NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 18

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

39283

Licensee	
1. Mallinckrodt Medical, Inc. 2. 2703 Wagner Place Maryland Heights, MO 63043	In accordance with letter dated October 10, 1995 3. License Number 24-04206-05MD is amended in its entirety to read as follows: 4. Expiration Date December 31, 2000 5. Docket or Reference No. 030-10801

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Chromium-51	A. Sodium Chromate (NDA 16-708)	A. Not Applicable
B. Xenon-133	B. Gas (NDA 18-327)	B. Not Applicable
C. Iodine-125	C. Radioiodinated Human Serum Albumin (NDA 17-844)	C. Not Applicable
D. Iodine-131	D. Sodium Iodohippurate (NDA 16-666)	D. Not Applicable
E. Iodine-131	E. Sodium Iodide Capsules (NDA 16-517)	E. Not Applicable
F. Iodine-131	F. Sodium Iodide Solution (NDA 16-515)	F. Not Applicable
G. Phosphorus-32	G. Chromic Phosphate NDA 17-084)	G. Not Applicable
H. Phosphorus-32	H. Sodium Phosphate (NDA 11-777)	H. Not Applicable
I. Molybdenum-99	I. Molybdenum-99/ Technetium-99m generators (Mallinckrodt, Inc. Ultra-Technekow FM Generators NDA 17-243)	I. Not Applicable

280017

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 24-04206-05MD
Docket or Reference Number: 030-10801
Amendment No. 18

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
J. Molybdenum-99	J. Molybdenum-99/ Technetium-99m generators (Mallinckrodt, Inc. Ultra-Technekow FM, NDA No. 17-243)	J. No single generator to exceed 12 curies on day of shipment
K. Molybdenum-99	K. Molybdenum-99/ Technetium-99m generators (Mallinckrodt, Inc. Ultra-Technekow FM, generators modified to use Medi-Physics depleted uranium (DU) shields, NDA No. 17-243)	K. No single generator to exceed 12 curies on day of shipment
L. Rhenium-186	L. Sodium Perrhenate or Rhenium-186 Etidronate (IND 34,326)	L. Not Applicable
M. Molybdenum-99	M. Molybdenum-99/ Technetium-99 generators (Mallinckrodt, Inc. Ultra-Technekow FM Dry Top Eluting Generators NDA No. 17-243/S-012)	M. No single generator to exceed 12 curies on day of shipment

9. Authorized Use:

Pursuant to Section 32.72 and 32.74 of 10 CFR Part 32, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 of this license to persons licensed pursuant to Sections 35.14 and 35.100 of 10 CFR Part 35 (superseded) or Sections 35.100, 35.200 and 35.300 of 10 CFR Part 35 (effective April 1, 1987), or under equivalent licenses of Agreement Stations, for the Groups or Sections indicated below:

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
24-04206-05MD

Docket or Reference Number
030-10801

Amendment No. 18

A. Group I (superseded) or Section 35.100 (effective April 1, 1987).

B. Section 35.200 (effective April 1, 1987).

C. Group I (superseded) or Section 35.100 (effective April 1, 1987).

D. Group I and Group II (superseded) or Section 35.100 (effective April 1, 1987).

E. Group I, Group II, Group IV, and Group V (superseded) or Sections 35.100 or 35.300 (effective April 1, 1987).

F. Group IV and Group V (superseded) or Section 35.300 (effective April 1, 1987).

G. Group IV (superseded) or Section 35.300 (effective April 1, 1987).

H. Group IV (superseded) or Section 35.300 (effective April 1, 1987).

I. Group III (superseded) or Section 35.200 (effective April 1, 1987).

J. For distribution to Mallinckrodt, Inc. nuclear pharmacy licenses and other commercial nuclear pharmacies as described in letter dated March 14, 1994 with attachments and in accordance with statements, representations, and procedures listed in letters dated November 15, 1985 and October 3, 1986.

K. For distribution to nuclear pharmacy and hospital licenses, who are customers of Medi-physics, in accordance with statements, representations, and procedures listed in letters dated May 14, 1993 and May 25, 1993.

L. Group II (superseded) or Section 35.200 (effective April 1, 1987).

M. For Distribution to Mallinckrodt, Inc. nuclear pharmacy licenses and other commercial nuclear pharmacies as described in letters dated 10/10/95, 8/14/95, 9/26/96 and 10/10/96, in accordance with statements, representations, and procedures listed in letter dated 11/15/95 and 10/3/86.

CONDITIONS

10. This license does not authorize possession or use of licensed material.

11. The licensee shall notify the U.S. Nuclear Regulatory Commission within thirty (30) days of the termination of a "Notice of Claimed Investigational Exemption for a New Drug (IND) for licensed material described in Items 6 and 7.

12. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number 24-04206-05MD

Docket or Reference Number 030-10801

Amendment No. 18

13. Any proposed changes in packaging, shielding, labeling or the package insert shall be submitted for review to the Material Licensing Section, U.S. Nuclear Regulatory Commission, 801 Warrenville Road, Lisle, Illinois 60532-4351.

14. The distribution of the Mallinckrodt Ultra-TechneKow FM (UTK-FM) Molybdenum-99/Technetium-99m Generators which contain Medi-Physics depleted uranium (DU) shields authorized in License Items 6.K. and 7.K. of this license does not relieve Mallinckrodt Medical, Inc. from compliance with applicable Food and Drug Administration (FDA) requirements before distribution begins.

15. Except as specifically provided otherwise by this license, the licensee shall manufacture, package, label and distribute licensed material described in Items 6. and 7. of this license in accordance with the statements, representations, and procedures contained in:

    A. Application dated July 31, 1990; and

    B. Letters dated November 15, 1985, October 3, 1986, May 14, 1993, May 25, 1993, March 14, 1994 (with attachments) and October 10, 1995, August 14, 1996, September 26, 1996, and October 10, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date October 15, 1996

By Cynthia D. Pederson
Nuclear Materials Licensing Branch, Region III

COPY

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02511
STATUS CODE: 0
FEE CATEGORY: 3D
EXP. DATE: 19951231
FEE COMMENTS:
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: MALLINCKRODT MEDICAL INC.
RECEIVED DATE: 951012
DOCKET NO: 3010801
CONTROL NO.: 399283
LICENSE NO.: 24-04206-05MD
ACTION TYPE: AMENDMENT

R3

2. FEE ATTACHED
AMOUNT: 420
CHECK NO.: 8941

3. COMMENTS

SIGNED Doug Bell
DATE 10-19-95

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED)

1. FEE CATEGORY AND AMOUNT: 3D $420

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT ✓
RENEWAL
LICENSE

3. OTHER

SIGNED SC
DATE 10/20/95

R3

Log Oct 13 III
Remitter
Check No. 8941
Amount $420
Fee Category 3D
Type of Fee Amendment
Date Check Rec'd 10-19-95
Date Completed 10-20-95
By: SC

RECEIVED
OCT 25 1995
REGION III

R3

MALLINCKRODT
Nuclear Medicine

Mallinckrodt Medical, Inc.
2703 Wagner Place
Maryland Heights, MO 63043
Telephone (314) 770-7800

October 10, 1995

A

Cassandra F. Frazier
Nuclear Materials Licensing Section
U.S. Nuclear Regulatory Commission,
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

030-10801

RE: License No. 24-04206-05MD

Dear Ms. Frazier:

Mallinckrodt Medical Inc. (MMI) hearby applies for an amendment of the above referenced license for the distribution of the Dry Top Eluting Mo-99/Tc-99m Generator (DTE Generator). The DTE generator is an upgrade of the Ultra-TechnaKow (UTK Generator) presently distributed by MMI. These generators will contain the various activity sizes currently used in the UTK Generator, except for the 0.25 Ci size generator which will be discontinued. Please refer to Attachment VII for activity sizes and corresponding safe sizes.

The upgrade consists of a repositioning of the inner components, which includes a relocation of the internal plumbing, from the bottom to the top of the generator. The elution vial is no longer attached to the generator. The elution vial is included as a separate component and shipped as an insert in the final generator package. Please refer to Attachments IV and V.

Mr. Ashok Dhar requested an early NRC review of the DTE license amendment application with you during a telephone conversation in the first quarter of 1995. You agreed to review this license amendment application early with a condition of MMI sending the FDA final approvable letter as soon as it was received. The preliminary approvable letter has been received; MMI is responding to the FDA comments. MMI is anticipating final FDA approval by the end of October 1995.

On October 2, 1995 during a telephone conversation with the NRC, Mr. Kevin Null, stated that it would be acceptable for MMI to submit labels and/or stats in the MMI license amendment request.

399283

Enclosed are technical data tables and copies of all the labeling and/or stats which will be located on either the generator or the generator packaging. There are five copies of the label and/or stats for your review. MMI will submit all the final labels which are currently in stat form to the NRC, after FDA approval. The technical data tables include information regarding the generator safes and the maximum precalibration activity amounts and radiation levels for all unpackaged generator sizes. Also included are drawings of the three different generator safes with the corresponding packaging.

The Attachments are as follows:

ATTACHMENT	**DESCRIPTION**
Attachment I	The 38mm lead safe Contains the 0.25 Ci, 0.50 Ci, and 0.75 Ci generators The 48 mm lead safe. Contains the 1.00 Ci, 1.50 Ci, 2.00 Ci, 2.50 Ci, 3.00 Ci, 4.3 Ci, 5.3 Ci, and 6.4 Ci generators
Attachment Ia	The Lead Plug for the 38 mm and 48 mm lead safe
Attachment Ib	The plastic adapter for the small lead safe
Attachment Ic	The plastic adapter for the large lead safe
Attachment II	The Depleted Uranium (DU) safe Contains the 12.00 Ci size generator
Attachment IIa	The DU/Lead Plug for the 12 Ci DU safe
Attachment III	The plastic adapter top of the DTE generator
Attachment IV	The DTE generator assembly diagram
Attachment V	The DTE generator package diagram

Attachment VI	The DTE generator labels
Attachment VIa	AS497V-Test Elution Vial Label
Attachment VIb	AS498V-Generator Eluant Bottle Label
Attachment VIc	AS507V-TechneStat Vial Label
Attachment VId	AS508V-10 ml Evacuated Collecting Vial Label (STAT)
Attachment VIe	AS509V-20 ml Evacuated Collecting Vial Label (STAT)
Attachment VIf	A784K0-10 ml Evacuated Vial Pack Label (STAT)
Attachment VIg	A785K0-20 ml Evacuated Vial Pack Label
Attachment VIh	A80010-10 ml Accessory Pack Label
Attachment VIi	A80020-20 ml Accessory Pack Label
Attachment VIj	A880I0-Package Insert Label (STAT)
Attachment VIk	A880C0-Canister Label
Attachment VIl	Outer shipping carton surface label
Attachment VII	Surface Radiation and TI Levels and for the Packaged DTE
Attachment VIII	Product Information for the DTE Generator

We believe that we have included all of the information you will need for your assessment of the generator upgrade except for the final approvable letter from the FDA. NRC Form 313 and a $420 check for the license amendment fee is attached.

We would appreciate your prompt attention to this amendment request. Please contact me at (314) 770-7981 if you have any questions or require additional information.

Regards,

Daniel Riemer
Health Physics Supervisor

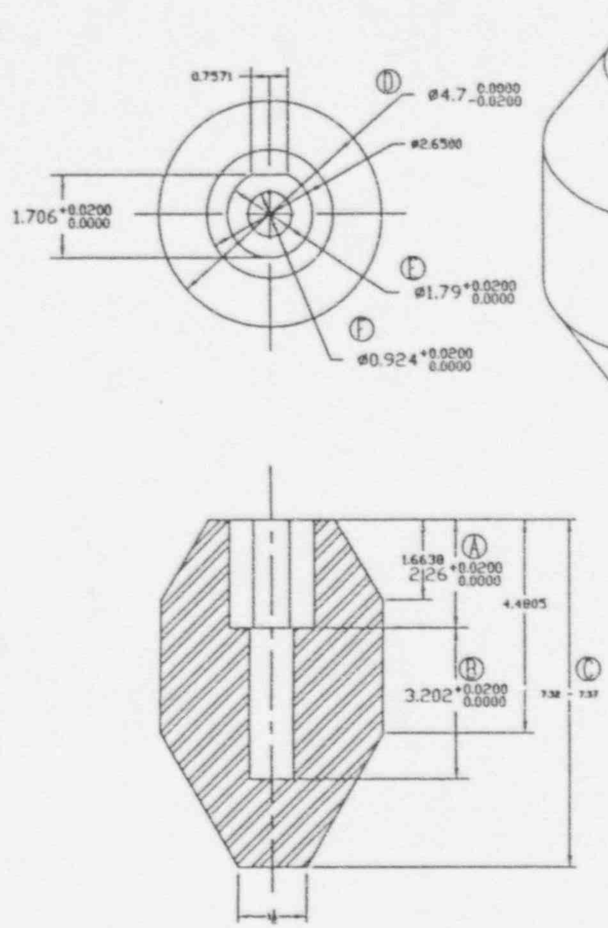
Attachments
Amendment Fee Check

4

Attachment I

NOTES:

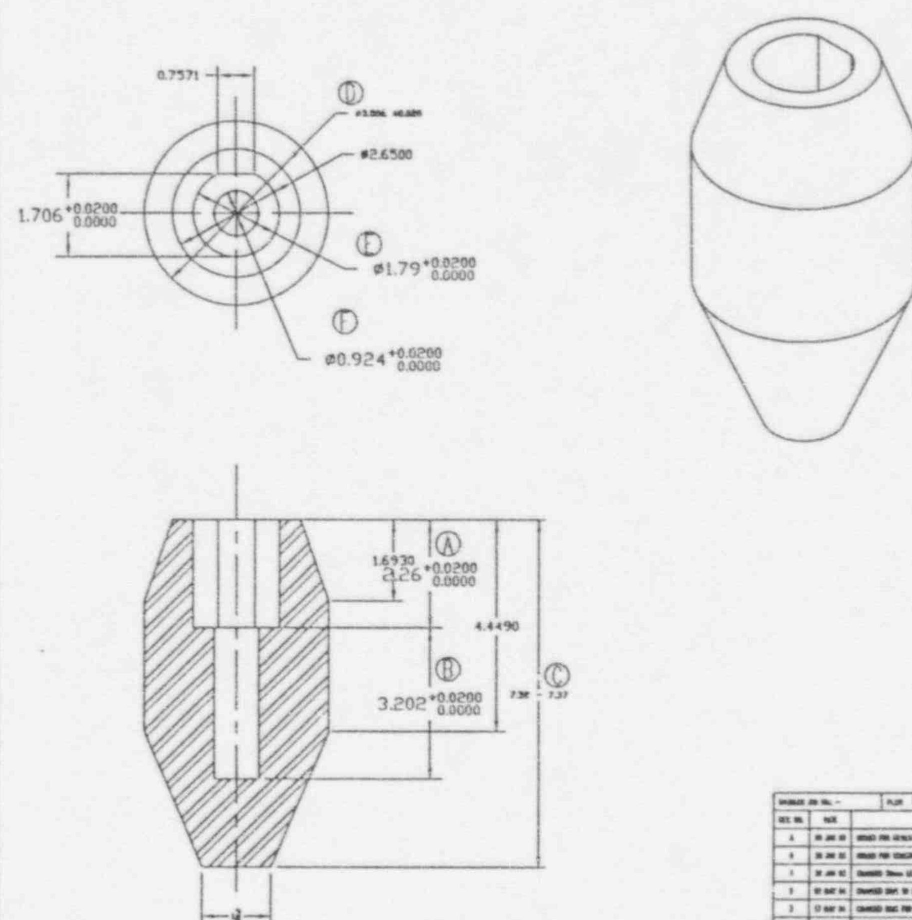
1. ALL DIMS ±0.020" UNLESS MARKED OTHERWISE
2. LEAD TO GE 99% PURE, MINIMUM



① 48 mm LEAD SAFE

SEE ASSEMBLY DWG. 8109-501-004

MIN. WT. - 34.20 lbs



② 38 mm LEAD SAFE

SEE ASSEMBLY DWG. 8109-501-004

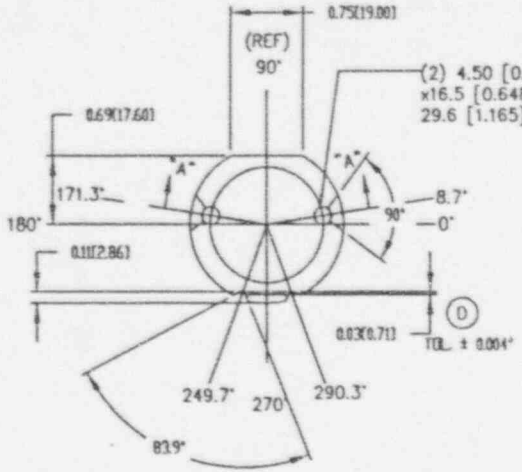
MIN. WT. - 22.20 lbs

MALLINCKRODT
Nuclear Medicine
MALLINCKRODT MEDICAL, INC.
2703 WAGNER PLACE
MARYLAND HEIGHTS, MISSOURI 63043-3493

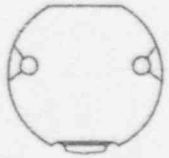
L330-00/48mm & L331-00/38mm
LEAD SAFES - DTE GENERATOR

