MATERIALS LICENSE

Amendment No. 12

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, 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.

Licensee	
1. DuPont Merck Pharmaceutical Company	In accordance with letter dated June 17, 1992, 3. License number 20-00320-16MD is amended in its entirety to read as follows:
2. 331 Treble Cove Road North Billerica, Massachusetts 01862	4. Expiration date December 31, 1994
	5. Docket or Reference No. 030-11164

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. Molybdenum 99	A. Molybdenum 99/ Technetium 99m Generators	A. Not applicable
B. Xenon-133	B. Gas or gas in solution	B. Not applicable

9. Authorized use

A. and B. Pursuant to 10 CFR 32.73, the licensee is authorized to distribute the licensed material described in Items 6 and 7 of this license to persons licensed pursuant to 10 CFR 35.57 and 10 CFR 35.200, or under equivalent licenses of Agreement States.

CONDITIONS

10. The licensee is authorized to distribute the licensed materials described in Items 6 and 7 of this license from the licensee's manufacturing plant at 331 Treble Cove Road, Billerica, Massachusetts; and to redistribute the licensed materials described in Items 6 and 7 of this license from the licensee's regional distribution centers anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the 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) or the withdrawal of approval of a "New Drug Application" (NDA) for any licensed material described in Items 6 and 7 of this license.

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

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 20-00320-16MD
Docket or Reference number: 030-11164
Amendment No. 12

(Continued) CONDITIONS

13. Any proposed changes in packaging, shielding, labeling or the package insert shall be submitted for review to the U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406 and approval of the changes shall be received by the licensee prior to implementing the changes.

14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Letter dated May 13, 1985
B. Application dated December 28, 1988
C. Letter dated April 12, 1989
D. Letter dated April 20, 1989
E. Letter dated June 2, 1989
F. Letter dated August 23, 1989
G. Letter dated October 11, 1989
H. Letter dated December 7, 1990
I. Letter dated February 14, 1992
J. Letter dated June 17, 1992
K. Letter dated January 15, 1993

For the U.S. Nuclear Regulatory Commission
Original Signed By:
Elizabeth Ullrich

Date FEB 0 8 1993

By
Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

FEB 0 8 1993

License No. 20-00320-16MD
Docket No. 030-11164
Control No. 116746

DuPont Merck Pharmaceutical Company
ATTN: Francis E. Roy, Jr.
Development Health Physicist
331 Treble Cove Road
North Billerica, Massachusetts 01862

Dear Mr. Roy:

Please find enclosed an amendment to your NRC Material License.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the Region I Material Licensing Section, (215) 337-5093, so that we can provide appropriate corrections and answers.

Please be advised that you must conduct your program involving licensed radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, please note the items in the enclosed, "Requirements for Materials Licensees."

In reference to the telephone conversation between Sheri Arredondo of this office on January 19, 1993 and yourself, since some of your generators do not have model numbers, we will no longer list model numbers under License Condition 7.A. or 7.B. of your license. Thus, License Condition 7.A. specifies Molybdenum 99/Technetium 99m Generators and 7.B. specifies gas or gas in solution with the specific characteristics defined in your letters listed under License Condition 14 of License No. 20-00320-16MD.

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, the NRC expects licensees to pay meticulous attention to detail and to achieve the high standard of compliance which the NRC expects of its licensees.

You will be periodically inspected by NRC. A fee may be charged for inspections in accordance with 10 CFR Part 170. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in prompt and

vigorous enforcement action against you. This could include issuance of a notice of violation, or in case of serious violations, an 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, 10 CFR Part 2, Appendix C.

We wish you success in operating a safe and effective licensed program.

Sincerely,

Original Signed By:
Elizabeth Ullrich

John D. Kinneman, Chief
Research, Development and
Decommissioning Section
Division of Radiation Safety
and Safeguards

Enclosures:
1. Amendment No. 12
2. Requirements for Materials Licensees

DRSS:RI
fc Arredondo/cmm
2/4/93

DRSS:RI
fc Kinneman
2/4/93

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NRC FORM 218 (4-78) NRCM 0240

U.S. NUCLEAR REGULATORY COMMISSION

TELEPHONE OR VERBAL CONVERSATION RECORD

DATE 1/19/83

TIME 3:40 ☐ A.M. ☐ P.M.

