DISTRIBUTION: Central File SS rf FCMC rf SLBaggett

JAN 3 1 1983

MEMORANDUM FOR: Joseph DelMedico Material Licensing Branch Division of Fuel Cycle and Material Safety, NMSS

FROM:

Steven L. Baggett Material Certification and Procedures Branch Division of Fuel Cycle and Material Safety, NMSS

SUBJECT: MINNESOTA MINING AND MANUFACTURING COMPANY MAIL CONTROL NO. 03701

Per your request dated December 10, 1982, we have reviewed 3M's application with respect to the update of sealed source/device reviews. We have concluded that the sources are still acceptable for licensing purposes. We have formulated new registry sheets from the information supplied by 3M.

We continue to approve the exemption from six month leak test requirements for the series 6500-6520 Cs-137 sources.

We have also reviewed Mr. Wright's letter dated July 20, 1981, and the answers provided by 3M in their letter dated September 23, 1981. We conclude that the information contained in the renewal application and this letter have satisfactorily answered Mr. Wright's questions.

> Original Signed By Steven L. Baggett

Steven L. Baggettt Material Certification and Procedures Branch Division of Fuel Cycle and Material Safety, NMSS

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OFFICE	FCMC						
SURNAME	SLBaggett:rad	1					
DATE 🌬	1/28/83		< · · · · · · · · · · · · · · · · · · ·				
NRC FORM	1 318 (10-80) NRCM 02	40	OFFICIAL	RECORD CO	DPY	180 5290	241

SEALED SOURCE & DEVICE TRACKING SHEET	REVIEW
DATE RECEIVED: 12/13/82 SEND TO	FEES? // YES Date Sent
CONTROL NUMBER: . 82-86	Date Returned
DESCRIPTION OF INC	OMING
Date of Incoming 9/23/81	Model Number(s) 6701
To:E. G. Wright	
Fm: Frank Copeland/Minnesota Min	ning and Manufacturing Company
SUBJECT: Renewal .	
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REVIEWER: S. L. Baggett	
TYPE OF REQUEST: // Certificate // Ame	REF LICENSE NO # 22-00057-59MD
- MILESTONES	Date Person-Hours
Request for Resubmission	and the second
Deficiency Letter	
Deficiency Telephone Call	
Response to Deficiency	
30 Day Abandonment Letter	
Request Denied	
Request Withdrawn by Applicant	
Certificate/Amendment/Custom Review Completed	1.0000
Void/Reason:	
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# UNITED STATES

Date December 10, 1982

TO: Material Certification & Procedures Branch, 426-SS

SUBJECT: MLB REQUEST FOR MCPB ASSISTAN

RETURN: MLB, 396-SS

Control No.: 03701 (attached) License No.: 22-00057-59MD (attached)

Letter No.: \_\_\_\_\_(attached)

Assistance requested:

Custom review

Custom review

New source review

New device review

X

Other (see remarks)

REMARKS :

Catalog has been checked. No informaton is available on the source/device.

We are not aware of any specific license which authorizes possession and use of this device.

Manufacturer is located in Agreement State. MLB has verified that no device review is completed or pending, and that a custom review is required.

Manufacturer is located in non-Agreement State.

Source/device will be imported.

If information provided by applicant is inadequate, assistance is required in the form of a letter/standard paragraphs and guides to request additional information from applicant.

X This case is being recorded in the computer as being assigned to I-5. When it is returned to MLB, it will be reassigned to a MLB reviewer.

Other -- See back of page

X

Requestor Joseph DelMedico

Since the source distribution license is in for renewal, it would be appropriate at this time to ask the manufacturer for any additional information that might be necessary to update the sealed source/device review, especially on Models 6D6C and 6B6G.