MARYLAND HEIGHTS
1 : 1 OF 1
05 JAN 93
MICHEAL J. PABICK
24 MAY 95
DAVE EDELEN

A Hachmeyer Ig



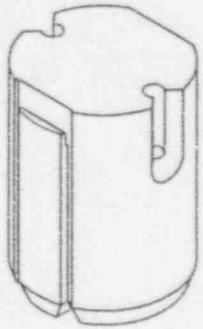
TOP VIEW

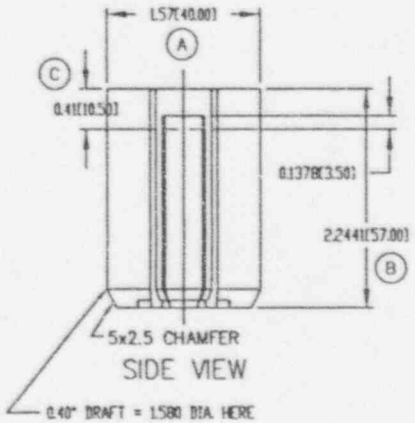


TOP VIEW
FULL SCALE DETAIL

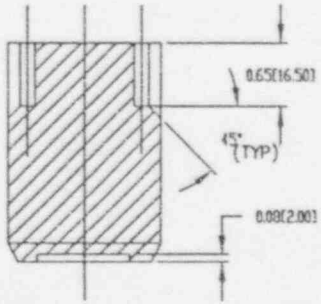
CRITICAL DIMENSIONS

A.	39.7 mm – 40.3 mm	1.563" – 1.587"
B.	56.5 mm – 57.5 mm	2.224" – 2.264"
C.	10.0 mm – 11.0 mm	0.394" – 0.433"
D.	0.64 mm – 0.89 mm	0.025" – 0.035"

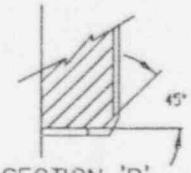




SIDE VIEW

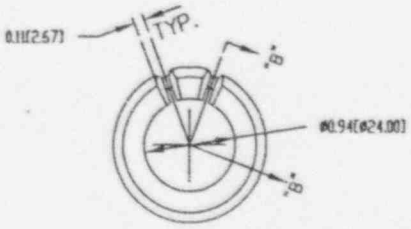


SECTION 'A'



SECTION 'B'

MIN. WEIGHT 678 GRAMS



BOTTOM VIEW

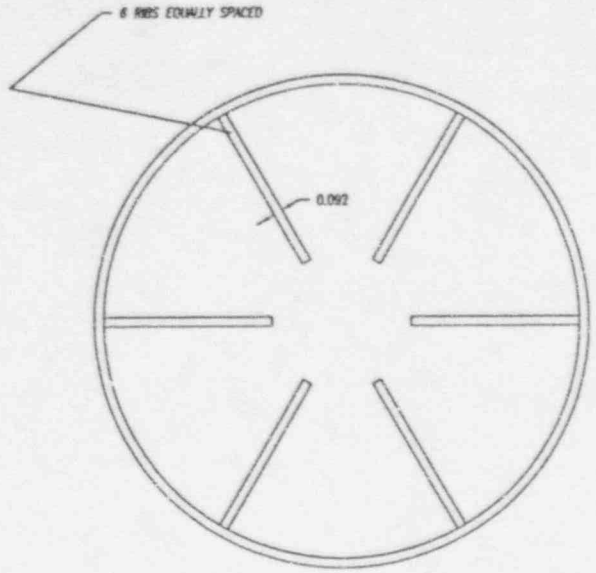
NOTES:
1. ALL TOLERANCES ARE ± 0.010", EXCEPT WHERE NOTED
2. LEAD TO BE 99% PURE, MINIMUM
3. ALL DIMENSIONS ARE FINISHED SIZES AFTER PLATING
4. FINISH IS TO BE NICKEL PLATE

PLANT	MARYLAND HEIGHTS	B.O. XXX	PLOT XXX
SCALE	1 : 1 @ C	DATE	13 DEC 94
DRAWN BY	MICHAEL J. PATRICK	DATE PLOTTED	24 MAY 95
FILE	L333	DRAWER	DAVE CHILEN
DRAWING NO.			00

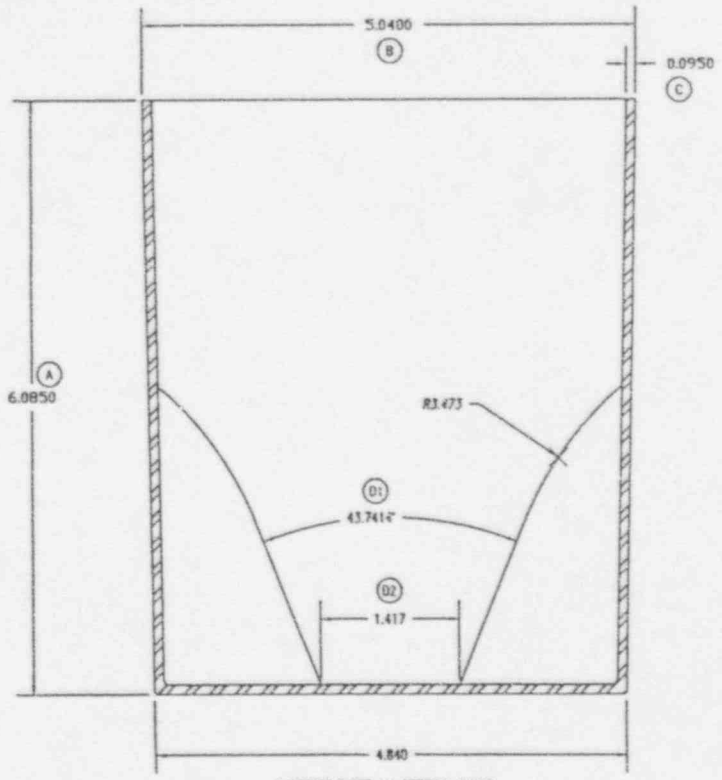
MALLINCKRODT Nuclear Medicine
MALLINCKRODT MEDICAL, INC.
2703 WAGNER PLACE
MARYLAND HEIGHTS, MISSOURI 63043-3483

L333-00 LEAD PLUG DETAIL
DTE GENERATOR

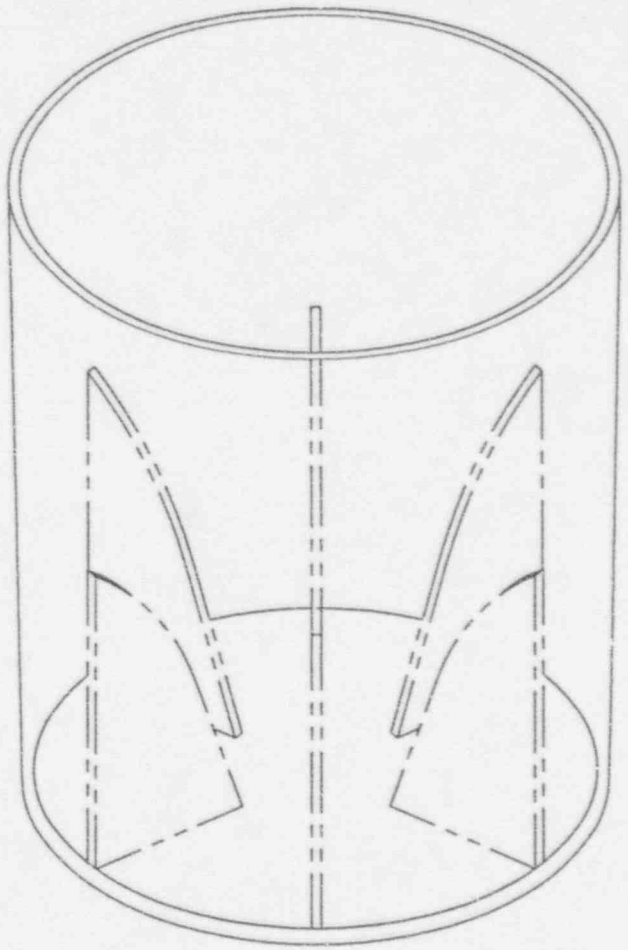
Attachment Ib



TOP VIEW



FRONT VIEW



TOLERANCES ±0.010"

ENGINEERING JOB NO.: -			PART: C	PROJECT NO.: 8888
REV. NO.	DATE		REVISIONS	
0	18 OCT 94	ADDED TOLERANCE NOTE TO DWG		
1	10 OCT 94	ADDED 2D AND CHANGED SCALE TO 1:2.5		
2	31 DEC 94	CHANGED TOP DIA. PER ACTUAL PART PERFORMANCE		
3	30 MAY 95	CHANGED TAPER DIA. PER ACTUAL PART PERFORMANCE		

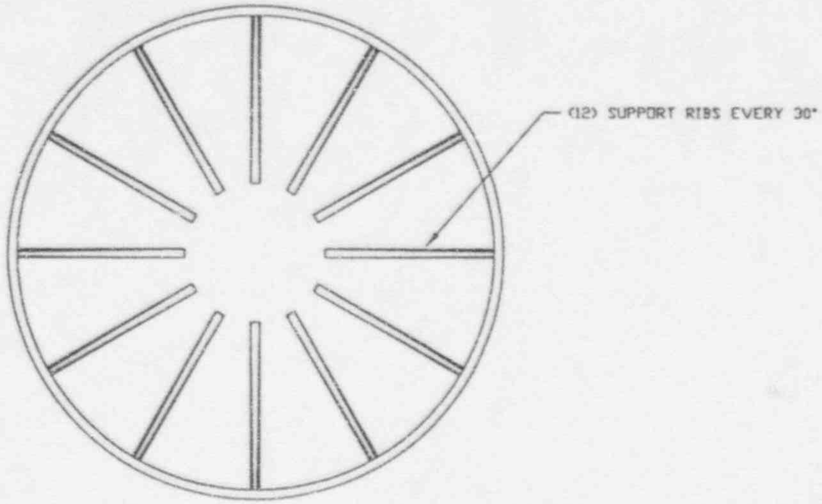
MALLINCKRODT
Nuclear Medicine
MALLINCKRODT MEDICAL, INC.
2703 WAGNER PLACE
MARYLAND HEIGHTS, MISSOURI 63043-3483

L336-00 SMALL PLASTIC ADAPTER BOTTOM - DTE GENERATOR

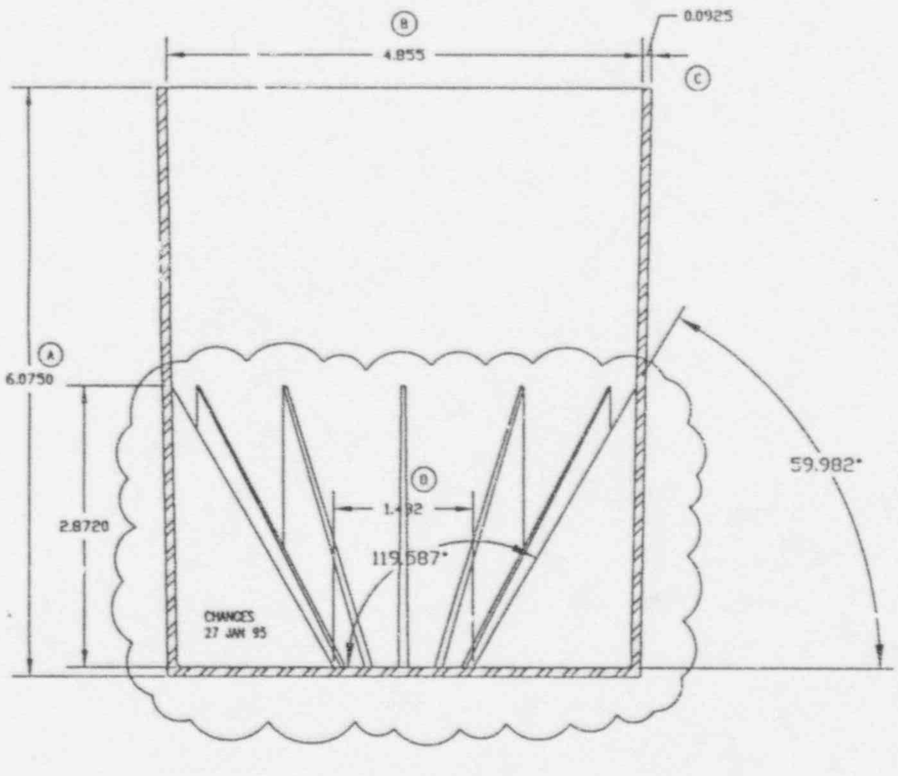
PLANT: MARYLAND HEIGHTS		AREA: XXX	FLOOR: XXX
SCALE: 1 : 1 @ C		DATE: 18 OCT 94	
DRAWN BY: MICHEAL J. PATRICK		DATE PLOTTED: 30 MAY 95	
FILE: L336		DRAWER: DAVE EDELEN	
DRAWING NO.		REV. 3	

Attachment I6

7

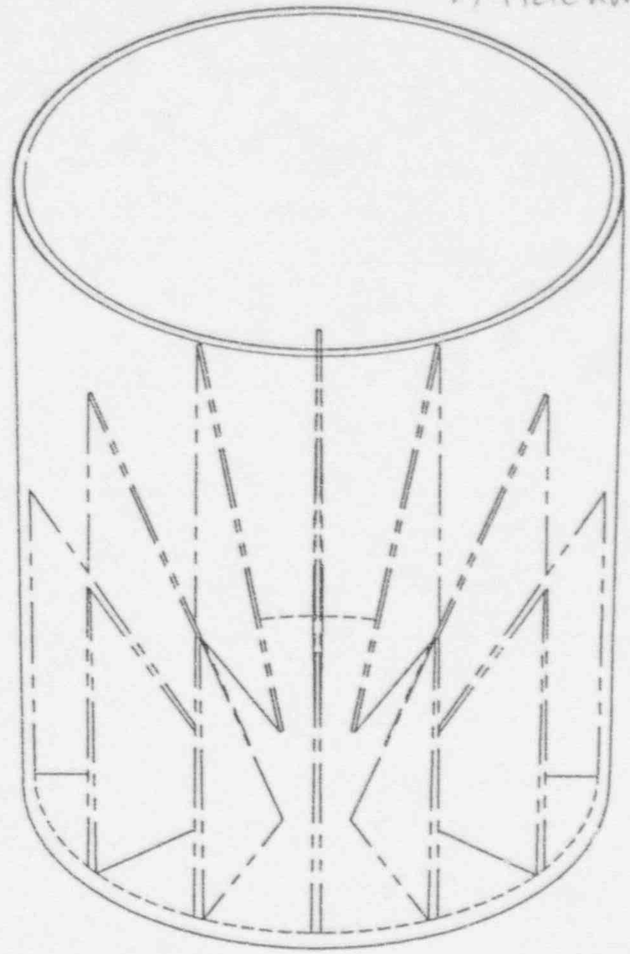


TOP VIEW



1 DEGREE TAPER ALL VERTICAL WALLS

FRONT VIEW



TOLERANCES ±0.010"

MALLINCKRODT
Nuclear Medicine
MALLINCKRODT MEDICAL, INC.
2703 WAGNER PLACE
MARYLAND HEIGHTS, MISSOURI 63043-3483

L335-00 LARGE PLASTIC ADAPTER
BOTTOM - DTE GENERATOR

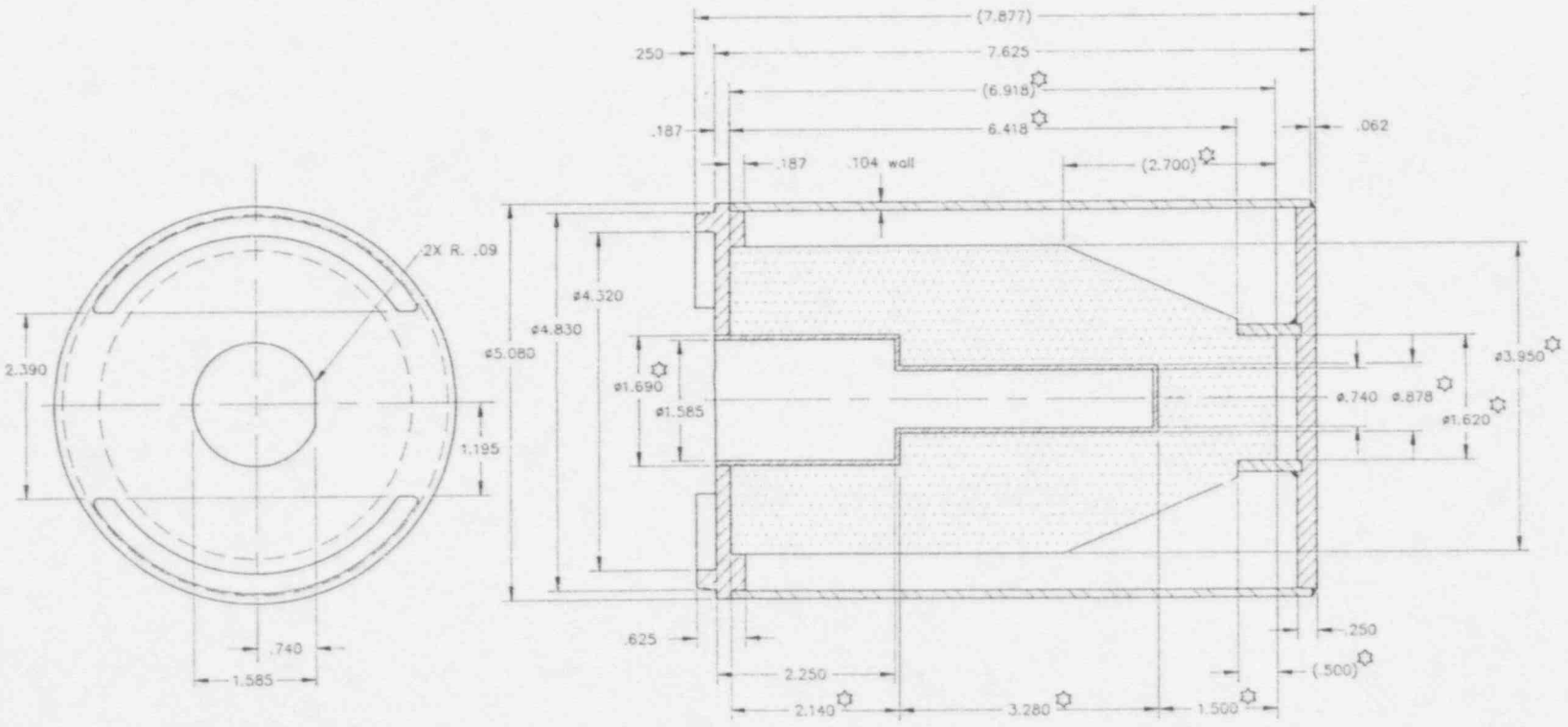
PLANT MARYLAND HEIGHTS	BLDG. XXX	FLOOR XXX	
SCALE 1 : 1 @ C	DATE 10 OCT 94		
DRAWN BY MICHEAL J. PATRICK	DATE PLOTTED 30 MAY 95		
FILE L335	CHECKED DAVE EDELEN		