☐ INCOMING CALL ☐ OUTGOING CALL ☐ VISIT

PERSON CALLING	OFFICE/ADDRESS	PHONE NUMBER	EXTENSION
Sheri Arredondo			

PERSON CALLED	OFFICE/ADDRESS	PHONE NUMBER	EXTENSION
Frances Roy	DuPont		

CONVERSATION

SUBJECT Audit No. 12

SUMMARY

I explained that we are taking model numbers off the license since we have not put some of them on in the past. Thus all of the generator model NO's that they will be allowed to distribute will be according to the tie downs.

REFERRED TO:

☐ ADVISE ME OF ACTION TAKEN.

ACTION REQUESTED

INITIALS

DATE

ACTION TAKEN

INITIALS

DATE

"OFFICIAL RECORD COPY" ML 10

The Du Pont Merck Pharmaceutical Company
Radiopharmaceutical Division
331 Treble Cove Road
N. Billerica, MA 01862
(508) 667 9531

0 30-11164

January 15, 1993

DU PONT
MERCK

United States Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

Attn: Sheri A. Arredondo

Reference: Materials License 20-00320-16MD
Mail Control Number 116746

Dear Ms. Arredondo:

This is written to provide the additional information needed to process our amendment request for a new technetium generator design to be added to the above-referenced license.

Attached is the approval letter from the FDA you requested for the Technelite™ Technetium-99m Generator. We just received the approval from the FDA this week.

I have also attached another copy of the Technelite™ package insert. After the FDA's review, a few changes were made to the insert. I highlighted the changes for you. Even though these changes are very minor, I sent the insert for your information in conformance with license condition #13, concerning the NRC's prior approval of any proposed changes to the package insert.

We now have an immediate business need for the Technelite™ generator and ask for approval of our license amendment request as soon as possible. I will follow-up with you early next week.

Please contact me if you need any additional information.

Sincerely,

Francis E. Roy Jr.

Francis E. Roy Jr. (Skip)
Development Health Physicist

Telephone: 508-671-8242

OFFICIAL RECORD COPY

Odd Info
116746

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 17-771/S-010

The DuPont Merck Pharmaceutical Company
Radiopharmaceutical Division
331 Treble Cove Road
North Billerica, MA 01862

JAN 12 1993

Attention: Laura A. Lee
Senior Regulatory Affairs Assistant

Dear Ms. Lee:

Reference is made to your supplemental new drug application (NDA) dated March 13, 1992, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Technetium Tc99m Generator (Fission).

The supplement provides for a modification to allow for terminal sterilization of the generator.

We acknowledge receipt of your amendments dated November 24 and January 7, 1992.

We have completed our review of this application, as amended, and it is approved as of the date of this letter.

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

Should you have any questions, please contact Ms. Susan Lange, Consumer Safety Officer, at (301) 443-5818.

