FEB 27 1964

L&R:IB:WCM

SEALED SOURCE FILES

Minnesota Mining and
Manufacturing Company
2501 Hudson Road
St. Paul 19, Minnesota

Attention: Mr. Robert J. Kunz, Supervisor
Administrative Services, TCAAP-588

Gentlemen:

Reference is made to your letter dated January 24, 1963, regarding the Minnesota Mining and Manufacturing Company Model 6B6F sealed source. We have evaluated this source and are prepared to accept applications for licensing purposes. The applications should describe the device in which the sealed source will be used.

Very truly yours,

William O. Miller
Isotopes Branch
Division of Licensing
and Regulation

L&R:LB
WCMiller/mog

2/ /64

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

NO.: NR-460-S-~~105~~ 847-S DATE: PAGE 1 OF 6

SEALED SOURCE TYPE: Medical Needle Source

MODEL: 6B6F

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

ISOTOPE: Cesium-137

MAXIMUM ACTIVITY: 500.0 millicuries (18.50 GBq)

LEAK TEST FREQUENCY: 6 Months

PRINCIPAL USE: (V) General Medical Use

CUSTOM SOURCE: _____ YES ___X___ NO

SEALED SOURCE TYPE: Medical Needle Source

DESCRIPTION:

The 6B6F sealed source is a stainless steel needle intended for interstitial implantation in cancer treatment. Cesium-137 (Cs-137) is absorbed into small ceramic particles. The isotope is then permanently fixed to the ceramic particles using a heat treatment to create 3M Brand Radiating Microspheres. The microspheres are then loaded into a 0.050 in. (0.127 cm) outer diameter tube with nominally 0.009 in. (0.023 cm) thick walls. The length of this tube (L_{IT}) and the active length (L_A) of the source vary according to Table I, below. A 0.040 in. (0.102 cm) thick plug is inserted into each end of this tube, and silver-soldered in place.

The entire assembly is inserted into a 0.072 in. (0.183 cm) outer diameter tube with 0.009 in. (0.023 cm) thick walls that extend 0.040 in. (0.102 cm) past both ends of the inner tube. A needle point is inserted into one end of the outer tube and silver-soldered in place. A long plug with an eyelet 0.125 in. (0.318 cm) from its rounded end is inserted into the other end of the outer tube and silver-soldered in place. The total length (L_T) of the completed source varies according to Table I.

TABLE I. Dimensions of the 6B6F Source

Size Code	Total Length (L_T)	Active Length (L_A)	Inner Tube Len. (L_{IT})
TNA	1.3779 in. 3.500 cm	0.7874 in. 2.000 cm	0.8924 in. 2.267 cm
TNB	1.7716 in. 4.500 cm	1.1811 in. 3.000 cm	1.2861 in. 3.267 cm
TNC	2.1653 in. 5.500 cm	1.5748 in. 4.000 cm	1.6798 in. 4.267 cm
TND	2.5590 in. 6.500 cm	1.9685 in. 5.000 cm	2.0731 in. 5.266 cm
TNE	2.9527 in. 7.500 cm	2.3622 in. 6.000 cm	2.4672 in. 6.267 cm

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

NO.: NR-460-S-105-S DATE:

SEALED SOURCE TYPE: Medical Needle Source

DIAGRAM:

See Attachment 1

LABELING:

The quantity of Cs-137 contained in the source and the date of manufacture are stamped on the eyelet end of the source.

CONDITIONS OF NORMAL USE:

This source is intended for use in interstitial brachytherapy, which involves implanting the source in the patient's body near a carcinoma or tumor so that the radiation will destroy the cancer. Therefore, the source is designed to withstand the internal environmental conditions inside the human body for extended periods. When the source is not in use, it is stored in a climate-controlled hospital room.

PROTOTYPE TESTING:

Prototype Model 6B6F sources containing between 1.000 mCi (37.00 MBq) and 5.000 mCi (185.0 MBq) of Cs-137 were subjected to the following tests:

1. The sources were dropped from a height of 48.00 in. (121.9 cm) onto a cement surface six times.
2. The sources were heated at 932°F (500°C) for 30 minutes.
3. The sources were soaked in a 5 percent saline solution at 140°F (60°C) for 24 hours.
4. The sources were soaked in blood at 140°F (60°C) for 24 hours.

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

SEALED SOURCE TYPE: Medical Needle Source

PROTOTYPE TESTING: (Continued)

After each test the sources were smear and leak tested. All smears revealed less than 0.001 μCi (37.00 Bq) and all leak tests were negative.