90

Attachment II

NOTES (UNLESS OTHERWISE SPECIFIED):
1. URANIUM DIMENSIONS INDICATED WITH THE SYMBOL ☼

REVISIONS			
REV	DESCRIPTION	DATE	ECO #
A	REDRAWN WITH AUTOCAD	5/30/95	



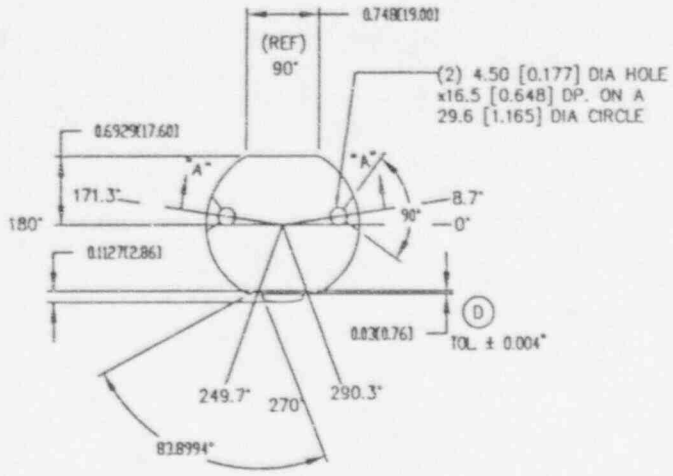
RIVERS COMPANY

TITLE	DU ASSEMBLY–RETROFIT DTE			
SIZE	CUST. MALLINCKRODT	DATE 5-3-94	DWG. NO.	REV
A	DRN BY R. DIAZ SHEET 1 OF 1	SCALE 1/1	C2305	A

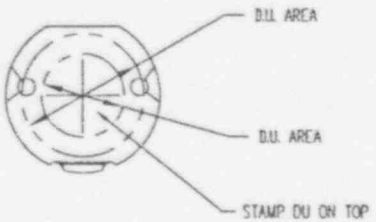
Attachment 9

CRITICAL DIMENSIONS

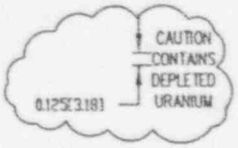
A.	39.7 mm – 40.3 mm	1.563" – 1.587"
B.	56.5 mm – 57.5 mm	2.224" – 2.264"
C.	10.0 mm – 11.0 mm	0.394" – 0.433"
D.	0.64 mm – 0.89 mm	0.025" – 0.035"



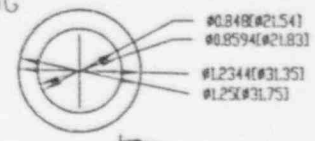
TOP VIEW

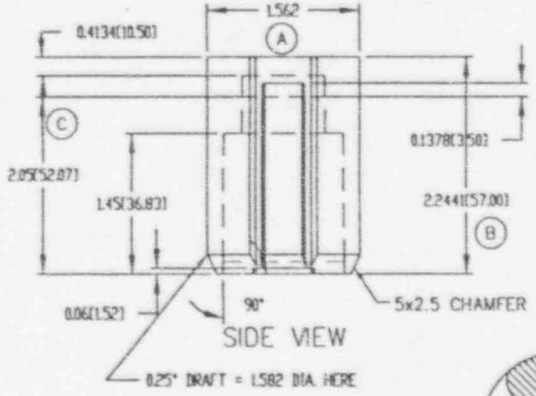


TOP VIEW
FULL SCALE DETAIL

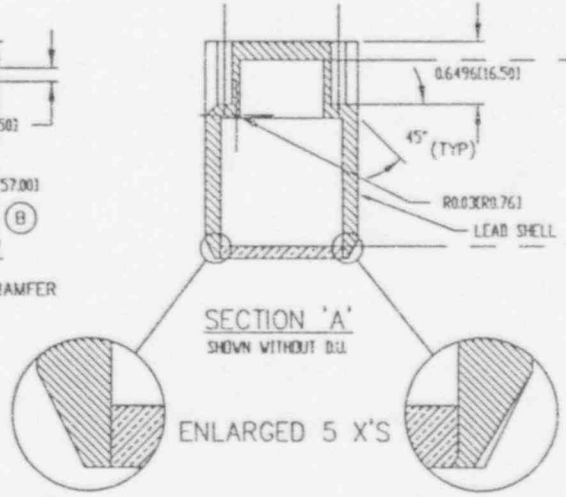


RAISED LETTERING
FOR TOP OF PLUG





SIDE VIEW

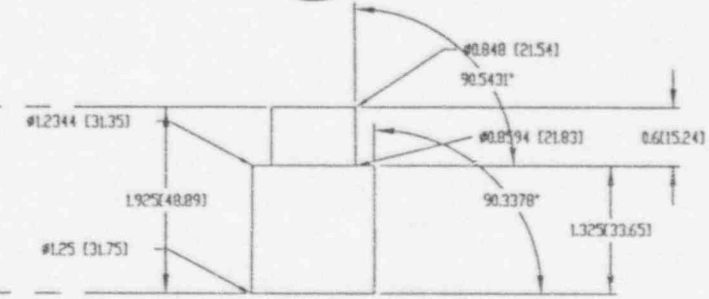


SECTION 'A'
SHOWN WITHOUT D.U.

ENLARGED 5 X'S

BEFORE CRIMPING

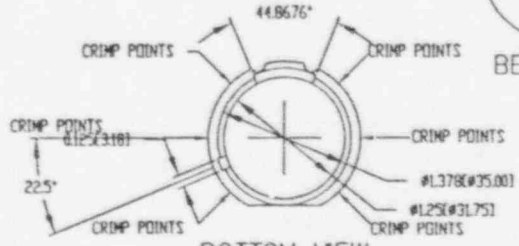
AFTER CRIMPING



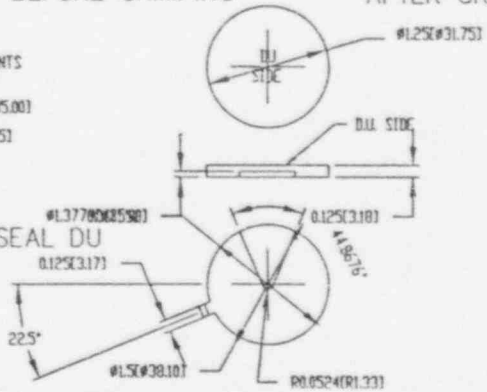
*D.U. MATERIAL

(DIM.'S SHOWN ARE FOR CORE CAVITY)
*ACTUAL DU MATERIAL DIM.'S TO BE CALCULATED
FROM AS BUILT PART MINUS PLATING THICKNESS.

MIN. WEIGHT 962 GRAMS



BOTTOM VIEW



LEAD DISK TO SEAL DU

NOTES:
1. ALL TOLERANCES ARE ± 0.010", EXCEPT WHERE NOTED
2. LEAD TO BE 99% PURE, MINIMUM
3. ALL DIMENSIONS ARE FINISHED SIZES AFTER PLATING, EXCEPT D.U. MATERIAL
4. FINISH IS TO BE NICKEL PLATE AFTER CRIMPING.

ORDER OF ASSEMBLY
1. D.U. IS MANUFACTURED.
2. D.U. IS NICKEL PLATED.
3. D.U. IS INSERTED INTO LEAD SHELL.
4. LEAD DISK IS PRESSED INTO POSITION, NOTING D.U. SIDE.
5. PART IS CRIMPED IN (6) PLACES.
6. ASSEMBLED PART IS COMPLETELY NICKEL PLATED.

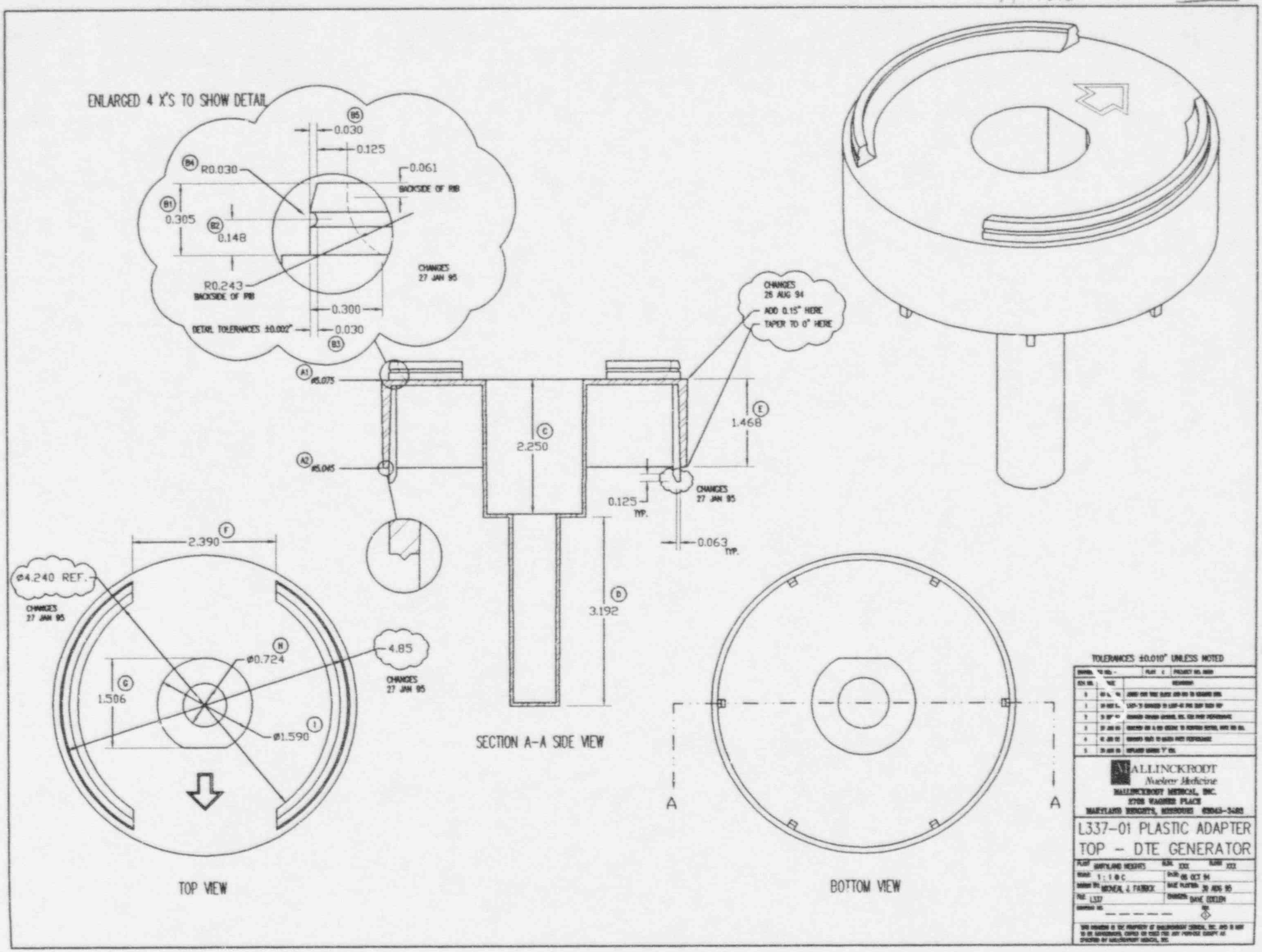
MALLINCKRODT
Nuclear Medicine
MALLINCKRODT MEDICAL, INC.
7733 WAGNER PLACE
MARYLAND HEIGHTS, MISSOURI 63043-5493

L334-00 DU/LEAD PLUG DETAIL
DTE GENERATOR

PLANT	MARYLAND HEIGHTS	SIZE XXX	PLAN XXX
SCALE	1 : 1 @ S	DATE	24 OCT 94
DRAWN BY	MICHEAL A. PATRICK	DATE PLOTTED	24 MAY 95
FILE	L334	ENGINEER	DAVE EISELEN
DRAWING NO.		REV	4