- According to the renewal application, the manufacturer no longer uses the model designations 6D6C and 6B6G. Instead, these sources now receive one of the following designations: Series 6500 or 6520 appears to replace 6D6C; and Series 6510, 6530, 6540, 6550, or 6570 appears to replace 6B6G. The catalogue sheets should be amended to reflect these changes and to explain the differences among the new series designations.
- As part of the renewal application, the manufacturer submitted complete sealed source/device information. Please review this information to determine if any of it is new or different from the original submission. This is important, since the information in the renewal application will become a part of the tie-down condition when the license renewal is issued.
- Part of the renewal application is a request to continue the exemption from 6 month leak test requirements for the Series 6500 and 6520 Cs-137 sources. Please evaluate this request and make a determination as to its acceptability. The catalogue sheet should be amended to reflect your determination.
- <sup>o</sup> To my knowledge, the issues raised in Earl Wright's letter of 7/20/80 (copy attached) have not been adequately resolved. In particular, the manufacturer's response to Item 2 of that letter makes reference to information contained in the license renewal application. I do not believe that Earl has had a chance to evaluate the referenced information in the renewal application to determine whether or not it adequately answers the question. What further action does the manufacturer need to take with regard to the problems detailed in Earl's letter before the distribution license can be renewed?

906 NO .: NR-460-S-187-S DATE :

PAGE 1 OF 9

SEALED SOURCE TYPE: Tube Source

MODEL: Series 6500, 6520 (formerly 6D6C)

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

ISOTOPE:

## MAXIMUM ACTIVITY:

Cesium-137

500.0 millicuries (18.50 GBq) (see description for activity per model)

LEAK TEST FREQUENCY: 36 Months

PRINCIPAL USE: (V) General Medical Use

CUSTOM SOURCE: YES X NO

<u>NO.:</u> NR-460-S-137-S <u>DATE:</u>

PAGE 2 OF 9

SEALED SOURCE TYPE: Tube Source

#### DESCRIPTION:

The 6500 Series and 6520 Series, together formerly known as the Model 6D6C source, are doubly-encapsulated gamma sources designed for use in brachytherapy applications. The 6500 Series, measuring approximately 0.787 in. (20.00 mm) long and 0.120 in. (3.050 mm) wide with a 0.551 in. (14.00 mm) active length, was formerly known as the size "CA" capsule of the 6D6C source. The 6520 Series, measuring approximately 0.630 in. (16.00 mm) long and 0.120 in. (3.050 mm) wide with a 0.394 in. (10.00 mm) active length, was formerly known as the size "CC" capsule of the 6D6C source.

Both the 6500 Series and the 6520 Series utilize cesium-137 (Cs-137) chloride contained in 3M Brand Radiating Microspheres. The microspheres are small ceramic particles into which the Cs-137 has been absorbed and then permanently fixed using a heat treatment. The microspheres are loaded into an inner capsule. That inner capsule either has a closed end and is sealed by one 0.043 in. (1.100 mm) stainless steel ball pressed into the open end and welded in place (sources made before 1985), or has two open ends and is sealed by two 0.043 in. (1.100 mm) stainless steel balls, one pressed into each end and welded in place (sources made after 1985). Sources made before 1985 were kept in stock until the stock was sold.

In either case, the inner capsule is inserted into an outer capsule. A welding plug is then inserted and welded in place. The outer capsule is either 0.787 in. (20.00 mm) long (for a 6500 Series source) or 0.630 in. (16.00 mm) long (for a 6520 Series source). For both Series, the outer capsule has an outer diameter of 0.120 in. (3.050 mm). After welding the outer plug, the entire source is nickel plated.

The outer capsule has an eyelet on one end. That end is also color coded with an epoxy resin to indicate the model number and activity of the source, according to the following chart:

<u>NO.:</u> NR-460-S-137-S <u>DATE:</u>

PAGE 3 OF 9

SEALED SOURCE TYPE: Tube Source

DESCRIPTION: (Continued)

# 6500 Series

Model	Color Code	Activity	mg Ra equiv.
6500	Blue	5 mCi (185 MBq)	12.56 mCi (464.7 MBq)
6501	Green	10 mCi (370 MBg)	25.13 mCi (929.8 MBq)
6502	Yellow	15 mCi (555 MBq)	37.69 mCi (1.395 GBq)
6503	Orange	20 mCi (740 MBq)	50.25 mCi (1.859 GBq)
6504	Red	25 mCi (925 MBg)	62.81 mCi (2.324 GBq)
6505	Violet	30 mCi (1.110 GBq)	75.38 mCi (2.789 GBq)
6506	White	35 mCi (1.295 GBq)	87.84 mCi (3.250 GBg)
6507	Black	40 mCi (1.480 GBq)	100.5 mCi (3.719 GBq)

