UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

June 27, 1980

3M Company
Medical Products Division
3M Center
St. Paul, MN 55101

Gentlemen:

This refers to your request of February 8, 1980, as supplemented by your letters dated April 18, 1980, May 8, 1980, and June 3, 1980.

Based on the information contained in these letters we find the Model 6711 sealed source design acceptable for licensing purposes.

In addition, we have amended the Certificates of Registration for your Models 6701 and 6702 to provide for revision of package inserts as specified in your letters of February 8, 1980 and June 3, 1980.

Copies of the Certificates of Registration are enclosed.

A copy of this letter along with your application for amendment of license 22-00057-59MD has been referred to Mr. J. DelMedico of the Material Licensing Branch for action.

If you have any questions, please contact me on (301) 427-4240.

Sincerely,

Earl G Wright

Earl G. Wright
Material Certification and
Procedures Branch
Division of Fuel Cycle and
Material Safety

cc: J. DelMedico, MLB

Enclosure: As stated

FOIA-84-801

Appendix / Item 7

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

CERTIFICATE OF REGISTRATION AND SAFETY ANALYSIS SUMMARY SEALED SOURCE

Manufacturer and Distributor

Medical Products Division
3M Company
3M Center
St. Paul, MN 55101

Sealed Source Model Designation

Model 6711

Isotope

Iodine-125

Maximum Activity per Source

62 Millicuries (because of capsule absorption, this is referred to as 40 millicuries compensated)

Conditions of Normal Use

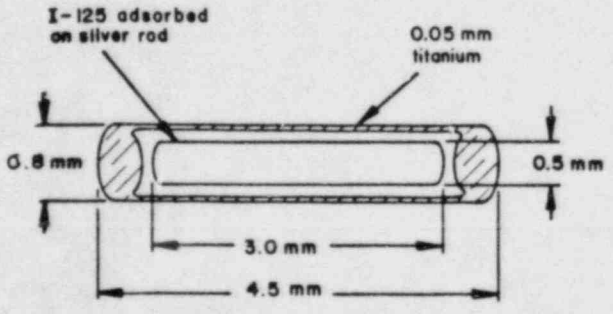
The 3M Company 6711 sealed source (therapeutic seed) is designed for use in the interstitial treatment of cancerous tumors. The seeds are designed to withstand normal autoclave temperature and pressure variations from 121°C at 15 PSI to 138°C at 35 PSI.

Ability to Withstand Loss of Containment Under Accident Conditions

3M high temperature test data reveals the source retains its integrity to at least 400°C. However, the capsule does lose its integrity at temperatures of about 600 C. The capsule leaks iodine. 3M Company states that the sources should not be subjected to temperatures in excess of 138°C and 35 PSI. In addition, the sources should not be placed in concentrated acids or sterilized by dry heat methods.

Sealed Source Description

The 3M Company Model 6711 seed contains iodine-125 absorbed on a solid silver bar and encapsulated in a cylindrical titanium capsule which is sealed by tungsten-inert-gas weld at each end of the capsule. Typical capsule design is shown in the figure below.



Radiation Levels

External radiation levels from the Model 6711 was determined by the 3M Company using film badges (specified accuracy + 15%). Results are:

	I-125 Seed Activity	Average Dose Rates (mR/hr): at 5 cms	at 30 cms
Model 6711	0.1 mCi (comp)	2.5	0.053
Model 6711	40.0 mCi (comp)	1000	21.2

Prototype Testing

Prototypes of the Model 6711 sealed source (seeds) were subjected to tests to demonstrate that the source will maintain their integrity under stresses of use and accident. The tests performed were in accordance with ANSI N44.1-1973, paragraphs 4.2.2 and 4.2.3. 3M Company reports that the prototypes passed the specified ANSI tests for impact and percussion. High temperature tests results show that the Model 6711 sealed source retains its integrity to temperatures of at least 400°C.

Manufacturing Controls

The 3M Company conducts the following quality control tests and inspection of the Model 6711 sealed source prior to distribution, visual inspection, initial leak test, second leak test, and autoclave, assay for radioactivity. Complete details of the quality control program are included in the February 8, 1980 application.

Limitations of Use and/or Other Considerations

A. Licensees should observe the 3M Company 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 compatable materials such as stainless steel, glass, nylon and teflon should be used).

   3. Seeds should not be exposed to temperatures in excess of 138°C and pressures in excess of 35 PSI.

B. Labeling: Due to the small size, individual sources are not labeled. Source containers are labeled in accordance with 10 CFR Part 20.

C. Leak Testing: Six month intervals -- The test shall be capable of detecting the presence of 0.005 microcuries of iodine-125 on the test samples.

