3M Health Physics Services

3M Center Bldg. 224-2E-06
St Paul, MN 55144-1000
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Rec'd 1/5/93
Centre Zoleg

3M

December 21, 1992

Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
U. S. Nuclear Regulatory Commission
Washington D.C. 20555

Attention: Steven L. Baggett, Ph.D.
Medical, Academic, and Commercial Use Safety Branch

Subject: Source Reg. NR-460-S-166S and NR-460-S-167S

Dear Dr. Baggett:

3M has discontinued manufacturing and distribution of I-125 Seeds identified in source registrations NR-460-S-166S and NR-460-S-167S. The last 3M shipment to users of the Seeds was on July 24, 1992. All remaining inventory has been sent to Amersham/Medi-Physics who is continuing to manufacture and distribute the sources under Illinois License IL-01109-01. We understand that Amersham/Medi-Physics has their own source registrations.

A termination request for 3M's NRC license 22-00057-59MD, under which the sources were distributed, has been submitted to Region III.

It is requested that the registrations be terminated or placed in your inactive file, whichever is appropriate to eliminate the annual fee for these sources.

Yours truly,

Robert G. Wissink

Robert G. Wissink, Manager
Health Physics Services

RGW/ckm

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

NO.: NR-460-S-167-S DATE:

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: MAXIMUM ACTIVITY:

Iodine-125 100.0 millicuries (3.700 GBq)

LEAK TEST FREQUENCY: 6 Months

PRINCIPAL USE: (V) General Medical Use

CUSTOM SOURCE: _____ YES ___X___ NO

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

NO.: NR-460-S-167-S DATE:

SEALED SOURCE TYPE: Therapeutic Seed Source

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 welded shut at both ends, creating a hermetic seal to retain the radioactive silver rod inside.

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.

The labels for some of the newest sources bear the Medi+Physics, Inc. logo instead of the 3M logo. Under an agreement between 3M and Medi+Physics, Inc., 3M manufactured and distributed Model 6711 seeds for Medi+Physics, Inc. under 3M's distribution license from the 3M New Brighton, Minnesota, manufacturing plant for a short time prior to inactivating their license.

DIAGRAM:

See Attachment 1

SEALED SOURCE TYPE: Therapeutic Seed Source

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," and the designation of the isotope, activity range, total activity, assay date, 3M or Medi+Physics logo, and trefoil radiation symbol.

The lead storage container has a label attached to it which includes the following:

I-125 Seeds **3M**

Therapeutic For Interstitial Brachytherapy No. 6711

Made in U.S.A. for
Radiation Therapy Products
Medical Products Division/3M
St. Paul, MN 55501
(or Medi + Physics Info.)

radiation trefoil/
Caution Radioactive Material

Description: I-125 seeds consist of a welded titanium capsule containing iodine-125 adsorbed onto silver rod.

Activity Range _____mCi comp

Total activity this vial _____mCi comp

Number of seeds _____ Assay Date:_____

Lot no _____

See package insert for instructions on handling and storage of I-125 seeds.

WARNING: Licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to § 35.14 and § 35.100 Group VI of 10 CFR Part 35 or under equivalent licenses of Agreement States.
CAUTION: Federal law restricts this device to sale by or on the order of a physician. Maintain proper radiation safety precautions at all times.

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

SEALED SOURCE TYPE: Therapeutic Seed Source

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 implanters 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.

Following each of the prototype tests identified below, the tested I-125 seeds were subjected to a soak test in a wash solution containing 0.1 M KI, 0.1 M KOH, 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).

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 0.000011 μCi (0.407 Bq) of removable contamination.

SEALED SOURCE TYPE: Therapeutic Seed Source

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 0.0000077 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 0.0000058 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 0.00011 μCi (4.070 Bq) of removable contamination, and four of the five tested exhibited 0.0000088 μCi (0.326 Bq) or less of removable contamination.