# 6520 Series

Color Code	1	Activity	mq	Ra e	quivale	nt
Blue	5 mC	i (185 MBq)	12.56	mCi	(464.7	MBq)
Green	10 mC	Ci (370 MBq)	25.13	mCi	(929.8	MBq)
Yellow	15 mC	Ci (555 MBq)	37.69	mCi	(1.395	GBq)
Orange	20 mC	Ci (740 MBq)	50.25	mCi	(1.859	GBq)
Red	25 mC	Ci (925 MBq)	1.859	mCi	(3.719	GBq)

The Cs-137 tube source strengths listed above are "standard" activities. As the sources decay below the nominal activity, however, they fall into a "non-standard" activity category. The strengths of both the "standard" and "non-standard" activity sources are documented in the calibration certificate accompanying the sources at the time of distribution.

The 6500 Series and 6520 Series sources are stored in a lead pig container when not in use.

NO.: NR-460-S-137-S DATE:

PAGE 4 OF 9

SEALED SOURCE TYPE: Tube Source

DIAGRAM:

See Attachments 1 and 2

## LABELING:

3M stated that the exterior is engraved with a nominal activity and a serial number. In addition, the eyelet end of each 6500 Series and 6520 Series source is color-coded according to its nominal activity using a long-life epoxy resin. The <u>DESCRIPTION</u> section of this document has a table listing the colors and their corresponding nominal activities.

The lead pig container in which the 6500 Series and 6520 Series tube sources are stored has a label which includes the following:

Cesium-137	Description: Cesium-137 Sources capsules, an outer casing and an	
Brachytherapy	Cs-137 - labeled ceramic microspl	heres.
Sources	Product No	
0001000	Total Activity This Container	mCi Cs-137
Made in U.S.A. for	Number of Sources:	
Radistion Therapy Products Medical Products Division/3M	Assay Date:	
St. Paul, MN 55501	Store Source in shielded containe container with a shielding value e	a second s
radiation trefoil/	WARNING: Licensed by the U.S.	CAUTION: Federal law restricts
Caution Radioactive	Nuclear Regulatory Commission for distribution to persons	this device to sale by or on the order of 3 physician. Maintain
Material	licensed pursuant to \$ 35.14 and \$ 35.100 Group VI of 10 CFR Part 35 or under equivalent licenses of Agreement States.	proper radiation safety precautions at all times.

## <u>NO.:</u> NR-460-S-137-S <u>DATE:</u>

PAGE 5 OF 9

SEALED SOURCE TYPE: Tube Source

#### CONDITIONS OF NORMAL USE:

The 6500 Series and 6520 Series sources are intended for use in treating cancer in body cavities, such as gynecological cancers. These sources may be used in conjunction with other treatment modalities. The sources are loaded into an applicator for use in treating a patient. Treatment takes place in a hospital room, so environmental conditions are tightly controlled.

### PROTOTYPE TESTING:

Prototypes of the 6500 Series sources containing approximately 12.50 mCi (462.5 MBq) of Cs-137 were subjected to the following prototype tests:

- Temperature Test: Two 6500 Series sources were placed in a 1558.4°F ± 36°F (848°C ± 20°C) oven and left there for 77 minutes. Upon removal from the oven, the sources were dropped into water at a temperature of 57.2°F (14.0°C). Visual inspection of the sources after heating revealed no obvious structural defects. The wipe, leak, and soak tests were all negative for these two sources.
- 2. <u>Impact Test</u>: Two 6500 Series sources were dropped from a height of 29.53 feet (9.000 m) onto a flat, 0.500 in. (1.270 cm) thick steel plate. Visual inspection of the sources after the impact test revealed no obvious defects. The wipe, leak, and soak tests were all negative for these two sources.
- 3. <u>Percussion Test</u>: A 0.984 in. (2.500 cm) diameter steel bar weighing 3.198 lbs (1.451 kg) was dropped through a 1.378 in. (3.500 cm) inner diameter guiding sleeve onto each of the sources used in the Impact Test. The sources were lying horizontally on a 1.000 in. (2.540 cm) thick lead brick. One source was positioned so the center of the bar hit the source's center, and the other source was positioned so the edge of the bar hit the center of the source. Upon visual inspection after the percussion test, the former source