D. Handling, Storage, Use, Transfer, and Disposal: To be determined by the licensing authority.

References

The safety review and registration of the Model 6711 sealed source design is based on information and test data contained in the 3M Company application received February 8, 1980 and letters dated April 18, 1980, May 8, 1980 and June 3, 1980 and enclosures thereto (see also 3M Company license No. 22-00057-59MD).

Date June 23, 1980 Reviewed By Earl A Wright

Date June 23, 1980 Concurrence Donald Singer

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

CERTIFICATE OF REGISTRATION
AND SAFETY ANALYSIS SUMMARY
SEALED SOURCE
(Amended in Entirety)

Amendment No. 1

Manufacturer and Distributor

3M Company
Medical Products Division
3M Center
St. Paul, MN 55101

Sealed Source Model Designation

Model 6701

Isotope

Iodine-125

Maximum Activity per Source

1.25 Millicuries (because of capsule absorption, this is referred to as 1.0 millicuries compensated) 50 millicuries (40 millicuries/comp)

Condition of Normal Use

The Model 6701 sealed source (therapeutic seed) is designed for use in the interstitial treatment of cancerous tumors. The seeds are designed to withstand normal autoclave temperature and pressure variations from 121°C at 15 PSI to 138°C at 35 PSI. This design may contain up to 50 millicuries for use as a calibration source.

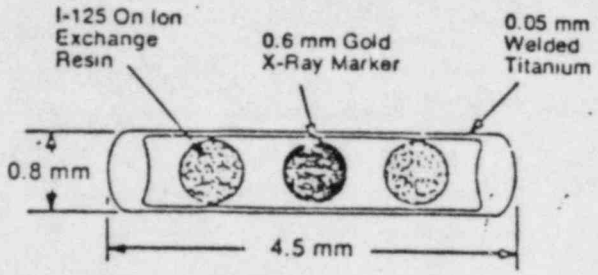
Ability to Withstand Loss of Containment Under Accident Conditions

3M high temperature test data reveals the source retains its integrity up to about 250°C. At that temperature the anion exchange resin breaks down and releases the iodine. However, the capsule does lose its integrity and leaks iodine at temperatures of about 600°C. 3M Company states that the sources should not be subjected to temperatures in excess of 138°C and 35 PSI. In addition, the sources should not be placed in concentrated acids or sterilized by dry heat methods.

Sealed Source Description

The 3M Model 6701 seed contains iodine-125 absorbed on anion exchange resin spheres and encapsulated in a cylindrical titanium capsule which is sealed

by tungsten-inert-gas weld at each end of the capsule. The resin beads are separated by a 0.6 mm diameter gold sphere. A typical capsule design is shown in the figure below.



Radiation Levels

External radiation levels from the Model 6701 was determined by the 3M Company using film badges (specified accuracy ± 15%). Results are:

Model 6701	2.5 mr/hr at 5 cms	0.05 mr/hr at 30 cms

Prototype Testing

Prototypes of the Model 6701 sealed source (seeds) were subjected to tests to demonstrate that the sources will maintain their integrity under stresses of use and accident. The tests performed were in accordance with ANSI N44.1-1973 paragraphs 4.2.2 and 4.2.3. 3M reports that the prototype passed the ANSI tests for impact and percussion. High temperature test results show that the Model 6701 sealed source retains its integrity up to temperatures of 250°C.

Manufacturing Controls

The 3M Company conducts the following quality control tests and inpsection of the Model 6701 sealed sources prior to distribution: visual inspection, initial leak test, second leak test, and autoclave, x-ray inspection, and assay for radioactivity. Complete details of the quality control program are included in the March 23, 1979 application.

Limitations of Use and/or Other Considerations

A. Licensees should observe the 3M Company 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 compatable materials such as stainless steel, glass, nylon and teflon should be used).

3. Seeds should not be exposed to temperatures in excess of 138°C and pressures in excess of 35 PSI.

B. Personnel monitoring is required by persons using the sources and the sources shall be handled only with appropriate handling equipment.

C. Labeling: Due to the small size, individual sources are not labeled. Source containers are labeled in accordance with 10 CFR Part 20.

D. Leak Testing: Six month intervals -- The test shall be capable of detecting the presence of 0.005 microcuries of iodine-125 on the test samples.

E. Handling, Storage, Use, Transfer, and Disposal: To be determined by the licensing authority.

References

The safety review and registration of the Model 6701 sealed source design is based on information and test data contained in the 3M Company application received March 23, 1979 and letters dated May 30, 1979, September 12, 1979, and enclosures thereto.

This amendment is issued in accordance with information and test data provided in 3M Company letters dated February 8, 1980, April 18, 1980, May 8, 1980, June 3, 1980 and enclosures thereto (see also 3M Company License No. 22-00057-59MD).