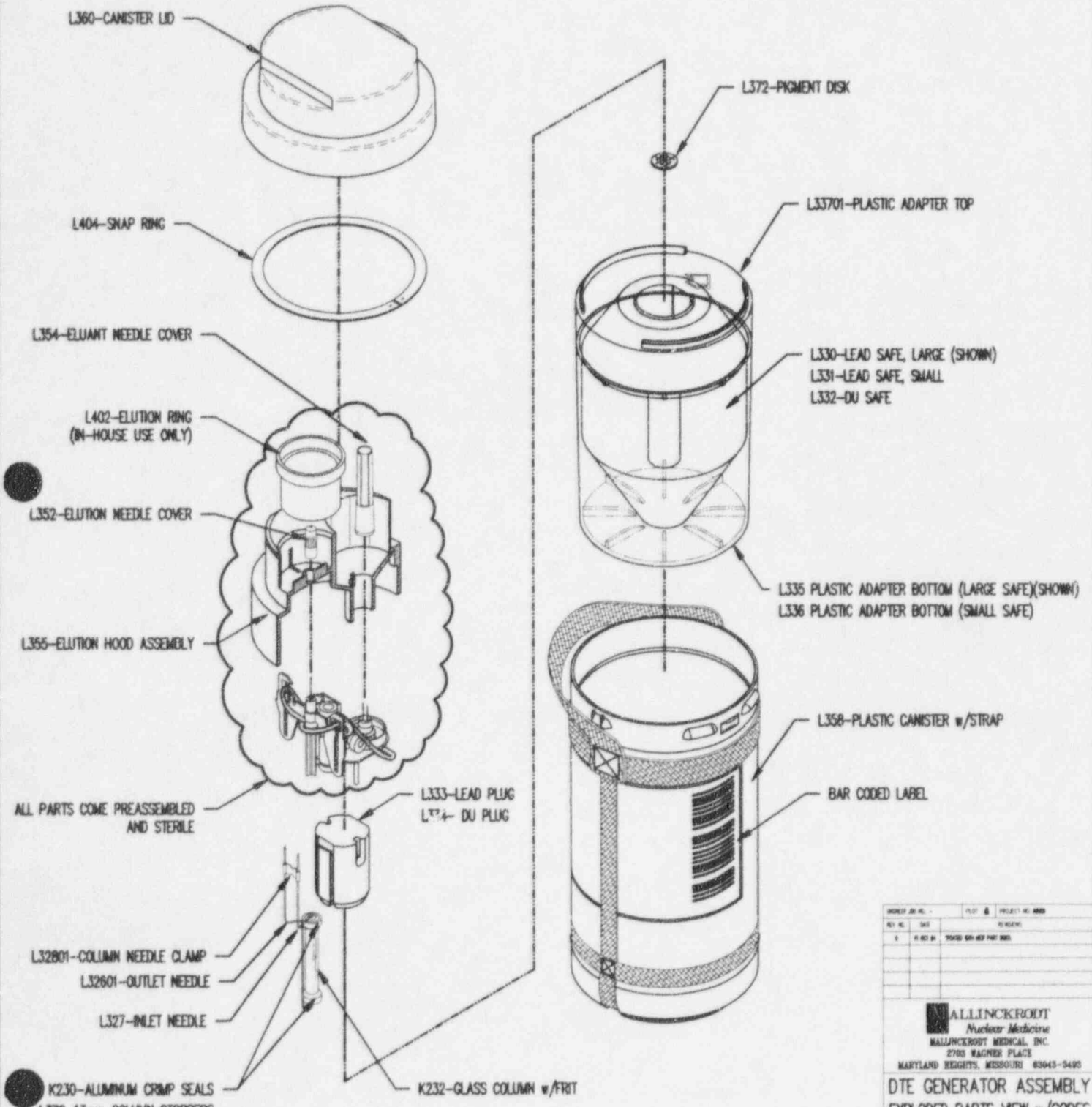
10

Attachment III



Attachment IV

UTK DTE GENERATOR
ASSEMBLY DIAGRAM



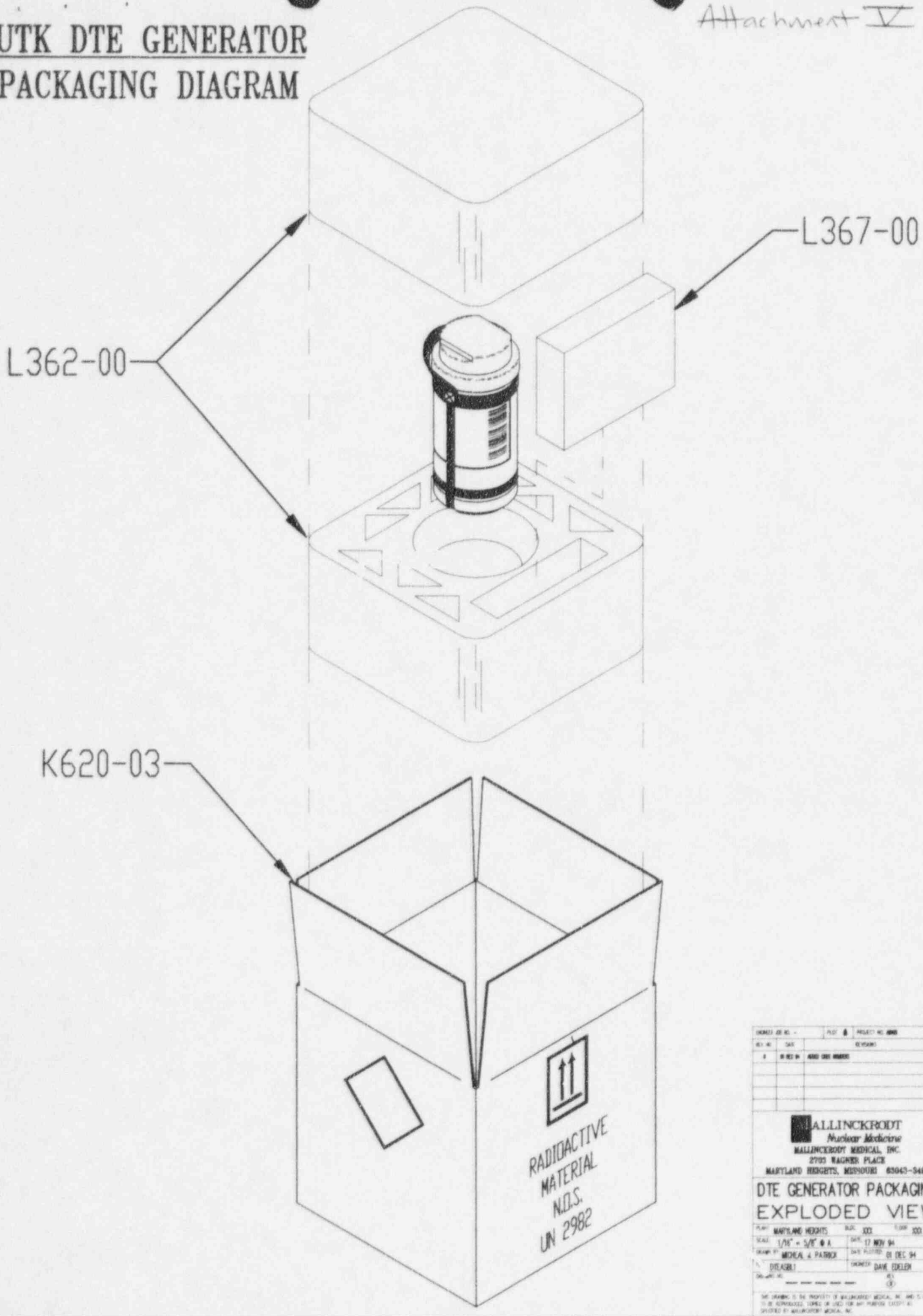
MALLINCKRODT
Nuclear Medicine
MALLINCKRODT MEDICAL, INC.
2703 WAGNER PLACE
MARYLAND HEIGHTS, MISSOURI 63043-3493

DTE GENERATOR ASSEMBLY
EXPLODED PARTS VIEW w/CODES

PLANT: MARYLAND HEIGHTS	BLDG: 100
SCALE: NTS	DATE: 06 OCT 94
DRAWN BY: MICHEAL J PATRICK	DATE PLOTTED: 29 NOV 94
FILE: DTEASSLY	DRAWING NO:

Attachment V

UTK DTE GENERATOR PACKAGING DIAGRAM



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2703 WAGNER PLACE
MARYLAND HEIGHTS, MISSOURI 63043-3493

DTE GENERATOR PACKAGING
EXPLODED VIEW

MARYLAND HEIGHTS
1/16" = 1/16" @ A
MICHEAL A PATRICK
17 NOV 94
01 DEC 94
DAVE EDELEN

Attachment VI 1

MALLINCKRODT MEDICAL INC.

TOTAL ACTIVITY (Mo 99) SHIPPED
AS OF 2000 CT

R3/94

444.000 GBq (12.00 Ci)

FOR USE BY MALLINCKRODT MEDICAL, INC. NUCLEAR PHARMACIES
AND OTHER COMMERCIAL NUCLEAR PHARMACIES ONLY
NOT FOR GENERAL DISTRIBUTION

Attachment IX k

Ultra TechneKow DTE

UTK-DTE

TECHNETIUM Tc 99m GENERATOR

Parent Molybdenum 99 prepared from Fission Produced Molybdenum 99

A5860D 7/94

MOLYBDENUM-99 DECAY CHART HALF-LIFE 66.0 HOURS		TECHNETIUM-99m DECAY CHART HALF-LIFE 6.02 HOURS	
DAYS	FRACTION REMAINING	HOURS	FRACTION REMAINING
0	1.000	0	1.000
1	0.777	1	0.891
2	0.604	2	0.794
3	0.469	3	0.708
4	0.365	4	0.631
5	0.284	5	0.562
6	0.220	6	0.501
7	0.171	7	0.447
8	0.133	8	0.398
9	0.103	9	0.355
10	0.080	10	0.316
11	0.062	11	0.282
12	0.049	12	0.251
13	0.038	13	0.224
14	0.029	14	0.199
15	0.023	15	0.178
20	0.008	16	0.158
25	0.002	17	0.141
30	0.0008	18	0.126
		24	0.063

Store At Room Temperature
(Below 86°F/30°C)

CAUTION

RADIOACTIVE MATERIAL

WARNING: Radiopharmaceuticals, produced by nuclear reactor or particle accelerator, should be used only by physicians who are qualified by specific training in the use and safe handling of radionuclides and whose experience and training have been approved by an individual agency or institution already licensed in the use of radionuclides.

For the production of sterile, non-pyrogenic Sodium Pertechnetate Tc 99m injection.

Caution: Federal (U.S.A.) law prohibits dispensing without prescription.

This generator, its manufacture and use are covered by one or more of the following U.S. patents: 3,382,152; 3,446,966; 3,535,089; 3,865,981

FOR ADDITIONAL INFORMATION SEE PACKAGE INSERT

Mallinckrodt Medical, inc.
St. Louis, MO 63134 USA

MALLINCKRODT MEDICAL

TOTAL ACT. (Mo 99)

GBq

Ci

AS OF 2100 CT

LOT

EXP

TOTAL ACT. (Mo 99)

GBq

Ci

AS OF 2100 CT

LOT

EXP

MALLINCKRODT MEDICAL

Table 4. Absorbed Radiation Doses From Intravenous Injection (ADULT)

Tissue	1110 MBq (30 mCi) Dose				111 MBq (3mCi) Dose	
	Resting Population		Active Population			
	mGy	rads	mGy	rads	mGy	rads
Bladder Wall	15.8	1.58	26.5	2.55		
Gastrointestinal tract						
Stomach wall	76.0	7.60	15.3	1.58		
Upper large intestine wall	20.4	2.04	36.9	3.60		
Lower large intestine wall	18.3	1.83	33.0	3.30		
Red Marrow	5.7	0.57	5.1	0.51		
Testes	2.7	0.27	2.7	0.27		
Ovaries	8.8	0.88	9.0	0.90		
Thyroid	39.0	3.90	39.0	3.90		
Brain	4.2	0.42	3.6	0.36		
Total Body	4.4	0.42	3.9	0.39		
Placenta					0.5	0.05
Fetus					0.5	0.05

Table 5. Absorbed Radiation Doses from Dacryocystingraphy

Tissue	3.7 MBq (100 µCi) Dose of Sodium Pertechnetate Tc 99m	
	mGys	mrads
Eye Lens		
If lacrimal fluid turnover is 16%/min	0.140	14.0
If lacrimal fluid turnover is 100%/min	0.022	2.2
If drainage system is blocked	4.020	402
Total Body*	0.011	1.1
Ovaries*	0.030	3.0
Testes*	0.009	0.9
Thyroid*	0.130	13.0

*Assuming no blockage of draining system. MIRD Dose Estimate Report No. 8. J Nucl. Med., 17: 74-77, 1976

In **PEDIATRIC** patients, the maximum radiation doses when a dose of 185 megabecquerels (5 millicuries) Sodium Pertechnetate Tc 99m is administered to a neonate (3.5 kg) for brain or blood pool imaging with radionuclide angiography are shown in Table 6.

In pediatric patients, an average 30 minute exposure to 37 megabecquerels (1 millicurie) of Sodium Pertechnetate Tc 99m following instillation for direct cystography, results in an estimated absorbed radiation dose of approximately 300 micrograys (30 millirads) to the bladder wall and 40 to 50 micrograys (4 to 5 millirads) to the gonads.[3]

Table 6. Absorbed Radiation Doses From Intravenous Injection (PEDIATRIC)

Tissue	37 MBq (1 mCi) Dose		185 MBq (5mCi) Dose	
	mGy	rads	mGy	rads
Thyroid (without perchlorate)	46.0	4.60	230.0	23.0
Thyroid (with perchlorate)	9.7	0.97	48.5	4.85
Large Bowel (with perchlorate)	19.0	1.90	95.5	9.55
Testes	1.9	0.19	6.1	0.61
Ovaries	2.2	0.22	11.0	1.10
Total Body	1.5	0.15	7.6	0.76

HOW SUPPLIED:

The Ultra-TechneKow DTE (Technetium Tc 99m) Generators contain the following amount of molybdenum 99 at the date and time of calibration stated on the label.

Catalog No.		
881	18.5	gigabecquerels (0.50 curie)
886	27.75	gigabecquerels (0.75 curie)
882	37	gigabecquerels (1.0 curie)
883	56.5	gigabecquerels (1.5 curies)
884	74	gigabecquerels (2.0 curies)
885	92.5	gigabecquerels (2.5 curies)
887	111	gigabecquerels (3.0 curies)

Each generator is supplied with the following components for the elution of the generator:

7 — Evacuated Collecting Vials, 10 mL, Sterile, Non-pyrogenic.
or
5 — Evacuated Collecting Vials, 20 mL, Sterile, Non-Pyrogenic

7 — 70% (w/v) Isopropyl Alcohol Wipes

7 — Pressure-sensitive "Caution - Radioactive Material" collecting vial labels

7 — Pressure-sensitive radioassay data labels for lead elution shield

1 — Generator Eluant Vial, 135 mL, Sterile, Non-Pyrogenic

1 — TechneStat™ Vial, 5mL, containing 0.5 mL of 70% (w/v) Isopropyl Alcohol

The sterile, non-pyrogenic solution used to elute the generator column contains 0.9% sodium chloride. The eluant does not contain an antimicrobial agent.

EVACUATED COLLECTING VIALS. Collecting vials are available on request in 10 and 20 milliliter sizes.

Storage:
Store generator and Sodium Pertechnetate Tc 99m solution at room temperature (15°C to 30°C).

Expiration Date:
The generator should not be used after the expiration date stated on the label.

The expiration time of the Sodium Pertechnetate Tc 99m solution is not later than 12 hours after time of elution. If the eluate is used to reconstitute a kit, the radiolabeled kit should not be used after 12 hours from the time of generator elution or after the expiration time stated on the labeling for the prepared drug, whichever is earlier.

Directions for Use of the Technetium Tc 99m Generator:

NOTE 1: Immediately upon delivery, the generator should be placed within a minimum of one-inch of lead shielding in such a manner so as to minimize radiation exposure to attending personnel.

NOTE 2: Wear waterproof gloves during the elution procedure and during subsequent reconstitution of kits with the eluate.

NOTE 3: Use a shielded syringe to withdraw patient dose or to transfer Sodium Pertechnetate Tc 99m into mixing vials during kit reconstitution.

NOTE 4: The needles in the generator are sterile beneath their covers, and the generator has been cleaned underneath the top cover. Additional disinfection of those areas with agents containing alcohol may unfavorably [illegible] the Tc 99m yield.

Eluting the generator every 24 hours will provide optimal amounts of Sodium Pertechnetate Tc 99m. However, the generator may be eluted whenever sufficient amounts of technetium 99m have accumulated within the column.

For Example:

Time After First Elution (hrs.)	Approximate Yield (% of Final Elution)
1	10
2	19
3	27
4	36
5	41
6	47

Preparation:

1. Rotate the top cover 30° counter clockwise and lift up to remove.
2. Lift generator by its handle and position inside the auxiliary shield, aligning the notch in the elution station with leaded glass window in the auxiliary shield.
3. Remove the flip-top cap of the eluant vial, disinfect the stopper, remove and store the needle cover over the eluant needles, invert the eluant vial and push down into place on the eluant needles.
4. Remove the flip-top cap of the TechneStat vial and place it into the TechneStat vial shield.
5. Remove and store the needle cover from the elution station, replace the lid of the auxiliary shield and insert the shielded TechneStat vial into the elution station.

Elution:

1. Remove the flip-top cap of the appropriate evacuated vial, disinfect the stopper, and put the vial into the elution shield aligning the volume scale on the evacuated vial with the leaded glass window.
2. Replace the shielded TechneStat vial with the shielded evacuated vial, aligning the two leaded glass windows. Piercing the septum of the evacuated vial with the elution needle will begin the elution process.
3. Wait until the evacuated vial has completely filled itself (a few minutes). **Never interrupt the elution by lifting the vial shielding!** When smaller elution volumes are required, the elution may be interrupted by rotating the vial shield a quarter turn clockwise and pushing it downwards for a few seconds (this stops the elution and fills the remainder of the vial with sterile air). **NOTE: Do not use generator eluate if its appearance is discolored.**
4. Replace the shielded vial with the shielded TechneStat vial.
5. Determine the technetium 99m concentration and molybdenum 99 content for dispensing purposes. **NOTE: Molybdenum 99 Breakthrough Limit** - The acceptable limit is 0.15 kilobecquerel molybdenum 99 per megabecquerel technetium 99m (0.15 microcurie Mo 99 per millicurie Tc 99m) at the time of administration.
6. Determine the aluminum ion concentration of the eluate. **NOTE: Aluminum Ion Breakthrough Limit** - The acceptable limit is not more than 10 micrograms per milliliter of eluate.

Subsequent Elutions:
Repeat steps 1 through 6 of the Elution procedure above.

Vacuum Loss:
If the vacuum in the collecting vial is lost, do not attempt to re-evacuate the vial, but discard and use a new collecting vial.

EXPIRED GENERATOR DISPOSAL:

1. Following the life of the generator, remove and dispose of the used TechneStat vial and the eluant vial.
2. Cover the inlet and outlet needles with the stored needle covers.
3. Close the generator system with its top cover and the lever closing ring by rotating with downward pressure.
4. The intact generator assembly should be either returned to Mallinckrodt Medical, Inc. or allowed to decay for 20 half-lives of the molybdenum 99. Monitor the unshielded generator column with a low level survey meter. If no significant radiation level above background is indicated, the column may be disposed of through the regular refuse system.

This generator is approved for use by persons licensed by the U.S. Nuclear Regulatory Commission to use by-product material identified in Section 35.200 or under equivalent licenses of Agreement States.

7/94
Mallinckrodt Medical, Inc.
St. Louis, MO 63134

TECHNE (TECHNICIUM GENERATOR)

880/887

MALLINCKRODT MEDICAL

880-887

[1] Kocher, David C., "Radioactive Decay Data Tab[illegible] DOE/TIC-11026, 108 (1981).

[2] Modified from: Summary of Current Radiation D[illegible] Estimates to Normal Humans from Tc 99m Sodium Pertechnetate. MIRD Dose Estim[illegible] Report No. 8. J. Nucl. Med., 17 (1):74-7, 197[illegible]

[3] Conway, J.J., et al., Direct and indirect radionuc[illegible] cystography. J. Urol. 113:689-690, May 1975

...Manufactured by:
...Petechnetate Tc 99m Injection

...RIPTION:
...m Technekow® DTE Generator is prepared ...ion produced molybdenum-99 adsorbed onto ...n a lead shielded column. This generator ...s a closed system for the production of sterile ...dium-99m, which is produced by ...ay of molybdenum-99. Sterile, non-pyrogenic ...solutions of Sodium Pertechnetate Tc 99m ...obtained conveniently by periodic aseptic ...of the generator. These solutions should be ...clear.

...mal saline solution may be used as a diluent to ...proper concentration. Over the life of the ...tor, an elution will contain an amount of ...dium-99m in direct proportion to the quantity of ...decay since the previous elution of the ...tor. The exact quantity of Tc 99m in the eluate ...mined by column elution efficiency, quantity ...99 on the column, and the elapsed time ...n elutions.

...uate of the generator should not contain more ...he U.S.P. limit of 0.15 kilobecquerel ...dium-99 per megabecquerel technetium-99m ...ecurie Mo 99 per millicurie Tc 99m) per ...tered dose at the time of administration and ...dium-ion concentration of not more than ...grams per milliliter of the generator eluate, ...which must be determined by the user before ...tration.

...he eluate does not contain an antimicrobial ...t should not be used after 12 hours from the ...generator elution.

...al Characteristics:
...dium-99m decays by isomeric transition with ...ical half-life of 6.02 hours. The principal ...that is useful for detection and imaging studies ...in Table 1.

...ble 1. Principal Radiation Emission Data

...ation	Mean % Per Disintegration	Energy (keV)
...ma-2	89.07	140.5

...al Radiation:
...ecific gamma ray constant for technetium-99m ...R/hr-mC at 1 cm. The first half value layer ...7 cm of lead (Pb). A range of values for the ...attenuation of the radiation emitted by this ...uclide that results from interposition of ...thicknesses of Pb is shown in Table 2. For ...e, the use of 0.25 cm thickness of Pb will ...ce the radiation emitted by a factor of about ...