<u>NO.:</u> NR-460-S-137-S <u>DATE:</u>

PAGE 6 OF 9

SEALED SOURCE TYPE: Tube Source

### PROTOTYPE TESTING (Continued)

showed a bend of about 20° from the long axis of the source. No defects were observed in the latter source. The wipe, leak, and soak tests were all negative for these two sources.

After each test, the tested sources were subjected to wipe/smear, leak, and soak tests. The allowable limit of removable contamination for the wipe and soak tests was 0.0005  $\mu$ Ci (18.50 Bq). The soak test involved completely immersing the sources in distilled water heated to a temperature of at least 104°F (40°C) for a minimum of 16 hours. The leak test involved immersing the sources in glycerin heated to about 302°F (150°C) for at least one minute. Failure of this test occurred when any bubbles were observed coming from the source.

#### EXTERNAL RADIATION LEVELS:

The following dose rates were calculated from the dose rates at 39.37 in. (100 cm), which were measured by NIST (formerly NBS). NIST stated that the measured values were accurate to within 0.9 percent. The estimated activity for each source was calculated from the measured data using the exposure rate constant of 0.328 m<sup>2</sup>•mr/hr•mCi as described on page 8 of <u>Specification of Gamma-Ray Brachytherapy Sources</u>, NCRP Report No. 41, Washington, DC 20014.

	DOSE RATE AT				
	5 cm (1.97 in.) mR/hr (mSv/hr)	30 cm (11.8 in.) mR/hr (mSv/hr)	100 cm (39.4 in.) mR/hr (mSv/hr)		
11.6 (429.2)	1,524 (15.24)	42.30 (0.423)	3.810 (0.038)		
25.1 (928.7)	3,288 (32.88)	92.30 (0.923)	8.220 (0.082)		
37.2 (1376)	4,880 (48.80)	135.5 (1.355)	12.20 (0.122)		
57.1 (2113)	7,492 (74.92)	208.0 (2.080)	18.70 (0.187)		
72.6 (2686)	9,520 (95.20)	264.0 (2.640)	23.80 (0.238)		
93.0 (3441)	12,200 (122.0)	338.9 (3.389)	30.50 (0.305)		

<u>NO.:</u> NR-460-S-137-S <u>DATE:</u>

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PAGE 7 OF 9

SEALED SOURCE TYPE: Tube Source

#### QUALITY ASSURANCE AND CONTROL:

The following quality control procedures were followed during production of these sources:

- Each inner capsule was leak tested after it was sealed. A negative leak test meant that no air leaks or holes were detected while the capsule was immersed in glycerine at a temperature of 248°F - 302°F (120°C - 150°C) for at least 10 seconds.
- 2. Each inner capsule was wipe tested after it was sealed. The allowable limit was 0.0002  $\mu \text{Ci}$  (7.400 Bq) of removable Cs-137.
- 3. Each inner capsule was soak tested after it was sealed in 6-7 ml of distilled water at 68°F (20°C) for 16 hours. The allowable limit was 0.0002  $\mu\rm Ci$  (7.400 Bq) of detectable Cs-137.
- 4. Each source was wipe tested, after the outer capsule was sealed, as in test 2 above, except that the allowable limit for this test was 0.0001  $\mu$ Ci (3.700 Bq).
- 5. Each source was leak tested after the outer capsule was sealed, as in test 1 above.
- 6. Each completed source was leak tested as in test 1 above.
- 7. Each completed source was soak tested. The maximum allowable limit was 0.0005  $\mu$ Ci (18.50 Bq).
- 8. Each completed source was visually inspected to ensure it was nickel plated smoothly and completely with no discoloration, to check for uniform, smooth welds, to check for the proper color code, and to check that the activity (in mg Radium equivalent) and serial number were properly engraved on the source.
- 9. Each completed source was assayed to ensure its activity was 0-10 percent above the nominal activity.