Date June 23, 1980 Reviewed By Earl G. Wright

Date June 23, 1980 Concurrence

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

CERTIFICATE OF REGISTRATION
AND SAFETY ANALYSIS SUMMARY
SEALED SOURCE
(Amended in Entirety)

Amendment No. 1

Manufacturer and Distributor

3M Company
Medical Products Division
3M Center
St. Paul, MN 55101

Sealed Source Model Designation

Model 6702

Isotope

Iodine-125

Maximum Activity per Source

50 Millicuries (because of capsule self absorption, this is referred to as 40 millicuries compensated)

Condition of Normal Use

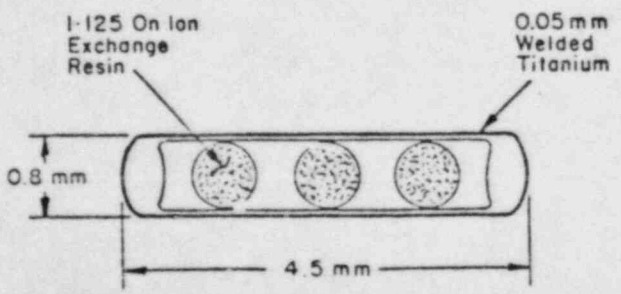
The Model 6702 sealed source (therapeutic seed) is designed for use in the interstitial treatment of cancerous tumors. The seeds are designed to withstand normal autoclave temperature and pressure variations from 121°C at 15 PSI to 138°C at 35 PSI.

Ability to Withstand Loss of Containment Under Accident Conditions

3M high temperature test data reveals the source retains its integrity up to about 250°C. At that temperature the anion exchange resin breaks down and releases the iodine. However, the capsule does lose its integrity and leak iodine at temperatures of about 600°C. 3M Company states that the sources should not be subjected to temperatures in excess of 138°C and 35 PSI. In addition, the sources should not be placed in concentrated acids or sterilized by dry heat methods.

Sealed Source Description

The 3M Model 6702 seed contains iodine-125 absorbed on anion exchange resin spheres and encapsulated in a cylindrical titanium capsule which is sealed by tungsten-inert-gas weld at each end of the tube. A typical capsule design is shown in the figure below.



Radiation Levels

External radiation levels from the Model 6702 was determined using film badges for exposure times ranging from 0.4 to 43 hours. 3M Company states an accuracy of ± 15% for the determination. Results are:

Model 6702	1000 mr/hr at 5 cms	21.5 mr/hr at 30 cms

Prototype Testing

Prototypes of the Model 6702 sealed source (seeds) were subjected to tests to demonstrate that the sources will maintain their integrity under stresses of use and accident. The tests performed were in accordance with ANSI N44.1-1973 paragraphs 4.2.2 and 4.2.3. 3M reports that the prototype sources passed the ANSI tests for impact and percussion. High temperature test results show that the Model 6702 sealed source retains its integrity up to temperatures of 250°C.

Manufacturing Controls

The 3M Company conducts the following quality control tests and inpsection of the Model 6701 and 6702 sealed sources prior to distribution: visual inspection, initial leak test, second leak test, and autoclave, x-ray inspection, and assay for radioactivity. Complete details of the quality control program are included in the March 23, 1979 application.

Limitations of Use and/or Other Considerations

A. Licensees should observe the 3M Company 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 compatable materials such as stainless steel, glass, nylon and teflon should be used).

   3. Seeds should not be exposed to temperatures in excess of 138°C and pressures in excess of 35 PSI.

B. Dose rates of about 1000 mr/hr at 5 cms from these sources are possible. Personnel monitoring is required by persons using the sources (extremity monitoring, i.e., ring dosimeter are suggested) and the source shall be handled only with appropriate handling equipment.

C. Labeling: Due to the small size, individual sources are not labeled. Source containers are labeled in accordance with 10 CFR Part 20.

D. Leak Testing: Six month intervals -- The test shall be capable of detecting the presence of 0.005 microcuries of iodine-125 on the test samples.

E. Handling, Storage, Use, Transfer, and Disposal: To be determined by the licensing authority.

References

The safety review and registration of the Model 6702 sealed source design is based on information and test data contained in the 3M Company application received March 23, 1979 and letters dated May 30, 1979, September 12, 1979, and enclosures thereto.

This amendment is issued in accordance with information and test data provided in 3M Company letters dated February 8, 1980, April 18, 1980, May 8, 1980, June 3, 1980 and enclosures thereto (see also 3M Company License No. 22-00057-59MD).

Date June 23, 1980 Reviewed By Earl A Wright

Date June 23, 1980 Concurrence Donald Sanger