...2. Radiation Attenuation by Lead Shielding

Shield ...ness (Pb) cm	Coefficient of Attenuation
0.017	0.5
0.08	10^{-1}
0.16	10^{-2}
0.25	10^{-3}
0.33	10^{-4}

...dium-99 decays to technetium-99m with a ...dium-99 half-life of 2.75 days. The physical ...characteristics of molybdenum-99 are such that ...6% of the decaying molybdenum-99 atoms ...technetium-99m. Generator elutions may be ...at any time, but the amount of technetium-99m ...ble will depend on the interval measured from ...elution. Approximately 47% of the maximum ...ble technetium-99m is reached after 6 hours and ...ter 25 hours. To correct for physical decay of ...dium-99m, the fractions that remain at selected ...s of time are shown in Table 3.

...3. Physical Decay Chart: Technetium-99m, Half-Life 6.02 Hours

...urs	Fraction Remaining	Hours	Fraction Remaining
0	1.000	7	0.447
1	0.891	8	0.398
2	0.794	9	0.355
3	0.708	10	0.316
4	0.631	11	0.282
5	0.562	12	0.251
6	0.501		

...ation time

...al Pharmacology:
...rhenetate ion distributes in the body similarly ...oride ion but is not organified when trapped in ...oid gland. Pertechnetate tends to accumulate ...oranial lesions with excessive neovascularity ...ered blood-brain barrier. It also concentrates ...thyroid gland, salivary glands, stomach and ...d plexus. After intravenous administration it ...s in the circulatory system for sufficient time to ...

Following the administration of Sodium Pertechnetate Tc 99m as an eye drop, the drug mixes with tears within the conjunctival space. Within seconds to minutes it leaves the conjunctival space and escapes into the inferior meatus of the nose through the nasolacrimal drainage system. During this process the pertechnetate ion passes through the canaliculi, the lacrimal sac and the nasolacrimal duct. In the event of any anatomical or functional blockage of the drainage system there will be a backflow resulting in tearing (epiphora). Thus the pertechnetate escapes the conjunctival space in the form.

While the major part of the pertechnetate escapes within a few minutes of normal drainage and tearing, it has been documented that there is some degree of transconjunctival absorption with turnover of 1.5% per minute in normal individuals, 2.1% per minute in patients without any sac and 2.7% per minute in patients with inflammed conjunctiva due to chronic dacryocystitis. Individual values may vary but these rates are probably representative and indicate that the maximum possible pertechnetate absorbed will remain below one thousandth of that used in other routine diagnostic procedures.

INDICATIONS AND USAGE:
Sodium Pertechnetate Tc 99m is used **IN ADULTS** as an agent for:

- Brain imaging (including cerebral radionuclide angiography)
- Thyroid imaging
- Salivary Gland Imaging
- Placenta Localization
- Blood Pool Imaging (including radionuclide angiography)
- Urinary Bladder Imaging (direct isotopic cystography) for detection of vesico-ureteral reflux
- Nasolacrimal Drainage System Imaging (dacryoscintigraphy)

Sodium Pertechnetate Tc 99m is used **IN PEDIATRIC PATIENTS** as an agent for:

- Brain imaging (including cerebral radionuclide angiography)
- Thyroid imaging
- Blood Pool Imaging (including radionuclide angiography)
- Urinary Bladder Imaging (direct isotopic cystography) for the detection of vesico-ureteral reflux

CONTRAINDICATIONS:
None known.

WARNINGS:
Radiation risks associated with the use of Sodium Pertechnetate Tc 99m are greater in children than in adults and, in general, the younger the child the greater the risk owing to greater absorbed radiation doses and longer life expectancy. These greater risks should be taken firmly into account in all benefit-risk assessments involving children.

Only use generator eluant specified for use with the Ultra-Technekow® DTE Generator. Do not use any other generator eluant or saline from any other source.

PRECAUTIONS:
As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient consistent with proper patient management and to insure minimum radiation exposure to occupational workers.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

After the termination of the nasolacrimal imaging procedure, blowing the nose and washing the eyes with sterile distilled water or an isotonic sodium chloride solution will further minimize the radiation dose.

Since the eluate does not contain an antimicrobial agent, it should not be used after 12 hours from time of generator elution.

Carcinogenesis, Mutagenesis, Impairment of Fertility:
No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential or whether Sodium Pertechnetate Tc 99m may affect fertility in males or females.

Pregnancy Category C:
Animal reproductive studies have not been conducted with Sodium Pertechnetate Tc 99m. It is also not known whether Sodium Pertechnetate Tc 99m can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Sodium Pertechnetate Tc 99m should be given to pregnant women only if the expected benefits to be gained clearly outweigh the potential hazards.

Nursing Mothers:
Technetium-99m is excreted in human milk during lactation, therefore, formula-feedings should be substituted for breast-feedings.

Pediatric Use:
See **Indications and Usage** and **Dosage and Administration** sections. Also see the description of additional risk under **Warnings.**

ADVERSE REACTIONS:
Allergic reactions including anaphylaxis have been reported infrequently following the administration of Sodium Pertechnetate Tc 99m.

DOSAGE AND ADMINISTRATION:
Sodium Pertechnetate Tc 99m is usually administered by intravenous injection, but can be given orally. When imaging the nasolacrimal drainage system, instill the Sodium Pertechnetate Tc 99m by the use of a device such as a micropipette or similar method which will ensure the accuracy of the dose.

For imaging the urinary bladder and ureters (direct isotopic cystography), the Sodium Pertechnetate Tc 99m is administered by direct instillation aseptically into the bladder via a urethral catheter, following which the catheter is flushed with approximately 200 mL of sterile saline directly into the bladder.

The dosage employed varies with each diagnostic procedure. If the oral route is elected, the patient should fast for at least six (6) hours before and two (2) hours after administration.

The suggested dose ranges employed for various diagnostic indications in the average ADULT PATIENT (70 kg) are as follows:

Vesico-ureteral imaging:	18.5 to 37 MBq (0.5 to 1 mCi)
Brain imaging:	370 to 740 MBq (10 to 20 mCi)
Thyroid gland imaging:	37 to 370 MBq (1 to 10 mCi)
Salivary gland imaging:	37 to 185 MBq (1 to 5 mCi)
Placenta localization:	37 to 111 MBq (1 to 3 mCi)
Blood pool imaging:	370 to 1110 MBq (10 to 30 mCi)
Nasolacrimal drainage system:	Maximum dose of 3.7 MBq (100 µCi)

The recommended dosages in PEDIATRIC PATIENTS are:

Vesico-ureteral imaging:	18.5 to 37 MBq (0.5 to 1 mCi)
Brain imaging:	5.18 to 10.36 MBq (140 to 280 µCi) per kg body weight
Thyroid gland imaging:	2.22 to 2.96 MBq (60 to 80 µCi) per kg body weight
Blood pool imaging:	5.18 to 10.36 MBq (140 to 280 µCi) per kg body weight

Minimum dose of 111 to 185 MBq (3 to 5 mCi) should be employed if radionuclide angiography is performed as part of the brain imaging or blood pool imaging procedures.

NOTE: Up to 1 gram of pharmaceutical grade potassium perchlorate in a suitable base or capsule may be given orally prior to administration of Sodium Pertechnetate Tc 99m for brain imaging, placenta localization and blood pool imaging. When Sodium Pertechnetate Tc 99m is used in pediatric patients for brain or blood pool imaging, administration of potassium perchlorate is especially important to minimize the absorbed radiation dose to the thyroid gland.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. The solution to be administered as the patient dose should be clear, colorless, and contain no particulate matter.

Radiation Dosimetry:
The estimated absorbed radiation doses[1] to an average ADULT patient (70 kg) from an intravenous injection of a maximum dose of 1110 megabecquerels (30 millicuries) of Sodium Pertechnetate Tc 99m distributed uniformly in the total body of subjects not pretreated with blocking agents, such as pharmaceutical grade potassium perchlorate, are shown in Table 4. For placental localization studies, when a maximum dose of 111 megabecquerels (3 millicuries) is used, it is assumed to be uniformly equilibrated between maternal and fetal tissues.

The estimated absorbed radiation doses to an ADULT patient from the nasolacrimal imaging procedure using a maximum dose of 3.7 megabecquerels (100 microcuries) of Sodium Pertechnetate Tc 99m are shown in Table 5.

Attachment VI

GENERATOR ACCESSORY PACK 20 mL

For Use Only With
the Mallinckrodt Medical, Inc. UTK-DTE™ Generator

Pack Contains:

- 5 - 20 mL Evacuated Vials
- 1 - TechneStat™ Vial (5 mL vial containing 0.5 mL of 70% (v/v) Isopropyl Alcohol)
- 7 - 70% (v/v) Isopropyl Alcohol Wipes
- 1 - 0.9% Sodium Chloride Eluant, 135 mL, Sterile, Non-Pyrogenic
- 1 - Package Insert
- 7 - Pressure Sensitive Radioactive Material/Sodium Pertechnetate Tc 99m Labels
- 7 - Pressure Sensitive Radioassay Safe Labels

A80328 7/94

Mallinckrodt Medical, Inc.
St. Louis, MO 63134 USA

MALLINCKRODT MEDICAL

Attachment III h

GENERATOR ACCESSORY PACK, 10 mL

For Use Only With
the Mallinckrodt Medical, Inc. UTK-DTE™ Generator

Pack Contains:

- 7 - 10 mL Evacuated Vials
- 1 - TechneStat™ Vial (5 mL vial containing 0.5 mL of 70% (v/v) Isopropyl Alcohol)
- 7 - 70% (v/v) Isopropyl Alcohol Wipes
- 1 - 0.9% Sodium Chloride Eluant, 135 mL, Sterile, Non-Pyrogenic
- 1 - Package Insert
- 7 - Pressure Sensitive Radioactive Material/Sodium Pertechnetate Tc 99m Labels
- 7 - Pressure Sensitive Radioassay Safe Labels

Mallinckrodt Medical, Inc.
St. Louis, MO 63134 USA

MALLINCKRODT MEDICAL

Attachment VI g 17

EVACUATED VIAL PACK 20 mL

For Use With the Mallinckrodt Medical, Inc.
Ultra-TechneKow® DTE Generator

Pack Contains:

49 - 20 mL Evacuated Collecting Vials, Sterile, Non-Pyrogenic

A7884C 3/95

Mallinckrodt Medical, Inc.
St. Louis, MO 63134 USA

MALLINCKRODT MEDICAL

Attachment VI f

EVACUATED VIAL PACK 10 mL

For Use Only With the Mallinckrodt Medical, Inc.
Ultra-TechneKow® DTE Generator

Pack Contains:

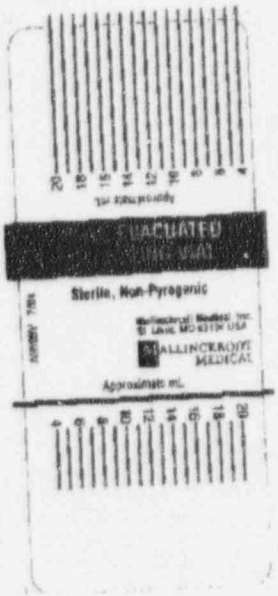
81 - 10 mL Evacuated Collecting Vials, Sterile, Non-Pyrogenic

A7846 3/95

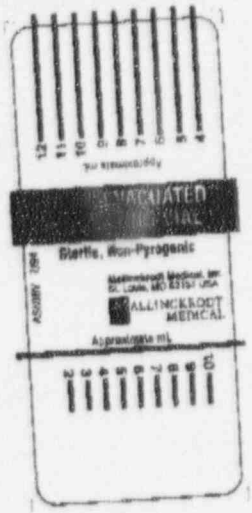
Mallinckrodt Medical, Inc.
St. Louis, MO 63134 USA

MALLINCKRODT MEDICAL

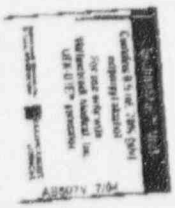
Attachment VI'e

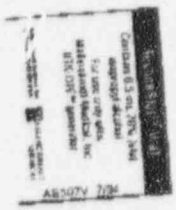


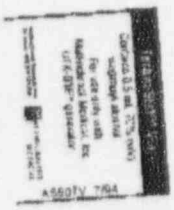
Attachment VI d



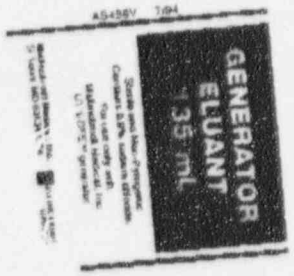
Attachment VIc







Attachment VI-b



Attachment VII

Radiation Levels for Packaged DTE Generators (mR/hr)

Size (Ci)	Safe Type	Surface	TI
0.50	38 mm	39.0	1.2
0.75	38 mm	57.0	1.9
1.00	48 mm	25.0	1.0
1.50	48 mm	39.0	1.4
2.00	48 mm	51.0	1.9
2.50	48 mm	64.0	2.4
3.00	48 mm	76.0	2.9
4.20	48 mm	109.0	4.1
5.20	48 mm	136.0	5.2
6.30	48 mm	162.0	6.1
12.00	DU	18.0	0.8

The DTE Generator

Product Catalog No.; Size, Precalibration, Overlabeled Size, Surface Radiation Level and NDA Number

Catalog Number	Product (Day of Shipment)	Size (mCi)	[b] Number of Days Precalibration	Multiplier Factors For Over Labeled Size	Shield Size	[c] mR/hr at Shield Surface @ Pre-Cal	NDA Number
N881A0	DTE-Mon	500	3	2.11	L331d	166	17-243
	DTE-Fri	500	3	2.11	L331	130	17-243
N882A0	DTE-Mon	750	3	2.11	L331	247	17-243
	DTE-Fri	750	3	2.11	L331	193	17-243
N883A0	DTE-Mon	1000	3	2.11	L330e	113	17-243
	DTE-Fri	1000	3	2.11	L330	88	17-243
N884A0	DTE-Mon	1500	3	2.11	L330	170	17-243
	DTE-Fri	1500	3	2.11	L330	132	17-243
N885A0	DTE-Mon	2000	3	2.11	L330	224	17-243

Catalog Number	Product (Day of Shipment)	Size (mCi)	[b] Number of Days Precalibration	Multiplier Factors For Over Labeled Size	Shield Size	[c] mR/hr at Shield Surface @ Pre-Cal	NDA Number
	DTE-Fri	2000	3	2.11	L330	176	17-243
N885A0	DTE-Mon	2000 (4300)a	3	2.11	L330	484	17-243
	DTE-Fri	2000 (4300)a	3	2.11	L330	380	17-243
N886A0	DTE-Mon	2500	3	2.11	L330	282	17-243
	DTE-Fri	2500	3	2.11	L330	221	17-243
	DTE-Mon	2500 (5300)a	3	2.11	L330	477	17-243
	DTE-12Ci-Mon	2500	6	4.47	L332f	130	17-243
	DTE-12Ci-Fri	2500	6	4.47	L332	102	17-243
N887A0	DTE-Mon	3000	3	2.11	L330	339	17-243
	DTE-Fri	3000	3	2.11	L330	265	17-243
	DTE-Mon	3000 (6400)a	3	2.11	L330	723	17-243
	DTE-Fri	3000 (6400)a	3	2.11	L330	565	17-243

a. Size on day of shipment.
b. These values may be less than or equal to the maximum days of precalibration.
c. These radiation levels may be less than or equal to the maximum mR/hr.
d. Small lead safe.
e. Large lead safe.
f. DU safe.

NRC FORM [redacted]
(1-88)
10 CFR 30, 32, 33, 34
35 and 40

APPROVED BY OMB
3150-0120
Expires: 5/31/87

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
NUCLEAR MATERIALS SAFETY SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- [ ] A. NEW LICENSE
- [X] B. AMENDMENT TO LICENSE NUMBER 24-04206-05MD
- [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code)

Mallinckrodt Medical
2703 Wagner Place
Maryland Heights, MO 63043

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.

2703 Wagner Place
aryland Heights, MO 63043

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Daniel Riemer

TELEPHONE NUMBER: 314-770-7981

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)
FEE CATEGORY: 3D
AMOUNT ENCLOSED: $ 420.00

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE-CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
[signature]	Les Sabo	Director of U.S. Nuclear Operations	10-9-95

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS
- [ ] <$250K
- [ ] $250K-500K
- [ ] $500K-750K
- [ ] $750K-1M
- [ ] $1M-3.5M
- [ ] $3.5M-7M
- [ ] $7M-10M
- [ ] >$10M

b. NUMBER OF EMPLOYEES (Total for entire facility including outside contractors)

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (dollar and/or staff hours) ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? (NRC regulations permit it to protect confidential commercial or financial proprietary information furnished to the agency in confidence)
- [ ] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
				DATE
AMOUNT RECEIVED	CHECK NUMBER			

OCT 16 1996

Les Sabo
Director, US Nuclear Medicine
Operations
Mallinckrodt Medical, Inc.
2703 Wagner Place
Maryland Heights, MO 63043

Dear Mr. Sabo:

Enclosed is Amendment No. 18 to your NRC Material License No. 24-04206-05MD in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC, in writing, within 30 days:

   a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.

4. Request and obtain a license amendment before you:

   a. Change Radiation Safety Officers;

399283

b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

d. Change ownership of your organization.