<u>NO.:</u> NR-460-S-137-S <u>DATE:</u>

PAGE 8 OF 9

SEALED SOURCE TYPE: Tube Source

#### QUALITY ASSURANCE AND CONTROL: (Continued)

10. Prior to shipment, each source was visually inspected for proper labeling, assayed for radioactivity as in (9) above, and wipe tested, with an allowable limit of 0.0001  $\mu$ Ci (3.700 Bq) of removable contamination. Any sources not meeting these final checks were rejected.

## LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- These sources may be distributed only to persons specifically licensed by the NRC or an Agreement State.
- At time of distribution of both "standard" and "nonstandard" activity Cs-137 sources, a calibration certificate will accompany the shipment which shows for each source the actual measured output activity in millicuries of Cs-137 and the calculated milligram radium equivalent Cs-137 activity.
- Handling, storage, use, transfer, and disposal: to be determined by the licensing authority.
- As of July 1992, 3M Health Physics Services' entire inventory of 6500 Series and 6520 Series sources were bought by Medi+Physics of Arlington Heights, IL. They are intended for distribution under Medi+Physics' distribution license.
- The sealed sources shall be leak tested at intervals not to exceed 36 months (3 years) 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.

<u>NO.:</u> NR-460-S-137-S <u>DATE:</u>

PAGE 9 OF 9

SEALED SOURCE TYPE: Tube Source

#### SAFETY ANALYSIS SUMMARY:

The 6500 Series and 6520 Series sources are not current products manufactured or distributed by 3M Health Physics Services. However, 3M Health Physics Services will continue to receive these sources for disposal.

Based on our review of the information and test data cited below, and the past history of the source design, we continue to conclude that the 6500 Series and 6520 Series tube sources are acceptable for specific licensing purposes.

Furthermore, we continue to conclude that these sources would be expected to maintain their containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

## **REFERENCES**:

The following supporting documents for the 6500 Series and 6520 Series (formerly 6D6C) sources are hereby incorporated by reference and are made a part of this registry document:

• 3M Health Physics Services' letters dated August 6, 1991, February 15, 1991, November 6, 1990, July 24, 1989, January 17, 1985, and May 1, 1980, with enclosures thereto

#### ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date:	

Reviewer:

Thomas W. Rich

Date:

Concurrence:

Steven L. Baggett

<u>NO.:</u> NR-460-S-137-S <u>DATE:</u>

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ATTACHMENT 1

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<u>NO.:</u> NR-460-S-137-S <u>DATE:</u>

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ATTACHMENT 2

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3M Health Physics Services

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

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3M

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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:

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

Yours truly,

Robert G. Wissink, Chairman Isotope Committee

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

9608270101

07/29/91

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MINNESOTA MINING & MFG (TO INACTIVE STATUS)