EXTERNAL RADIATION LEVELS:

External radiation dose rates were calculated for a 500.0 mCi (18.50 GBq) Cs-137 source. The dose rates are based on an NIST traceable standard and are as follows:

Distance (from surface)		Maximum Radiation Level	
(cm)	(in)	(R/hr)	(Sv/hr)
5	1.97	66	0.66
30	11.81	1.83	0.018
100	39.37	0.165	0.002

QUALITY ASSURANCE AND CONTROL:

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

1. Each source was smear tested upon completion of fabrication, after a 7-day storage period, and immediately prior to shipment.

2. Each source was bubble-leak-tested in water at 200°F (93.33°C) for a minimum of 10 seconds. If any bubbles were observed coming from the source, the source failed the test.

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

NO.: NR-460-S-105-S DATE:

SEALED SOURCE TYPE: Medical Needle Source

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.
- 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 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 6B6F sealed source is not a current product manufactured or distributed by 3M Health Physics Services. However, 3M Health Physics Services will continue to receive 6B6F sources for disposal.

Based on our review of the Model 6B6F sealed source, and the information and test data cited below, we continue to conclude that this sealed source is acceptable for specific licensing purposes.

Furthermore, we continue to conclude that the Model 6B6F sealed source 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

NO.: NR-460-S-105-S DATE:

SEALED SOURCE TYPE: Medical Needle Source

REFERENCES:

The following supporting documents for the Model 6B6F sealed source are hereby incorporated by reference and are made a part of this registry document:

- 3M Health Physics Services' letters dated August 6, 1991, and January 24, 1964, 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-105-S DATE: ATTACHMENT 1

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

NO.: NR-460-S-105-S DATE:

SEALED SOURCE TYPE: Medical Needle Source

MODEL: 6B6F

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

ISOTOPE: Cesium-137

MAXIMUM ACTIVITY: 500 millicuries (18.50GBq)

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-105-S DATE: PAGE 2 OF 6

SEALED SOURCE TYPE: Medical Needle Source

DESCRIPTION:

The 6B6F sealed source is a stainless-steel needle intended for interstitial implantation in cancer treatment. Cesium-137 (Cs-137) is absorbed into small ceramic particles. The isotope is then permanently fixed to the ceramic particles using a heat treatment to create 3M Brand Radiating Microspheres. The microspheres are then loaded into a 0.050 in. (0.13 cm) outer diameter tube with 0.0085 in. (0.02 cm) thick walls. The length of the ~~inner~~ tube (L_{IT}) and the active length (L_A) of the source vary according to Table I, below.

TABLE I. Dimensions of the 6B6F Source

Size Code	Total Length (L_T)	Active Length (L_A)	Inner Tube Len. (L_{IT})
TNA	1.3779 in.	0.7874 in.	0.8924 in.
	3.500 cm	2.000 cm	2.267 cm
TNB	1.7716 in.	1.1811 in.	1.2861 in.
	4.500 cm	3.000 cm	3.267 cm
TNC	2.1653 in.	1.5748 in.	1.6798 in.
	5.500 cm	4.000 cm	4.267 cm
TND	2.5590 in.	1.9685 in.	2.0731 in.
	6.500 cm	5.000 cm	5.266 cm
TNE	2.9527 in.	2.3622 in.	2.4672 in.
	7.500 cm	6.000 cm	6.267 cm

A 0.040 in. (0.1 cm) thick plug is inserted into each end of the ~~inner~~ tube, and silver-soldered in place. The entire ~~inner~~ assembly is inserted into a 0.072 in. (0.18 cm) outer diameter tube with 0.009 in. (0.02 cm) thick walls that extend 0.040 in. (0.1 cm) past both ends of the inner tube. A needle point is inserted into one end of the outer tube and silver-soldered in place. A long plug with an eyelet 0.125 in. (0.32 cm) from its rounded end is inserted into the other end of the outer tube and silver-soldered in place. The total length (L_T) of the completed source varies according to Table I.

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DIAGRAM:

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

NO.: NR-460-S-105-S DATE: PAGE 3 OF 6

SEALED SOURCE TYPE: Medical Needle Source

See Attachment 1.

LABELING:

The quantity of Cs-137 contained in the source and the date of manufacture are stamped on the eyelet end of the source.

CONDITIONS OF NORMAL USE:

This source is intended for use in interstitial brachytherapy, which involves implanting the source in the patient's body near a carcinoma or tumor so that the radiation will destroy the cancer. Therefore, the source ~~must be able~~ is designed to withstand the internal environmental conditions inside the human body for extended periods. When the source is not in use, it is stored in a climate-controlled hospital room.

