY ASSURANCE AND CONTROL: (Continued)

5. Seeds were assayed for radioactivity and placed in a vial with other seeds within the specified activity range for that vial.
6. Seeds were subjected to another leak test as a final quality control test. A maximum of 500 seeds were placed into a glass vial, immersed in cleaning solution, and allowed to soak overnight. The vial was then placed in an ultrasonic bath for no more than 10 minutes. Any vial showing a total in excess of 0.005 μCi (185.0 Bq) of removable contamination had each seed in it tested separately, using the same procedure as the full vial test. At this stage, any seed showing more than 0.005 μCi (185.0 Bq) of removable contamination was rejected.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- This source may be used only by persons specifically licensed by the NRC or an Agreement State.
- Handling, storage, use, transfer, and disposal: to be determined by the licensing authority.
- Licensees should observe 3M Company's instructions for handling and using the I-125 seeds; specifically, these instructions warn that:
 1. Seeds should not be exposed to concentrated acids.
 2. Seeds should not be autoclaved in plastic tubing or other plastic containers (only autoclave-compatible materials such as stainless steel, glass, nylon, and Teflon should be used).
 3. Seeds should not be exposed to temperatures in excess of 280.4°F (138°C) and pressures in excess of 35.00 psi (241.3 kPa).

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LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE: (Continued)

- Model 6711 sealed sources shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185.0 Bq) of removable contamination.
- REVIEWER NOTE: Please ensure the safety procedures outlined in 10 CFR Part 35 Subpart G are adhered to, especially as they pertain to the handling of the sources.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

The Model 6711 interstitial brachytherapy seed is not a current product manufactured or distributed by 3M Health Physics Services. However, 3M Health Physics Services will continue to receive Model 6711 sources for disposal.

Based on our review of the Model 6711 interstitial brachytherapy seed, and the information and test data cited below, we continue to conclude that this source is acceptable for specific licensing purposes.

Furthermore, we continue to conclude that the Model 6711 interstitial brachytherapy seed 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. In addition, the manufacturer indicated that no Model 6711 sources were distributed after July 24, 1992.

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REFERENCES:

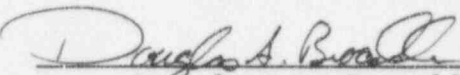
The following supporting documents for Model 6711 interstitial brachytherapy seeds are hereby incorporated by reference and are made a part of this registry document:

- 3M Health Physics Service: letters dated December 21, 1992, April 5, 1991, February 15, 1991, July 24, 1989, August 15, 1988, July 8, 1988, October 1, 1987, January 17, 1985, January 11, 1983, June 3, 1980, May 8, 1980, April 18, 1980, and February 8, 1980, with enclosures thereto.
- 3M Health Physics Services' application dated May 1, 1980, with enclosures thereto.

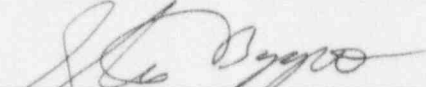
ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: February 16, 1996