SOURCE INVOICE # LICENSE # MODEL # AMO 6645 91 STB 1129 THORIUM AMO 6541 91 22 00057 34G 703 AMO 6628 91 NR 04595 101 5 4F6Y AMO 6629 91 NR 04595 102 5 3F1G AMO 6551 91 NR 04605 101 U 4F60 ~ AMO 6552 91 NR 04605 102 5 4F6H-- NR460867 41460 874 4F6G / AMO 6553 91 NR 04605 103 UV AMO 6554 91 NR 04605 105 U 686F V 4 F6P . AMO 6555 91 NR 04605 106 U AMO 6556 91 NR 04605 107 S 1C2A, 1C2B AMO 6557 91 NR 04605 108 U 4F38 / AMO 6558 91 NR 04605 109 U 4F3C / AMO 6543 91 NR 04600 110 U 3M1C / AMO 6544 91 NR 0460D 111 U 3M1B/ AMO 6559 91 NR 04605 112 U 3E4G / AMO 6560 91 NR 04605 113 U. 4D3AV AMO 6561 91 NR 04605 114 U 4D3BV AMO 6562 91 NR 04605 115 U 4060 AMO 6563 91 NR 04605 116 U 406F -AMO 6564 91 NR 04605 117 U 5F1D / AMO 6565 91 NR 04605 118 U 5F1E -AMO 6556 91 NR 04605 119 U SF1F / AMO 6567 91 NR 04605 120 U 5F1G / AMO 6568 91 NR 04605 121 U 3L2B / AMO 6569 91 NR 04605 122 U 3L2AJ AMO 6545 91 NR 0460D 123 U 3M1FV AMO 6570 91 NR 04605 124 U 3L2C / AMO 6571 91 NR 04605 125 U 1E2JV AMO 6572 91 NR 04605 126 U 3F1G / AMO 6573 91 4F1EV NR 04605 127 U AMO 6574 91 NR 04605 128 U 5F1H 3E40 / AMO 6575 91 NR 04605 129 U AMO 6576 91 SFINV NR 04605 130 U AMO 6577 91 NR 04605 131 U 5F1N (MODIFIED) AMO 6578 91 NR 04605 132 U 788L V AMO 6579 91 NR 04605 133 U 6H6A -AMO 6580 91 NR 04605 134 U 6H68 V AMO 6581 91 NR 04605 135 U 406M / AMO 6582 91 3L2E/ NR 04605 136 U AMO 6583 91 NR 04605 137 Sau 6500 & 6520 (FORMERLY 606C) NR 04605 138 U AMO 6584 91 3L2D 3010 / AMO 6585 91 NR 04605 139 U AMO 6586 91 NR 04605 140 U 3E4L, 3E45 / £ NR 04605 141 U AMO 6587 91 3F1R / AMO 6546 91 902, 902F, 903-NR 0460D 142 G AMO 6588 91 D NR 04605 143 S 4P6E/ AMO 6589 91 0 NR 04605 144 5 4 P 6 M V NR 0460D 145 U AMO 6547 91 3M1L / S NR 04605 146 U 3G9A / AMO 6590 91 3840 S ( AMO 6592 91 NB 04605 147 U SAMA 384G 3 AMO 6591 91 NR 04605 147 S AMO 6593 91 4F3F / NR 04605 148 U

4F36 -

NR 04505 149 U

AMO 6594 91

PAGE 1

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SOURCE	
INVOICE # LICENSE # MODEL #	
ANO 6595 91 NR 04605 151 5 6530, 8540 (FORMERLY 6866)	
AMO 6596 91 NR 04605 153 S ALBUMIN MICROSPHERES (HUMAN) T	C-DOM and wit
AMO 6548 91 NR 0460D 152 U 6H6D √ AMO 6596 91 NR 0460S 153 S ALBUMIN MICROSPHERES (HUMAN) T AMO 6549 91 NR 0460D 154 U 6H6E SOURCE APPLICATOR, 8C9T S	AFF
ANO 6597 91 NR 04605 155 5 4D6L	
AMO 6598 91 NR 04605 156 5 4D6P	
AMO 6599 91 NR 04605 158 U 3F1I, 3F1J, 3F1L /	
AMO 6600 91 NR 04605 159 U 3F1V	
AMO 6601 91 NR 04605 160 U 4P6T - NA4603 8735	
AMO 6602 91 NR 04605 161 U 4F3D	
AMO 6603 91 NR 04605 162 U 4F3HV	
AMO 6604 91 NR 04605 163 5 4F65	
AMO 6605 91 NR 04605 164 5 3E40	
AMO 6606 91 NR 04605 165 5 6701	
AMO 6550 91 NR 0460D 168 G 702, 703, 704 D	
AMO 6609 91 NR 04605 169 550,6550,6570 (FORMERLY 686G)	
AMO 6610 91 NR 04605 170 5 4P6V	-
AMO 6611 91 NR 04605 171 5 4F65T	