PROTOTYPE TESTING:

Prototype Model 6B6F sources containing between 1 mCi (37 MBq) and 5 mCi (185 MBq) of Cs-137 were subjected to the following tests:

1. The sources were dropped from a height of 48.0 in. (121.9 cm) onto a cement surface six times.

2. The sources were heated at 932°F (500°C) for 30 minutes.

3. The sources were soaked in a 5 percent saline solution at 140°F (60°C) for 24 hours.

4. The sources were soaked in blood at 140°F (60°C) for 24 hours.

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

SEALED SOURCE TYPE: Medical Needle Source

PROTOTYPE TESTING: (Continued)

After each test the sources were smear and leak tested. All smears revealed less than 0.001 μCi (37 Bq) and all leak tests were negative.

EXTERNAL RADIATION LEVELS:

External radiation dose rates were calculated for a 500 mCi (18.5 GBq) Cs-137 source. The dose rates are based on an NIST traceable standard and are as follows:

Distance (from surface)		Maximum Radiation Level	
(cm)	(in)	(R/hr)	(Sv/hr)
5	1.97	66	0.66
30	11.81	1.83	0.018
100	39.37	0.165	0.002

QUALITY ASSURANCE AND CONTROL:

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

1. ~~The~~ Each source was smear tested upon completion of fabrication, after a 7-day storage period, and immediately prior to shipment.
2. ~~The~~ Each source was bubble-leak-tested in water at 200°F (93.33°C) for a minimum of 10 seconds. If any bubbles were observed coming from the source, the source failed the test.

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

NO.: NR-460-S-105-S DATE: PAGE 5 OF 6

SEALED SOURCE TYPE: Medical Needle Source

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- This source has been distributed only to persons specifically licensed by the NRC or an Agreement State. (See previous
- Handling, storage, use, transfer, and disposal: to be determined by the licensing authority.
- This source shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185 Bq) of 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:

Based on our review of the Model 6B6F sealed source, and the information and test data cited below, we continue to conclude that this sealed source was acceptable for specific licensing purposes.

Furthermore, we continue to conclude that the 6B6F sealed source 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.

As of the effective date of this document, the Model 6B6F sealed source is not a current product manufactured or distributed by 3M Health Physics Services. However, 3M Health Physics Services will continue to receive 6B6F sources for disposal.

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

NO.: NR-460-S-105-S DATE:

SEALED SOURCE TYPE: Medical Needle Source

REFERENCES:

The following supporting documents for the Model 6B6F sealed source are hereby incorporated by reference and are made a part of this registry document:

- 3M Health Physics Services' letters dated August 6, 1991, and January 24, 1964, 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-105-S DATE: ATTACHMENT 1

NR4605105S

686F

SSDs: 2/27/64

Corresp: 1/24/64 LTR: 3M → AEC: pls. reg. 686F. max: 500 mCi ^{137}Cs. interstitial brachytherapy needles. Labeling: activity & date of mfr. stamped in eyelet end. Shipped in a 10 CFR 20-OK container. QA/QC PT.
w/ 3M Medical Radiation Sources brochure.

Dwg. A-1921-19 4/10/63

Outer tube: 15 ga. (0.072" od × 0.009" wall) tube } S.S. hypodermic tubing
Inner tube: 17 ga. (0.050" od × 0.008" wall) tube }

0.04" th plug silver soldered in 1/32" from tube.

3M Health Physics Services

3M Center Bldg. 224-2E-06
St. Paul, MN 55144-1000
612/736 0498

Rec'd 8/7/91

August 6, 1991

U.S. Nuclear Regulatory Commission
Washington D.C. 20555

Attn: Mr. Steven L. Baggett
Nuclear Material Safety and Safeguards
Medical and Commercial Use Safety Branch
Mail Stop 6H3

Subject: Inactive Source Registrations

Gentlemen:

In accordance with a July 25, 1991 telephone conversation between Mr. Melvin R. Peters, 3M, and Mr. John W. Lubinski, NRC, enclosed is a listing of registered 3M sources which should be terminated. The manufacturing of these sources either has been, or will have been, permanently discontinued by September 30, 1991.

It is our understanding that upon termination:

1. The registrations will become part of NRC's inactive file, but present users of the sources may continue to use them.

2. 3M can accept the sources for disposal and leak testing, but cannot refurbish or repair them.

3. 3M, on a best effort basis, will provide the NRC with a listing of the total number of sources sold and the date of the last sale.