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

NO.: NR-460-S-167-S DATE: PAGE 6 OF 9

SEALED SOURCE TYPE: Therapeutic Seed Source

EXTERNAL RADIATION LEVELS:

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

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

Additionally, as of the effective date of this certificate, it is estimated that external radiation levels produced by this sealed source do not pose a significant radiological hazard, given the latest date of manufacture was July 24, 1992, as reported by the manufacturer.

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 μCi (185.0 Bq) of removable contamination had each seed in it t sted separately, using the same procedure as the full vial leak test. At this stage, any individual seed showing in excess of 0.005 μCi (185.0 Bq) of removable contamination was rejected.

SEALED SOURCE TYPE: Therapeutic Seed Source

QUALITY ASSURANCE AND CONTROL: (Continued)

3. Seeds were soak tested again as in Procedure 2, above. Seeds showing more than 0.005 μCi (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.

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.

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

NO.: NR-460-S-167-S DATE:

SEALED SOURCE TYPE: Therapeutic Seed Source

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

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).

- This source 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.

- 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.

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

SEALED SOURCE TYPE: Therapeutic Seed Source

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 Services' letters dated August 6, 1991, April 5, 1991, July 8, 1988, January 17, 1985, January 11, 1983, June 3, 1980, May 8, 1980, May 1, 1980, and February 8, 1980, with enclosures thereto

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: _____ Reviewer: _____
Thomas W. Rich

Date: _____ Concurrence: _____
Steven L. Baggett

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

NO.: NR-460-S-167-S DATE: ATTACHMENT 1

NR460816TS 6711

SSDs: 9/16/88, 6/25/85, 6/23/80

CORRESP:
4/5/91 LTR: 3M → RIII: re: sale of seeds to Medi-Physics w/new labels & pkg. inserts.
10/10/89 LTR: 3M → SLB: pls. req. 6712
11/88 PROD BROCHURE
7/31/91 CR: TWR (ANL) Oklahoma (3N): close out actin (6712??)
7/8/88 LTR: 3M → SLB: re: recent mtg. justification for change from 710 → plasma arc welding.

SEE ALSO NR460165 & NR460166 BKGRND FILES

1/17/85 LTR: 3M → RIII: revise info from 5/1/80 renewal app.
p. 125 ion exchange resin & 6701 discontinuation stmt.
p. 126 100 mCi max 4/35% attenuation.
pp. 129, 136 PT
p. 137 Dose Rates
pp. 138-150 QA/QC
pp. 112-151 Labeling
p. 169 Pkg. Inserts
1/11/83 LTR: 3M → NRC: QA/QC changes - NBS traceable sources & change from "mCi/comp." to "apparent activity in mCi"
Labels Pkg Inserts
11/26/80 LTR: 3M → NRC: revised pkg. inserts
6/3/80 LTR: 3M → EGW: (responds to 6/2/80 telecon)
5/8/80 LTR: 3M → NRC: 6711 drwg OK to xerox
4/18/80 LTR: 3M → NRC: additional info on 6711 re: telecon of 4/9/80 - PT

5/1/80 APP: renew 22-00057-59MD:

pp. 125-6 anion exchange rpn.

p. 126 100 mCi: mfrs 35% attenuation

pp. 127-8 Const & dwgs. (sketches) ~~not~~

pp. 129-130 PT

p. 131 Dose Rates

pp. 138-151 QA/QC

pp. 152-154 Labeling

pp. 155-6 Shipping

pp. 168-173 Pkg Inserts

2/8/80 LTR: 3M → NRC: pls. req. 6711

p. 07 rpn 62 mCi max. all covered in later corresp

BROCHURE

6/14/90 MMO: SLB → RIII: rpt. rec'd SSDs. OK to lic.

10/1/87 LTR: 3M → RIII: labeling changes → C711, etc.

8/15/88 LTR: 3M → RIII: (responds to VLMinor's 9/24/87 letter)
revised labeling & pkg. inserts