5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By
Cassandra Frazier
Nuclear Materials Licensing Branch

License No. 24-04206-05MD
Docket No. 030-10801

Enclosure: Amendment No. 18

DOCUMENT NAME: M:\03010801.CL6

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII								
NAME	CFRAZIER:sid								
DATE	10/ /96								

OFFICIAL RECORD COPY

MALLINCKRODT
Nuclear Medicine

October 10, 1996

Ms. Cassandra Frazier
Nuclear Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Mallinckrodt Medical, Inc.
2703 Wagner Place
Maryland Heights, MO 63043
Telephone (314) 770-7800

RE: Second Additional DTE DU Safe Drawing for the Pending NRC 24-04206-0MD License Amendment for DTE Generator Distribution

Dear Ms. Frazier:

This letter is in reference to our telephone conversation, from this morning, in which you inquired if the second (additional) Ultra-TechnaKow Dry Top Eluting (DTE) Depleted Uranium (DU) safe drawing would possibly require approval from the Food and Drug Administration (FDA). Mallinckrodt Medical, Inc. (MMI) submitted a September 26, 1996 document which contained a drawing of this second (additional) DU safe. MMI submitted the drawing so that it would be included with the October 10, 1995 license amendment application and the August 14, 1996 final approval letter, for the distribution of DTE generators.

This question was presented to Mr. Ron Bartnick, the Maryland Heights Manager of Quality/Regulatory Compliance. Mr. Bartnick stated that since the DTE Generator is registered with the FDA as a drug and not a device, the FDA would not be concerned about the shielding design of the DU safe.

Please contact me at (314) 770-7981 if you have any additional questions or comments regarding this issue.

Sincerely,

Daniel Riemer
Radiation Safety Officer
Mallinckrodt Medical
Maryland Heights Facility

pm: 10-11-96

399283

MALLINCKRODT
Nuclear Medicine

September 26, 1996

Mallinckrodt Medical, Inc.
2703 Wagner Place
Maryland Heights, MO 63043
Telephone (314) 770-7800

Ms. Cassandra Frazier
Nuclear Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

RE: Submittal of the Second DU Shielding Safe Drawing for the Pending NRC 24-04206-05MD License Amendment for DTE Generator Distribution

Dear Ms. Frazier,

Mallinckrodt Medical, Inc., MMI, hereby requests the addition of a second Ultra-TechnaKow Dry Top Eluting (DTE), two piece billet, depleted uranium (DU) generator shield to the existing pending 24-04206-05MD NRC license amendment. MMI has submitted an October 10, 1995 license amendment application and an August 14, 1996 final approval letter regarding this amendment request.

As I indicated to you in my September 13 and 20, 1996 telephone messages, MMI has discovered a slight, negligible difference between the DTE DU generator shield and the DTE DU generator shield drawing which was submitted with our amendment request. The drawing which was included in MMI's license amendment applications for the distribution of DTE Generators, indicates a stainless steel housing containing a one piece DU billet. Please refer to Attachment I. However, the actual DTE DU safe prototypes which were profiled for shielding effectiveness actually consisted of a stainless steel cladding containing a two piece DTE DU billet. The top section of the two piece DTE DU billet is comprised of a fitted DU ring. Please refer to Attachment II.

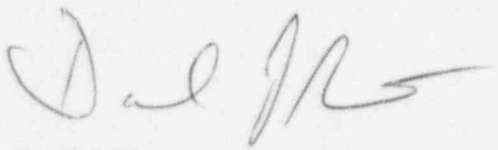
In reality, the radiation profile data in the October 10, 1995 license amendment application corresponds to the two piece DU billet DTE safe. As you have observed upon your review of this license amendment application, the two piece DU billet DTE DU shield is a more effective shield than the Ultra-TechnaKow (UTK) DU shield, which MMI is currently using.

The slight difference had been undetected since the DU is housed in welded stainless steel cladding. Since the discovery, MMI has contacted the vendor and they have committed to manufacture the remainder of the DTE DU safes with a one piece DTE DU billet.

MMI intends to utilize both the one piece billet and two piece billet versions of the DTE DU safe. The dimensions of the stainless steel cladding, and the thickness and purity of the DU are the same for both the one and two piece DTE DU shields.

MMI is very anxious to receive the NRC approval for this license amendment. Please call me at (314) 770-7981, at your earliest convenience, should you have any questions or need any clarification.

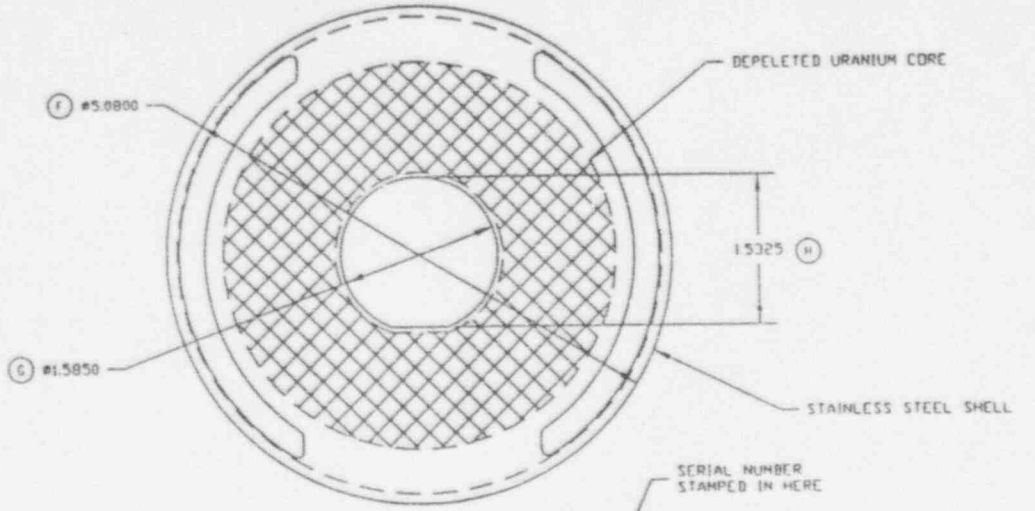
Sincerely,



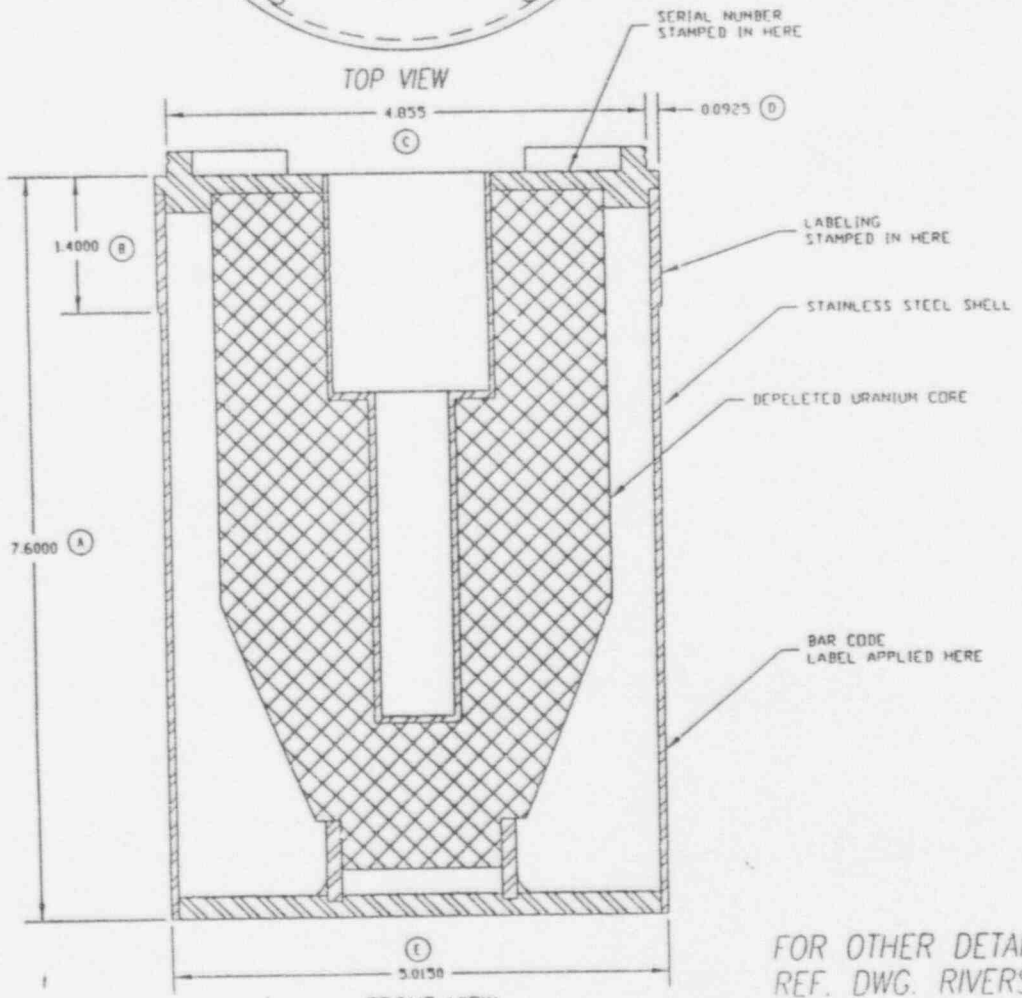
Daniel Riemer
Radiation Safety Officer
Mallinckrodt Medical, Inc.,
Maryland Heights Facility

Attachments

Attachment I



TOP VIEW



FRONT VIEW

ISO NOT AVAILABLE

LABELING FOR DU SAFES
"CAUTION RADIOACTIVE SHIELDING
URANIUM MALLINCKRODT"
MUST BE STAMPED ON THE SIDE
SERIAL NUMBER MUST BE STAMPED
ON THE TOP.

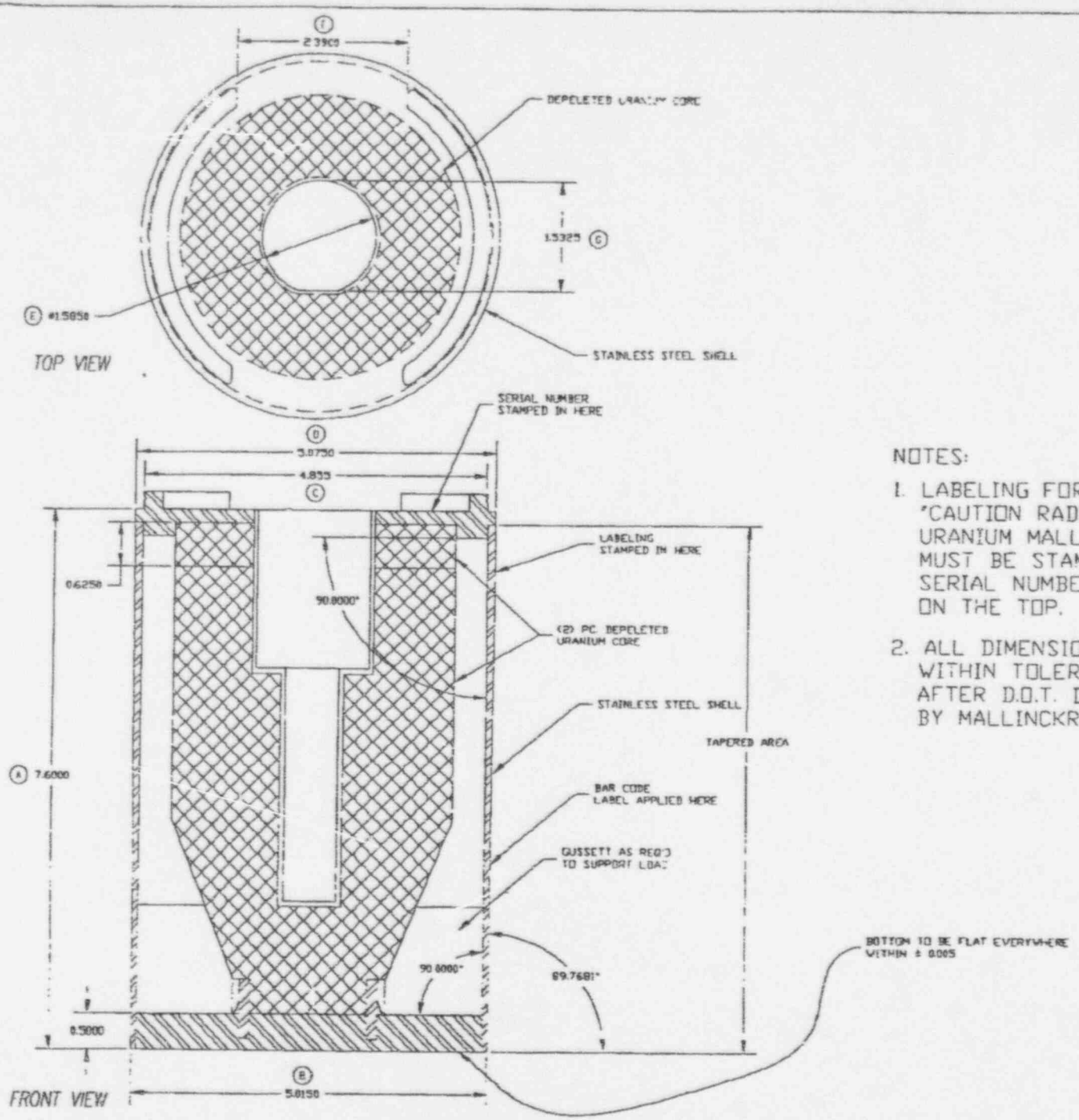
FOR OTHER DETAILS SEE ORIGINAL VENDOR DRAWING
REF. DWG. RIVERS COMPANY C2305 REV. A

TOLERANCES ±0.005"

MALLINCKRODT
Nuclear Medicine
MALLINCKRODT MEDICAL, INC.
8703 WAGNER PLACE
MARYLAND HEIGHTS, MISSOURI 63043-3493

L332-00 DU SAFE & S.S. SHEL
UNIT - DTE GENERATOR

Attachment II



NOTES:

1. LABELING FOR DU SAFES "CAUTION RADIOACTIVE SHIELDING URANIUM MALLINCKRODT" MUST BE STAMPED ON THE SIDE SERIAL NUMBER MUST BE STAMPED ON THE TOP.
2. ALL DIMENSIONS TO BE HELD WITHIN TOLERANCE AS MEASURED AFTER D.O.T. DROP TEST CONDUCTED BY MALLINCKRODT MEDICAL.

TOLERANCES ±0.005"

MALLINCKRODT
Nuclear Medicine
MALLINCKRODT MEDICAL, INC.
2703 WAGNER PLACE

L332-XX DU SAFE & S.S. SHELL
UNIT – DTE GENERATOR

MICHAEL J. PARRISH

L332-XX

MALLINCKRODT
Nuclear Medicine

Mallinckrodt Medical, Inc.
2703 Wagner Place
Maryland Heights, MO 63043
Telephone (314) 770-7800

August 14, 1996

Cassandra F. Frazier
Nuclear Materials Licensing Section
U.S. Nuclear Regulatory Commission,
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

RE: License No.24-04206-05MD

Dear Ms. Frazier:

Mallinckrodt Medical Inc. (MMI) hereby applies for final approval of the amendment request, to our License No.24-04206-05MD, for distribution of the Dry Top Eluting Mo-99/Tc-99m Generator (DTE Generator).

We had originally submitted our request for this license amendment on October 10, 1995. The only document that we had not submitted at that time was the FDA approvable letter which had not yet been issued.

We have now received the FDA approvable letter, included in this letter, along with a revised label and revised drawings.

Based on your previous conversations with Dan Riemer, RSO for our facility, your office had already reviewed our October 10, 1995 submittal and found no outstanding issues other than the FDA approvable letter.

We are requesting an expedited review of this additional documentation to facilitate the earliest possible production launch.

Only two label changes were made since the October 10, 1995 license amendment request. A copy of the new insert is attachment 1. The package insert was modified per FDA request as follows:

> Change 1: In the Description section, last sentence, change "crystal clear" to "clear, colorless and free from any particulate matter".
>
> Change 2: In How Supplied section, add "1 - Package Insert" to the list of components.

A detailed drawing of the depleted uranium safe is included as attachment 2.

The copy of the final FDA approvable letter is included as attachment 3.

We believe that we have included all of the information you will need for the final approval of the license amendment per our previous correspondence.

We would appreciate your prompt attention to this request. Please contact myself at (314) 770-7940 or Dan Riemer at (314) 770-7981if you have any questions or require additional information.

Regards,

Les Sabo
Director, US Nuclear Medicine Operations

Attachments

Ultra-TechneKow® DTE
(Technetium Tc 99m Generator)

For the Production of
Sodium Pertechnetate Tc 99m Injection

DESCRIPTION:
The Ultra-TechneKow DTE Generator is prepared with fission-produced molybdenum Mo 99 adsorbed onto alumina in a lead shielded column. This generator provides a closed system for the production of sterile metastable technetium Tc 99m, which is produced by the decay of molybdenum Mo 99. Sterile, non-pyrogenic isotonic solutions of Sodium Pertechnetate Tc 99m can be obtained conveniently by periodic aseptic elution of the generator. These solutions should be clear, colorless, and free from any particulate matter.

The carrier-free solution may be used as is, or diluted to the proper concentration. Over the life of the generator, an elution will contain an amount of technetium Tc 99m in direct proportion to the quantity of Mo 99 decay since the previous elution of the generator. The exact quantity of Tc 99m in the eluate is determined by column elution efficiency, quantity of Mo 99 on the column, and the elapsed time between elutions.

Each eluate of the generator should not contain more than the USP limit of 0.15 kilobecquerel molybdenum Mo 99 per megabecquerel technetium Tc 99m (0.15 microcurie Mo 99 per millicurie Tc 99m) per administered dose at the time of administration and an aluminum ion concentration of not more than 10 micrograms per milliliter of the generator eluate, both of which must be determined by the user before administration.

Since the eluate does not contain an antimicrobial agent, it should not be used after 12 hours from the time of generator elution.