4. The annual maintenance fee for the registrations will be waived.

Yours truly,

Robert G. Wissink

Robert G. Wissink, Chairman
Isotope Committee

Enclosure: 3M Inactive Source List (July 27, 1991)

9608270101 3pp. Subj 39

INVOICE #	LICENSE #	SOURCE MODEL #
AMO 6645 91	STB 1129	THORIUM
AMO 6541 91	22 00057 34G	703
AMO 6628 91	NR 0459S 101 S	4F6Y
AMO 6629 91	NR 0459S 102 S	3F1G
AMO 6551 91	NR 0460S 101 U	4F6D
AMO 6552 91	NR 0460S 102 S	4F6H
AMO 6553 91	NR 0460S 103 U	4F6G
AMO 6554 91	NR 0460S 105 U	6B6F
AMO 6555 91	NR 0460S 106 U	4F6P
AMO 6556 91	NR 0460S 107 S	1C2A, 1C2B
AMO 6557 91	NR 0460S 108 U	4F3B
AMO 6558 91	NR 0460S 109 U	4F3C
AMO 6543 91	NR 0460D 110 U	3M1C
AMO 6544 91	NR 0460D 111 U	3M1B
AMO 6559 91	NR 0460S 112 U	3E4G
AMO 6560 91	NR 0460S 113 U	4D3A
AMO 6561 91	NR 0460S 114 U	4D3B
AMO 6562 91	NR 0460S 115 U	4D6D
AMO 6563 91	NR 0460S 116 U	4D6F
AMO 6564 91	NR 0460S 117 U	5F1D
AMO 6565 91	NR 0460S 118 U	5F1E
AMO 6566 91	NR 0460S 119 U	5F1F
AMO 6567 91	NR 0460S 120 U	5F1G
AMO 6568 91	NR 0460S 121 U	3L2B
AMO 6569 91	NR 0460S 122 U	3L2A
AMO 6545 91	NR 0460D 123 U	3M1F
AMO 6570 91	NR 0460S 124 U	3L2C
AMO 6571 91	NR 0460S 125 U	1E2J
AMO 6572 91	NR 0460S 126 U	3F1G
AMO 6573 91	NR 0460S 127 U	4F1E
AMO 6574 91	NR 0460S 128 U	5F1H
AMO 6575 91	NR 0460S 129 U	3E4O
AMO 6576 91	NR 0460S 130 U	5F1N
AMO 6577 91	NR 0460S 131 U	5F1N (MODIFIED)
AMO 6578 91	NR 0460S 132 U	7B8L
AMO 6579 91	NR 0460S 133 U	6H6A
AMO 6580 91	NR 0460S 134 U	6H6B
AMO 6581 91	NR 0460S 135 U	4D6M
AMO 6582 91	NR 0460S 136 U	3L2E
AMO 6583 91	NR 0460S 137 S	6500 & 6520 (FORMERLY 6D6C)
AMO 6584 91	NR 0460S 138 U	3L2D
AMO 6585 91	NR 0460S 139 U	3Q1D
AMO 6586 91	NR 0460S 140 U	3E4L, 3E4S
AMO 6587 91	NR 0460S 141 U	3F1R
AMO 6546 91	NR 0460D 142 G	902, 902F, 903
AMO 6588 91	NR 0460S 143 S	4P6E
AMO 6589 91	NR 0460S 144 S	4P6M
AMO 6547 91	NR 0460D 145 U	3M1L
AMO 6590 91	NR 0460S 146 U	3G9A
AMO 6592 91	NR 0460S 147 U	3B4G
AMO 6591 91	NR 0460S 147 S	3B4G
AMO 6593 91	NR 0460S 148 U	4F3F
AMO 6594 91	NR 0460S 149 U	4F3G

INVOICE #	LICENSE #	SOURCE MODEL #
AMO 6595 91	NR 0460S 151 S	6530, ~~6540~~ (FORMERLY 6B6G)
AMO 6548 91	NR 0450D 152 U	6H6D
AMO 6596 91	NR 0460S 153 S	ALBUMIN MICROSPHERES (HUMAN) TC-99M
AMO 6549 91	NR 0460D 154 U	6H6E SOURCE APPLICATOR, 8C9T SAFE
AMO 6597 91	NR 0460S 155 S	4D6L
AMO 6598 91	NR 0460S 156 S	4D6P
AMO 6599 91	NR 0460S 158 U	3F1I, 3F1J, 3F1L
AMO 6600 91	NR 0460S 159 U	3F1V
AMO 6601 91	NR 0460S 160 U	4P6T — NR460873
AMO 6602 91	NR 0460S 161 U	4F3D
AMO 6603 91	NR 0460S 162 U	4F3H
AMO 6604 91	NR 0460S 163 S	4F6S
AMO 6605 91	NR 0460S 164 S	3E4O
AMO 6606 91	NR 0460S 165 S	6701
AMO 6550 91	NR 0460D 168 G	702, 703, 704
AMO 6609 91	NR 0460S 169 S	6510,6550,6570 (FORMERLY 6B6G)
AMO 6610 91	NR 0460S 170 S	4P6V
AMO 6611 91	NR 0460S 171 S	4F6ST