Reviewer: 
Douglas A. Broadus

Date: February 16, 1996

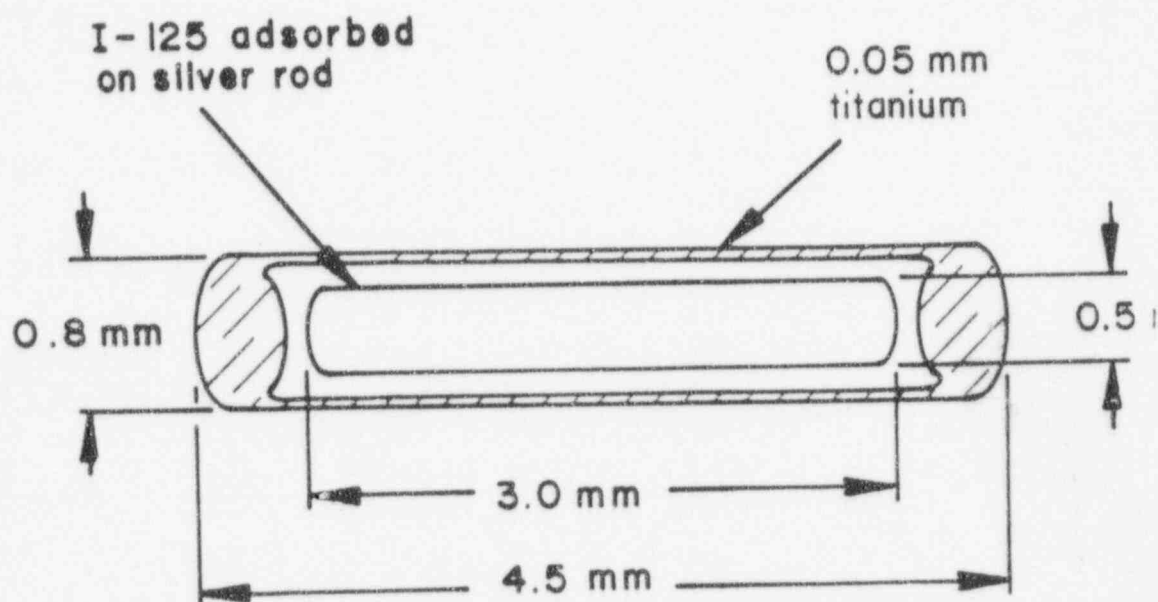
Concurrence: 
Steven L. Baggett

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ATTACHMENT 1



Schematic Diagram of I-125 Seed, Model 6711



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

February 12, 1996

NOTE TO: MINNESOTA MINING AND MANUFACTURING (3M) INACTIVE FILES
FROM: *Douglas A. Broadus*
DOUGLAS A. BROADDUS
SUBJECT: INACTIVATION OF REGISTRATIONS BASED ON AUGUST 6, 1991, LETTER.

A number of the background files for the registration certificates requested (by 3M letter dated August 6, 1991) to be made inactive contain limited information on the products. A search of 3M registration, archive, and license files, and information in NUDOS was performed to obtain additional information. Also, 3M was contacted to obtain any additional information that may have been in their files. 3M provided limited additional information concerning these products and indicated that the information provided represented all additional information in their files. Additional information obtained from these sources has been added to the applicable registration files.

At the present time, the information contained in the background registration files represents all available information for these products. In addition, a number of these products were originally reviewed and approved by the Atomic Energy Commission (AEC). The reviews performed for these products to make the certificates inactive were based on the information available, the previous reviews and approvals, and the historical use of the products (i.e., reports of failures or design problems, or the lack thereof). In several instances, insufficient information was available to perform an adequate safety review. In these instances, the certificates have been reissued based solely on the original AEC review and approval, and no additional safety review was performed.

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9608270104 YAP

ENCLOSURE 1

REGISTRATIONS TRANSFERRED TO INACTIVE STATUS

Old Certificate No.	New Certificate No.	Model Number(s)
NR-459-S-101-S	NR-8008-S-801-S	4F6Y
NR-459-S-102-S	NR-8008-S-802-S	3F1G
NR-460-S-101-S	NR-0460-S-875-S	4F6D
NR-460-S-102-S	COMBINED WITH NR-0460-S-874-S	4F6H, 4F6B
NR-460-S-103-S	NR-0460-S-876-S	4F6G
NR-460-S-104-S	COMBINED WITH NR-0460-S-865-S	6D6A
NR-460-S-105-S	NR-0460-S-877-S	6B6F
NR-460-S-106-S	NR-0460-S-878-S	4F6P
NR-460-S-107-S	NR-0460-S-879-S	1C2A, 1C2B
NR-460-S-108-S	NR-0460-S-880-S	4F3B
NR-460-S-109-S	NR-0460-S-881-S	4F3C
NR-460-S-110-S	NR-0460-S-882-S	3M1C
NR-460-S-111-S	NR-0460-S-883-S	3M1B
NR-460-S-112-S	NR-0460-S-884-S	3E4G
NR-460-S-113-S	NR-0460-S-885-S	4D3A
NR-460-S-114-S	NR-0460-S-886-S	4D3B
NR-460-S-115-S	NR-0460-S-887-S	4D6D
NR-460-S-116-S	NR-0460-S-888-S	4D6F
NR-460-S-117-S	NR-0460-S-889-S	5F1D
NR-460-S-118-S	COMBINED INTO NR-0460-S-890-S	5F1E
NR-460-S-119-S		5F1F
NR-460-S-120-S	NR-0460-S-891-S	5F1G
NR-460-S-121-S	NR-0460-S-892-S	3L2B
NR-460-S-122-S	NR-0460-S-893-S	3L2A
NR-460-S-123-S	NR-0460-S-894-S	3M1F
NR-460-S-124-S	NR-0460-S-895-S	3L2C