Physical Characteristics:
Technetium Tc 99m decays by isomeric transition with a physical half-life of 6.02 hours.[1] The principal photon that is useful for detection and imaging studies is listed in Table 1.

Table 1. Principal Radiation Emission Data

Radiation	Mean % Per Disintegration	Energy (keV)
Gamma-2	89.07	140.5

External Radiation:
The specific gamma ray constant for technetium Tc 99m is 0.78 R/hr-mCi at 1 cm. The first half-value layer is 0.01 7 cm of lead (Pb). A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of Pb is shown in Table 2. For example, the use of 0.25 cm thickness of Pb will attenuate the radiation emitted by a factor of about 1000.

Table 2. Radiation Attenuation by Lead Shielding

Shield Thickness (Pb) cm	Coefficient of Attenuation
0.017	0.5
0.08	10^{-1}
0.16	10^{-2}
0.25	10^{-3}
0.33	10^{-4}

Molybdenum Mo 99 decays to technetium Tc 99m with a molybdenum Mo 99 half-life of 2.75 days. The physical decay characteristics of molybdenum Mo 99 are such that only 88.6% of the decaying molybdenum Mo 99 atoms form technetium Tc 99m. Generator elutions may be made at any time, but the amount of technetium Tc 99m available will depend on the interval measured from the last elution. Approximately 47% of the maximum available technetium Tc 99m is reached after 6 hours and 95% after 23 hours. To correct for physical decay of technetium Tc 99m, the fractions that remain at selected intervals of time are shown in Table 3.

Table 3. Physical Decay Chart; Technetium Tc 99m, Half-Life 6.02 Hours

Hours	Fraction Remaining	Hours	Fraction Remaining
0*	1.000	7	0.447
1	0.891	8	0.398
2	0.794	9	0.355
3	0.708	10	0.316
4	0.631	11	0.282
5	0.562	12	0.251
6	0.501		

*Calibration time

Clinical Pharmacology:
The pertechnetate ion distributes in the body similarly to the iodide ion but is not organified when trapped in the thyroid gland. Pertechnetate tends to accumulate in intracranial lesions with excessive neovascularity or an altered blood-brain barrier. It also concentrates in the thyroid gland, salivary glands, stomach and choroid plexus. After intravenous administration it remains in the circulatory system for sufficient time to permit blood pool [illegible] perfusion, and major vessel studies. It grad[illegible] equilibrates with the extracellular space. A fraction [illegible] promptly excreted via the kidneys.

Following the administration of Sodium Pertechnetate Tc 99m as an eye drop, the drug mixes with tears within the conjunctival space. Within seconds to minutes it leaves the conjunctival space and escapes into the inferior meatus of the nose through the nasolacrimal drainage system. During this process the pertechnetate ion passes through the canaliculi, the lacrimal sac and the nasolacrimal duct. In the event of any anatomical or functional blockage of the drainage system there will be a backflow resulting in tearing (epiphora). Thus the pertechnetate escapes the conjunctival space in the tears.

While the major part of the pertechnetate escapes within a few minutes of normal drainage and tearing, it has been documented that there is some degree of transconjunctival absorption with turnover of 1.5% per minute in normal individuals, 2. 1% per minute in patients without any sac and 2.7% per minute in patients with inflammed conjunctiva due to chronic dacryocystitis. Individual values may vary but these rates are probably representative and indicate that the maximum possible pertechnetate absorbed will remain below one thousandth of that used in other routine diagnostic procedures.

INDICATIONS AND USAGE:
Sodium Pertechnetate Tc 99m is used IN ADULTS as an agent for:

- Brain Imaging (including cerebral radionuclide angiography)
- Thyroid Imaging
- Salivary Gland Imaging
- Placenta Localization
- Blood Pool Imaging (including radionuclide angiography)
- Urinary Bladder Imaging (direct isotopic cystography) for detection of vesico-ureteral reflux
- Nasolacrimal Drainage System Imaging (dacryoscintigraphy)

Sodium Pertechnetate Tc 99m is used IN PEDIATRIC PATIENTS as an agent for:

- Brain Imaging (including cerebral radionuclide angiography)
- Thyroid Imaging
- Blood Pool Imaging (including radionuclide angiography)
- Urinary Bladder Imaging (direct isotopic cystography) for the detection of vesico-ureteral reflux

CONTRAINDICATIONS:
None known.

WARNINGS:
Radiation risks associated with the use of Sodium Pertechnetate Tc 99m are greater in pediatric patients than in adults and, in general, the younger the patient the greater the risk owing to greater absorbed radiation doses and longer life expectancy. These greater risks should be taken firmly into account in all benefit-risk assessments involving pediatric patients.

Only use generator eluant specified for use with the Ultra-Technekow® DTE Generator. Do not use any other generator eluant or saline from any other source.

PRECAUTIONS:
As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient consistent with proper patient management and to insure minimum radiation exposure to occupational workers.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

After the termination of the nasolacrimal imaging procedure, blowing the nose and washing the eyes with sterile distilled water or an isotonic sodium chloride solution will further minimize the radiation dose.

Since the eluate does not contain an antimicrobial agent, it should not be used after 12 hours from time of generator elution.

Carcinogenesis, Mutagenesis, Impairment of Fertility:
No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential or whether Sodium Pertechnetate Tc 99m may affect fertility in males or females.

Pregnancy Category C:
Animal reproductive studies have not been conducted with Sodium Pertechnetate Tc 99m. It is also not known whether Sodium Pertechnetate Tc 99m can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Sodium Pertechnetate Tc 99m should be given to pregnant women only if the expected benefits to be gained clearly outweigh the potential hazards.

Ideally, examinations using radiopharmaceutical drug products - especially those elective [illegible] - of women of childbearing capability should be performed during the first ten days following the onset of menses.

Nursing Mothers:
Technetium Tc 99m is excreted in human milk during lactation, therefore, formula-feedings should be substituted for breast-feedings.

Pediatric Use:
See **Indications and Usage** and **Dosage and Administration** sections. Also see the description of additional risk under **Warnings**.

ADVERSE REACTIONS:
Allergic reactions including anaphylaxis have been reported infrequently following the administration of Sodium Pertechnetate Tc 99m.

DOSAGE AND ADMINISTRATION:
Sodium Pertechnetate Tc 99m is usually administered by intravenous injection, but can be given orally. When imaging the nasolacrimal drainage system, instill the Sodium Pertechnetate Tc 99m by the use of a device such as a micropipette or similar method which will ensure the accuracy of the dose.

For imaging the urinary bladder and ureters (direct isotopic cystography), the Sodium Pertechnetate Tc 99m is administered by direct instillation aseptically into the bladder via a urethral catheter, following which the catheter is flushed with approximately 200 mL of sterile saline directly into the bladder.

The dosage employed varies with each diagnostic procedure. If the oral route is elected, the patient should fast for at least six (6) hours before and two (2) hours after administration.

The suggested dose ranges employed for various diagnostic indications in the average ADULT PATIENT (70 kg) are as follows:

Vesico-ureteral imaging:	18.5 to 37 MBq (0.5 to 1 mCi)
Brain imaging:	370 to 740 MBq (10 to 20 mCi)
Thyroid gland imaging:	37 to 370 MBq (1 to 10 mCi)
Salivary gland imaging:	37 to 185 MBq (1 to 5 mCi)
Placenta localization:	37 to 111 MBq (1 to 3 mCi)
Blood pool imaging:	370 to 1110 MBq (10 to 30 mCi)
Nasolacrimal drainage system:	Maximum dose of 3.7 MBq (100µCi)

The recommended dosages in PEDIATRIC PATIENTS are:

Vesico-ureteral imaging:	18.5 to 37 MBq (0.5 to 1 mCi)
Brain imaging:	5.18 to 10.36 MBq (140 to 280 µCi) per kg body weight
Thyroid gland imaging:	2.22 to 2.96 MBq (60 to 80 µCi) per kg body weight
Blood pool imaging:	5.18 to 10.36 MBq (140 to 280 µCi) per kg body weight

Minimum dose of 111 to 185 MBq (3 to 5 mCi) should be employed if radionuclide angiography is performed as part of the brain imaging or blood pool imaging procedures.

NOTE: Up to 1 gram of pharmaceutical grade potassium perchlorate in a suitable base or capsule may be given orally prior to administration of Sodium Pertechnetate Tc 99m for brain imaging, placenta localization and blood pool imaging. When Sodium Pertechnetate Tc 99m is used in pediatric patients for brain or blood pool imaging, administration of potassium perchlorate is especially important to minimize the absorbed radiation dose to the thyroid gland.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. The solution to be administered as the patient dose should be clear, colorless, and contain no particulate matter.

Radiation Dosimetry:
The estimated absorbed radiation doses[2] to an average ADULT patient (70 kg) from an intravenous injection of a maximum dose of 1110 megabecquerels (30 millicuries) of Sodium Pertechnetate Tc 99m distributed uniformly in the total body of subjects not pretreated with blocking agents, such as pharmaceutical grade potassium perchlorate, are shown in Table 4. For placental localization studies, when a maximum dose of 111 megabecquerels (3 millicuries) is used, it is assumed to be uniformly equilibrated between maternal and fetal tissues.

The estimated absorbed radiation doses to an ADULT patient from the nasolacrimal imaging procedure using a maximum dose of 3.7 megabecquerels (100 microcuries) of Sodium Pertechnetate Tc 99m are shown in Table 5.

ULTRA-TECHNEKOW® DTE (TECHNETIUM Tc 99m GENERATOR)

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Ultra-TechneKow® DTE
(Technetium Tc 99m Generator)

Table 4. Absorbed Radiation Doses From Intravenous Injection (ADULTS)

Tissue	1110 MBq (30 mCi) Dose				111 MBq (3mCi) Dose	
	Resting Population		Active Population			
	mGy	rads	mGy	rads	mGy	rads
Bladder Wall	15.9	1.59	25.5	2.55		
Gastrointestinal tract:						
Stomach wall	75.0	7.50	15.3	1.53		
Upper large intestine wall	20.4	2.04	36.0	3.60		
Lower large intestine wall	18.3	1.83	33.0	3.30		
Red Marrow	5.7	0.57	5.1	0.51		
Testes	2.7	0.27	2.7	0.27		
Ovaries	6.6	0.66	9.0	0.90		
Thyroid	39.0	3.90	39.0	3.90		
Brain	4.2	0.42	3.6	0.36		
Total Body	4.2	0.42	3.3	0.33		
Placenta					0.5	0.05
Fetus					0.5	0.05

Table 5. Absorbed Radiation Doses from Dacryoscintigraphy

Tissue	3.7 MBq (100 µCi) Dose of Sodium Pertechnetate Tc 99m	
	mGys	rads
Eye Lens:		
If lacrimal fluid turnover is 16%/min	0.140	0.014
If lacrimal fluid turnover is 100%/min	0.022	0.002
If drainage system is blocked	4.020	0.402
Total Body*	0.011	0.001
Ovaries*	0.030	0.003
Testes*	0.009	0.001
Thyroid*	0.130	0.013

*Assuming no blockage of draining system. MIRD Dose Estimate Report No. 8, J Nucl. Med., 17: 74-77, 1976

In **PEDIATRIC** patients, the maximum radiation doses when a dose of 185 megabecquerels (5 millicuries) Sodium Pertechnetate Tc 99m is administered to a neonate (3.5 kg) for brain or blood pool imaging with radionuclide angiography are shown in Table 6.

In pediatric patients, an average 30 minute exposure to 37 megabecquerels (1 millicurie) of Sodium Pertechnetate Tc 99m following instillation for direct cystography, results in an estimated absorbed radiation dose of approximately 300 micrograys (30 millirads) to the bladder wall and 40 to 50 micrograys (4 to 5 millirads) to the gonads.[3]

Table 6. Absorbed Radiation Doses From Intravenous Injection (PEDIATRIC)

Tissue	37 MBq (1 mCi) Dose		185 MBq (5mCi) Dose	
	mGy	rads	mGy	rads
Thyroid (without perchlorate)	46.0	4.60	230.0	23.0
Thyroid (with perchlorate)	9.7	0.97	48.5	4.85
Large Bowel (with perchlorate)	19.0	1.90	95.5	9.55
Testes	1.0	0.10	5.1	0.51
Ovaries	2.2	0.22	11.0	1.10
Total Body	1.5	0.15	7.6	0.76

HOW SUPPLIED:

The Ultra-TechneKow DTE (Technetium Tc 99m) Generators contain the following amount of molybdenum Mo 99 at the date and time of calibration stated on the label.

Catalog No.

881	18.5	gigabecquerels	(0.50 curie)
882	27.75	gigabecquerels	(0.75 curie)
883	37	gigabecquerels	(1.0 curie)
884	55.5	gigabecquerels	(1.5 curies)
885	74	gigabecquerels	(2.0 curies)
886	92.5	gigabecquerels	(2.5 curies)
887	111	gigabecquerels	(3.0 curies)

Each generator is supplied with the following components for the elution of the generator

7 — Evacuated Collecting Vials, 10 mL, Sterile, Non-pyrogenic.
or
5 — Evacuated Collecting Vials, 20 mL, Sterile, Non-Pyrogenic

7 — 70% (v/v) Isopropyl Alcohol Wipes

7 — Pressure-sensitive "Caution - Radioactive Material" collecting vial labels

7 — Pressure-sensitive radioassay data labels for lead elution shield

1 — Generator Eluant Vial, 135 mL, Sterile, Non-Pyrogenic

1 — TechneStat™ Vial, 5mL, containing 0.5 mL of 70% (v/v) Isopropyl Alcohol

1 — Package Insert

The sterile, non-pyrogenic solution used to elute the generator column contains 0.9% sodium chloride. The eluant does not contain an antimicrobial agent.

EVACUATED COLLECTING VIALS: Collecting vials are available on request in 10 and 20 milliliter sizes.

Storage:
Store generator and Sodium Pertechnetate Tc 99m solution at room temperature (15°C to 30°C).

Expiration Date:
The generator should not be used after the expiration date stated on the label.

The expiration time of the Sodium Pertechnetate Tc 99m solution is not later than 12 hours after time of elution. If the eluate is used to reconstitute a kit, the radiolabeled kit should not be used after 12 hours from the time of generator elution or after the expiration time stated on the labeling for the prepared drug, whichever is earlier.

Directions for Use of the Technetium Tc 99m Generator:

NOTE 1: Immediately upon delivery, the generator should be placed within a minimum of one-inch of lead shielding in such a manner so as to minimize radiation exposure to attending personnel.

NOTE 2: Wear waterproof gloves during the elution procedure and during subsequent reconstitution of kits with the eluate.

NOTE 3: Use a shielded syringe to withdraw patient dose or to transfer Sodium Pertechnetate Tc 99m into mixing vials during kit reconstitution.

NOTE 4: The needles in the generator are sterile beneath their covers, and the generator has been cleaned underneath the top cover. Additional disinfection of these areas with agents containing alcohol may unfavorably influence the Tc 99m yield.

Eluting the generator every 24 hours will provide optimal amounts of Sodium Pertechnetate Tc 99m. However, the generator may be eluted whenever sufficient amounts of technetium Tc 99m have accumulated within the column.

For Example:

Time After First Elution (hrs.)	Approximate Yield (% of First Elution)
1	10
2	19
3	27
4	35
5	41
6	47

Preparation:

1. Rotate the top cover 30° counter clockwise and lift up to remove.
2. Lift generator by its handle and position inside the auxiliary shield, aligning the notch in the elution station with leaded glass window in the auxiliary shield.
3. Remove the flip-top cap of the eluant vial, disinfect the stopper, remove and store the needle cover over the eluant needles, invert the eluant vial and push down into place on the eluant needles.
4. Remove the flip-top cap of the TechneStat vial and place it into the TechneStat vial shield.
5. Remove and store the needle cover from the elution station, replace the lid of the auxiliary shield and insert the shielded TechneStat vial into the elution station.

Elution:

1. Remove the flip-top cap of the appropriate evacuated vial, disinfect the stopper, and put the vial into the elution shield aligning the volume scale on the evacuated vial with the leaded glass window.
2. Replace the shielded TechneStat vial with the shielded evacuated vial, aligning the two leaded glass windows. Piercing the septum of the evacuated vial with the elution needle will begin the elution process.
3. Wait until the evacuated vial has completely filled itself (a few minutes). **Never interrupt the elution by lifting the vial shielding!** When smaller elution volumes are required, the elution may be interrupted by rotating the vial shield a quarter turn clockwise and pushing it downwards for a few seconds (this stops the elution and fills the remainder of the vial with sterile air). **NOTE: Do not use generator eluate if its appearance is discolored.**
4. Replace the shielded vial with the shielded TechneStat vial.
5. Determine the technetium Tc 99m concentration and molybdenum Mo 99 content for dispensing purposes. **NOTE: Molybdenum Mo 99 Breakthrough Limit** - The acceptable limit is 0.15 kilobecquerel molybdenum Mo 99 per megabecquerel technetium Tc 99m (0.15 microcurie Mo 99 per millicurie Tc 99m) at the time of administration.
6. Determine the aluminum ion concentration of the eluate. **NOTE: Aluminum Ion Breakthrough Limit** - The acceptable limit is not more than 10 micrograms per milliliter of eluate.

Subsequent Elutions:
Repeat steps 1 through 6 of the Elution procedure above.

Vacuum Loss:
If the vacuum in the collecting vial is lost, do not attempt to re-evacuate the vial, but discard and use a new collecting vial.

EXPIRED GENERATOR DISPOSAL:

1. Following the life of the generator, remove and dispose of the used TechneStat vial and the eluant vial.
2. Cover the inlet and outlet needles with the stored needle covers.
3. Close the generator system with its top cover and the lever closing ring by rotating with downward pressure.
4. The intact generator assembly should be either returned to Mallinckrodt Medical, Inc. or allowed to decay for 20 half-lives of the molybdenum Mo 99. Monitor the unshielded generator column with a low level survey meter. If no significant radiation level above background is indicated, the column may be disposed of through the regular refuse system.