ENCLOSURE 1

REGISTRATIONS TRANSFERRED TO INACTIVE STATUS

Old Certificate No.	New Certificate No.	Model Number(s)
NR-460-S-125-S	NR-0460-S-896-S	1E2J
NR-460-S-126-S	NR-0460-S-897-S	3F1G
NR-460-S-127-S	NONE - NO INFORMATION AVAILABLE	4F1E
NR-460-S-128-S	NR-0460-S-899-S	5F1H
NR-460-S-129-S	NR-0460-S-900-S	3E40
NR-460-S-130-S	COMBINED INTO NR-0460-S-901-S	5F1N
NR-460-S-131-S		5F1N (MODIFIED)
NR-460-S-132-S	NR-0460-S-902-S	7B8L
NR-460-S-133-S	COMBINED INTO NR-0460-S-903-S	6H6A
NR-460-S-134-S		6H6B
NR-460-S-135-S	NR-0460-S-904-S	4D6M
NR-460-S-136-S	NR-0460-S-905-S	3L2E
NR-460-S-137-S	NR-0460-S-906-S	6500, 6520 (FORM. 6D6C)
NR-460-S-138-S	NR-0460-S-907-S	3L2D
NR-460-S-139-S	NR-0460-S-908-S	3Q1D
NR-460-S-140-S	NR-0460-S-909-S	3E4L, 3E4S
NR-460-S-141-S	NR-0460-S-910-S	3F1R
NR-460-S-142-S	NR-0460-S-911-S	902, 902F, 903
NR-460-S-143-S	COMBINED WITH NR-0460-S-871-S	4P6E
NR-460-S-144-S	COMBINED WITH NR-0460-S-872-S	4P6M
NR-460-S-145-S	NR-0460-S-912-S	3M1L
NR-460-S-146-S	NR-0460-S-913-S	3G9A
NR-460-S-147-S	NR-0460-S-914-S	3B4G
NR-460-S-148-S	COMBINED WITH NR-0460-S-871-S	4F3F
NR-460-S-149-S	NR-0460-S-915-S	4F3G

ENCLOSURE 1

REGISTRATIONS TRANSFERRED TO INACTIVE STATUS

Old Certificate No.	New Certificate No.	Model Number(s)
NR-460-S-150-S	NR-0460-S-916-S	6D1A
NR-460-S-151-S	COMBINED WITH NR-0460-S-869-S	6530, 6540 (FORM. 6B6G)
NR-460-S-152-S	NR-0460-S-917-S	6H6D
NR-460-S-153-S	NOT REQUIRED	ALBUMIN MICROSPHERES
NR-460-S-154-S	NR-0460-S-919-S	6H6E, 8C9T
NR-460-S-155-S	COMBINED INTO NR-0460-S-920-S	4D6L
NR-460-S-156-S		4D6P
NR-460-S-158-S	NR-0460-S-921-S	3F1I, 3F1J, 3F1L
NR-460-S-159-S	NR-0460-S-922-S	3F1V
NR-460-S-160-S	COMBINED WITH NR-0460-S-873-S	4P6T
NR-460-S-161-S	COMBINED INTO NR-0460-S-920-S	4F3D
NR-460-S-162-S	NR-0460-S-923-S	4F3H
NR-460-S-163-S	COMBINED INTO NR-0460-S-920-S	4F6S
NR-460-S-164-S	COMBINED WITH NR-0460-S-900-S	3E40
NR-460-S-165-S	NR-0460-S-924-S	6701
NR-460-S-166-S	NR-0460-S-925-S	6702
NR-460-S-167-S	NR-0460-S-926-S	6711
NR-460-S-168-G	NR-0460-S-927-G	702, 703, 704
NR-460-S-169-S	NR-0460-S-928-S	6510, 6550, 6570 (FORMERLY 6B6G)
NR-460-S-170-S	NR-0460-S-929-S	4P6V
NR-460-S-171-S	NR-0460-S-930-S	4F6ST

February 29, 1996

Robert G. Wissink
3M Health Physics Services
3M Center Bldg. 224-2E-06
St. Paul, MN 55144-1000

Dear Mr. Wissink:

This letter is in response to your request dated August 6, 1991, and subsequent letters, requesting to transfer to inactive status all registration sheets issued to 3M as listed in the first column of Enclosure 1. We have transferred the requested certificates to inactive status. The certificate numbers have been changed as listed in Enclosure 1. Copies of the inactive certificates are enclosed for your records.

Please read over the registration certificates and notify us immediately if there are any errors or inconsistencies.

If you have any questions, please contact me at (301) 415-5847 or Mr. Steven Baggett at (301) 415-7273.

Sincerely,

13/

Douglas A. Broaddus, Mechanical Engineer
Sealed Source Safety Section
Source Containment and
Devices Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosures: As stated

Distribution:

SSSS R/F NE01 SSD-91-71
Registration certificate files listed in Enclosure 1

DOCUMENT NAME: C:\WPDOCS\SSDS\INACTIVE\NRC\460INACT.CMP

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