This generator is approved for use by persons licensed by the U.S. Nuclear Regulatory Commission to use by-product material identified in Section 35.200 or under equivalent licenses of Agreement States.

Revised 3/96
Mallinckrodt Medical, Inc.
St. Louis, MO 63134

ULTRA-TECHNEKOW® DTE (TECHNETIUM Tc 99m GENERATOR)

880/887

MALLINCKRODT MEDICAL

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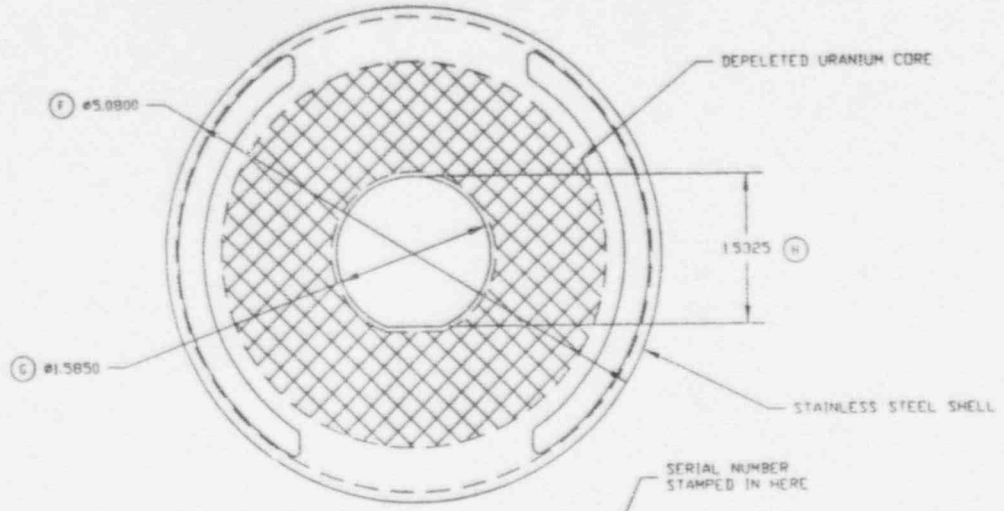
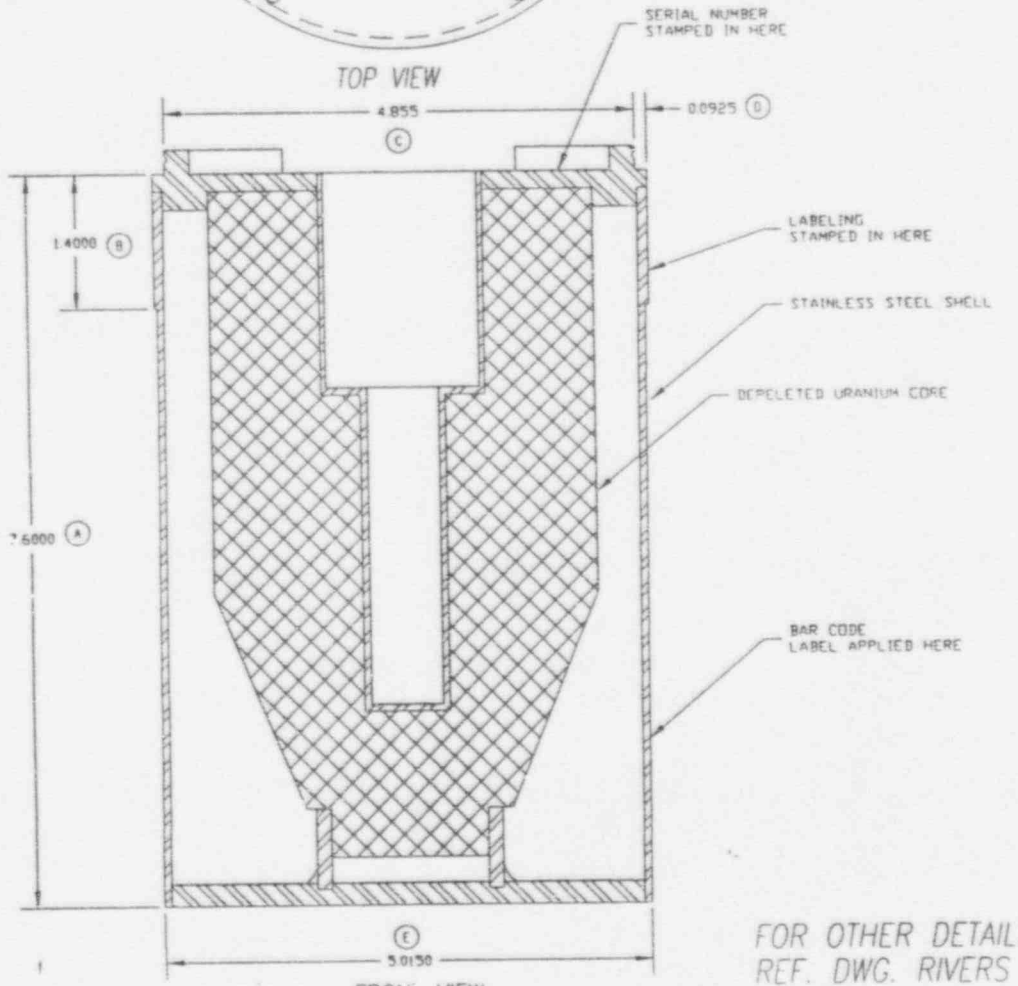
[1] Kocher, David C., "Radioactive Decay Data Tables", DOE/TIC-11026, 108 (1981).

[2] Modified from: Summary of Current Radiation Dose Estimates to Normal Humans from Tc 99m as Sodium Pertechnetate. MIRD Dose Estimate Report No. 8. J. Nucl. Med., 17 (1):74-7, 1976.

[3] Conway, J.J., et al., Direct and indirect radionuclide cystography. J. Urol. 113:689-693, May 1975.



TOP VIEW



FRONT VIEW

ISO NOT AVAILABLE

LABELING FOR DU SAFES
"CAUTION RADIOACTIVE SHIELDING
URANIUM MALLINCKRODT"
MUST BE STAMPED ON THE SIDE
SERIAL NUMBER MUST BE STAMPED
ON THE TOP.

FOR OTHER DETAILS SEE ORIGINAL VENDOR DRAWING
REF. DWG. RIVERS COMPANY C2305 REV. A

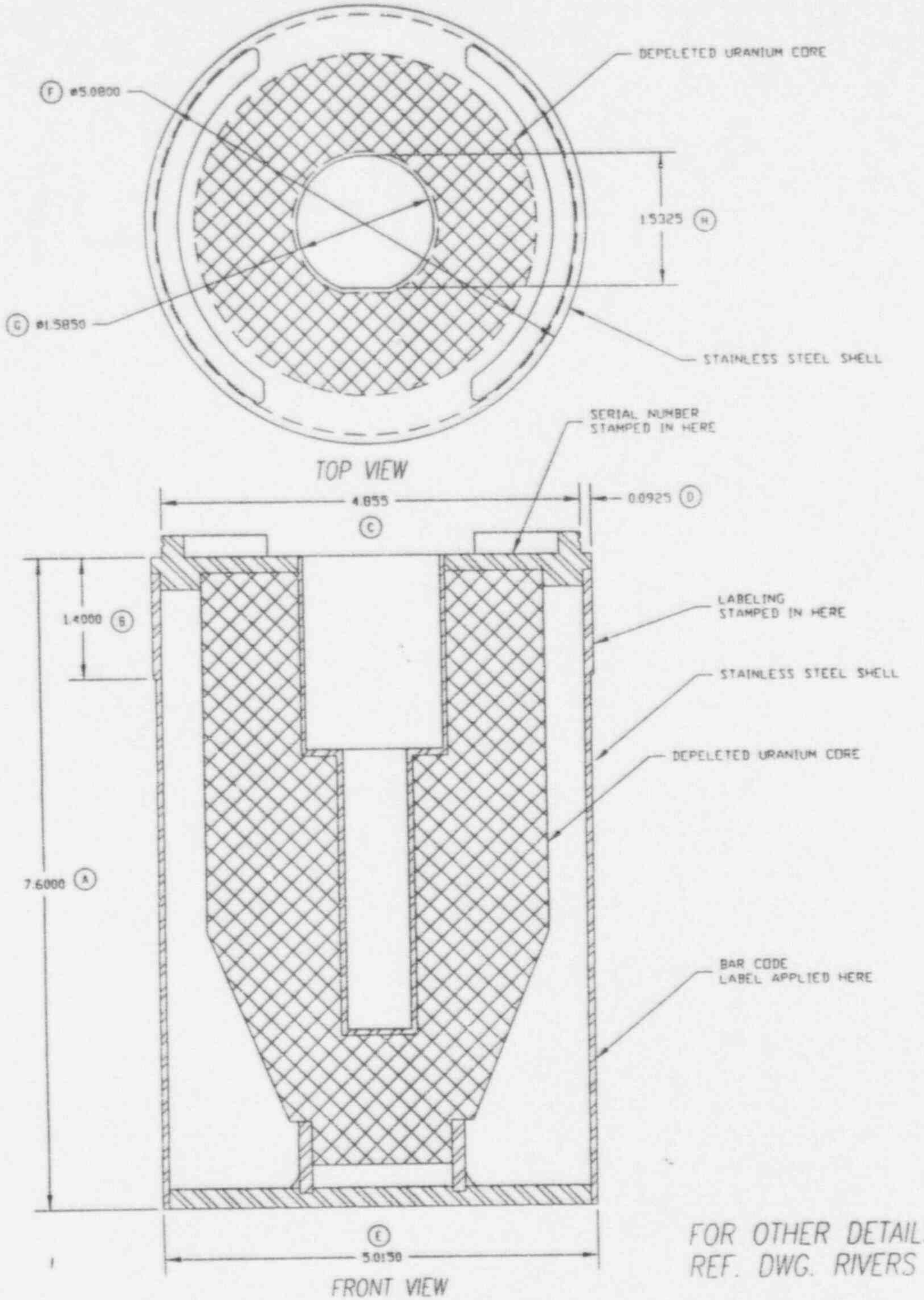
TOLERANCES ±0.005"

ENGINEER JOB NO. -		PLOT	PROJECT NO.
REV. NO.	DATE	REVISIONS	
0	15 JAN 96	RELEASED	
1	12 FEB 96	MACHINING & TESTING REQUIRED ON 1 of 2 TO BE CHANGED	
2	13 MAR 96	ADDED LABEL STAMPING INFORMATION	

MALLINCKRODT
Nuclear Medicine
MALLINCKRODT MEDICAL, INC.
2703 WAGNER PLACE
MARYLAND HEIGHTS, MISSOURI 63043-3493

L332-00 DU SAFE & S.S. SHELL
UNIT - DTE GENERATOR

PLANT MARYLAND HEIGHTS	SIZE D	FSCM 33333
SCALE 1 : 1 @ C	DATE 15 JAN 96	
DRAWN BY MICHEAL J. PATRICK	DATE PLOTTED 13 MAR 96	
FILE L332PLC	ENGINEER DAVE COULTER	
DRAWING NO. — — — — —	REV 2	



ISO NOT AVAILABLE

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REF. DWG. RIVERS COMPANY C2305 REV. A

TOLERANCES ±0.005"

MALLINCKRODT
Nuclear Medicine
MALLINCKRODT MEDICAL, INC.
2703 WAGNER PLACE
MARYLAND HEIGHTS, MISSOURI 63043-3493

L332-00 DU SAFE & S.S. SHELL
UNIT – DTE GENERATOR

PLANT MARYLAND HEIGHTS
DATE 15 JAN 96
DATE PLOTTED 13 MAR 96
DRAWN BY MICHEAL J. PATRICK
ENGINEER DAVE EDELEN

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 17-243/S-012

JUL 16 1996

Mallinckrodt Medical, Inc.
675 McDonnell Boulevard
P.O. Box 5840
St. Louis, Missouri 63134

Attention: Mary E. Hamilton
Sr. Regulatory Affairs Associate

Dear Ms. Hamilton:

Please refer to your July 31, 1992, supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ultra-TechneKow FM (Technetium Tc 99m Generator).

We acknowledge receipt of your amendments dated October 28, 1992; June 28, September 6, 1995; January 29, and March 19, 1996, and to our approvable letters of August 22, 1995, and February 29, 1996.

The supplemental application provides for multiple chemistry and manufacturing changes to the Hybrid Generator.

We have completed the review of this supplemental application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling in the submission dated March 19, 1996. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on March 19, 1996.

Please submit sixteen copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy weight paper or similar material. For administrative purposes this submission should be designated "FINAL PRINTED LABELING" for approved supplemental NDA 17-243/S-012. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Ms. Susan Cusack, B.S., R.N., Consumer Safety Officer at (301) 443-1560.

Sincerely yours,

Eldon E. Leutzinger, Ph.D.
Chemistry Team Leader, DNDC II
Division of Medical Imaging and Radiopharmaceutical
Drug Products (HFD-160)
Office of Drug Evaluation III
Center for Drug Evaluation and Research

PLEASE FILE

CONVERSATION RECORD

TIME: 9:30am

DATE: 7/29/96

O VISIT O CONFERENCE X TELEPHONE

O INCOMING
X OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT: Dan Riemer, RSO

ORGANIZATION (OFFICE, DEPT. ETC.): Mallinckrodt

TELEPHONE NO.: 314 770-7981

SUBJECT:
New Generator from Mallinckrodt

SUMMARY:
Called Mr. Riemer to get an update on getting FDA approval. I informed Mr. Riemer that we need to get FDA approval to issue amendment as discussed in earlier converations.

Mr. Riemer informed me that they had gotten FDA approval, with a minor change in the system. He will submit the FDA approval in approx. one week.

ACTION REQUIRED:
Submit response- FDA approval for new generator

NAME OF PERSON DOCUMENTING CONVERSATION: Cassandra Frazier

SIGNATURE:

DATE: 7/29/96

ACTION TAKEN:

CONVERSATION RECORD | TIME | DATE 3/5/96

O VISIT O CONFERENCE X TELEPHONE

X INCOMING
O OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT | ORGANIZATION (OFFICE, DEPT.,ETC.) | TELEPHONE NO.

Telecon Baggett, Camper and AyresHQ HQ

SUBJECT

New Generator from Mallinckrodt

SUMMARY

Telecon with HQ to discuss response to TAR to review new generator from Mallinckrodt:

Larry Camper indicated that there is no historical precedent or regulatory basis to review the design criteria of generators. Therefore, we have deferred to FDA to review Mo-99 Tc-99m generators.

Therefore: In accordance with 32.72 and 10 CFR 49(transportation), a device review is not required or suggested.

The generic issue of whether we should be reviewing generators as devices and DOT shielding requirements, etc. will be looked at and discussed with Don Cool.

ACTION REQUIRED

Issue amendment to add new generator, only after Mallinckrodt receives FDA approval.

(314) 720-7981

3/11 Left VM w/ above info & expect response w/in 15 days Don Riemer, Mallinckrodt

NAME OF PERSON DOCUMENTING CONVERSATION | SIGNATURE | DATE

Cassandra Frazier | 3/5/96

Per John Madera Notes

ACTION TAKEN

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 30, 1996

MEMORANDUM TO: John R. Madera, Chief
Materials Licensing Branch
Region III

FROM: Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: TECHNICAL ASSISTANCE REQUEST: MALLINCKRODT Mo-99/Tc-99m GENERATOR

I am responding to your technical assistance request (TAR) dated December 28, 1995, requesting a sealed source and device review of Mallinckrodt Medical, Inc. (MMI) Dry Top Eluting (DTE) Mo-99/Tc-99m Generator.

The MMI DTE does not contain a sealed source. Licensing of Mo-99/Tc-99m Generators are covered under 10 CFR 34.72. We note that your TAR states that, "FDA approval is pending". Once the provisions of 10 CFR 34.72, including FDA approval, have been satisfied, a license may be issued. No sealed source and device review is necessary.

CONTACT: Robert L. Baer
301/415-8125

DEC 2 8 1995

95-60

REQUEST FOR TECHNICAL ASSISTANCE

Date: December 22, 1995

Mail or E-Mail to: Donald A. Cool, Mail Stop: 6H3-OWFN, If E-mail, cc:CLE
Division of Industrial and Medical Nuclear Safety,
NMSS

From: John R. Madera (JRM4), Chief
Nuclear Materials Safety Branch
Region III

Licensee: Mallinckrodt Medical, Inc. (MMI) License No.: 24-04206-05MD

☐ Control No.: 99283

☐ Letter dated: October 10, 1995

☐ Suggested change in licensing procedure (enclosed): N/A

☐ Problem/Issue: Licensee is amending their license for distribution of an upgraded generator - DTE generator. This generator is an upgrade of their present authorized Ultra - TechnaKow (UTK Generator). The upgrade consists of a repositioning of the inner components, which includes a relocation of the internal plumbing, from the bottom to the top of the generator. The elution vial is no longer attached to the generator. NOTE: FDA approval is pending, but expected soon.

☐ Action Required: Perform Sealed Source and Device review for MMI's upgraded DTE generator.

☐ Recommended Active (with revisions): X Approve or X Reject, based on information submitted by licensee.

Headquarters Reviewer:
Regional Reviewer: Cassandra Frazier (CFF)
Reviewer Code: R3
Reviewer Phone No.: (708) 829-9830 Fax No.: (708) 515-1259
Requested Needed By: 12/04/95

cc: C. Pederson

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