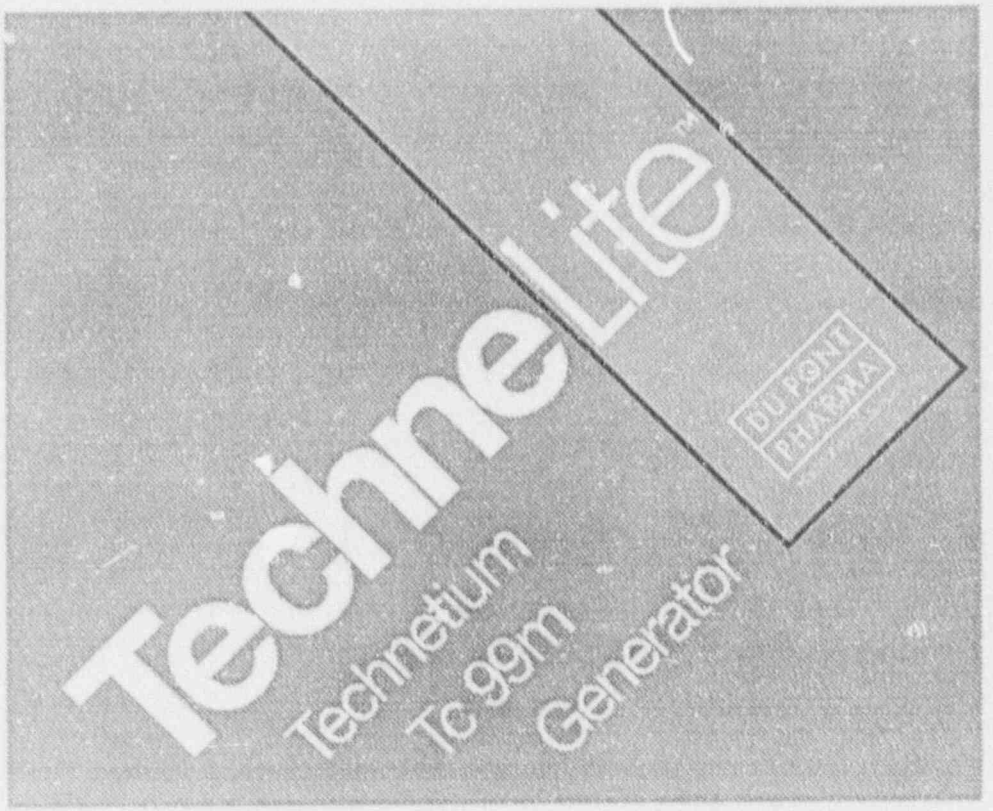
Sincerely yours,

Eric B. Sheinin

Eric B. Sheinin, Ph.D.
Supervisory Chemist
Division of Medical Imaging,
Surgical and Dental Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

November 1992

Du Pont Radiopharmaceutical Division
The Du Pont Merck Pharmaceutical Co.



FOR DIAGNOSTIC USE

DESCRIPTION: Sodium Pertechnetate Tc 99m Injection, as eluted according to the elution instructions with Du Pont Radiopharmaceutical's TECHNELITE™, Technetium Tc 99m Generator, is in Sodium Chloride 0.9% as a sterile, non-pyrogenic, diagnostic radiopharmaceutical suitable for intravenous injection, oral administration, and direct instillation. The pH is 4.5-7.5. The eluate should be clear, colorless, and free from visible foreign material. Each eluate of the TECHNELITE™, Technetium Tc 99m Generator should not contain more than 0.0056MBq (0.15 microcuries) of Molybdenum Mo99 per 37MBq (1 millicurie) of Technetium Tc 99m per administered dose at the time of administration, and not more than 10 micrograms of aluminum per milliliter of the Technetium Tc 99m 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 later than one (1) working day after the elution (12 hours).

Du Pont Radiopharmaceutical's TECHNELITE™, Technetium Tc 99m Generator consists of a column containing fission produced Molybdenum Mo99 adsorbed on alumina. The terminally sterilized and sealed column is enclosed in a lead shield; the shield and other components are sealed in a cylindrical plastic container with an attached handle. Built into the top surface are two recessed wells marked CHARGE and COLLECT. Needles protruding from these two wells accommodate supplied sterile eluant charge vials and sterile eluate collection vials. The eluting solvent consists of Sodium Chloride 0.9%, prepacked into septum-sealed vials.

The eluate collection vial is evacuated, sterile and non-pyrogenic. A sterile 0.22 micrometer bacteriological filter is incorporated between the column outlet and the collection vials. During and subsequent to elution, the eluate collection vial should be kept in a radiation shield. The Generator is shipped with a silicone needle seal over the charge needle and a vented needle cover over the collect needle. A sterile vial containing bacteriostat is supplied for the customer to aseptically reseal the collect needle after each elution.

PHYSICAL CHARACTERISTICS

Technetium Tc 99m decays by isomeric transition with a physical half-life of 6.02 hours.[1] Photons that are useful for imaging studies are listed in Table 1.

Table 1. Principal Radiation Emission Data – Technetium Tc 99m

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

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

EXTERNAL RADIATION

The specific gamma ray constant for Technetium Tc 99m is 5.4 microcoulombs/Kg-MBq-hr (0.78 R/mCi-hr) at 1cm. The first half-value thickness is 0.017cm of lead (Pb). To facilitate control of radiation exposure from millicurie amounts of Technetium Tc 99m, for example: the use of a 0.25cm thick standard radiation elution lead shield will attenuate the radiation emitted by a factor of about

1000. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of lead is shown in Table 2.

NOTE: Because the generator is well contained and essentially dry, there is little likelihood of contamination due to damage in transit. The most probable source of leakage resulting from damage in transit is the nonradioactive eluant charge vial.

Table 2. Radiation Attenuation of Technetium Tc 99m by Lead Shielding

Shield Thickness lead (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 Mo99 decays to Technetium Tc 99m with a Molybdenum Mo99 half-life of 66 hours. The physical decay characteristics of Molybdenum Mo99 are such that only 86.8% of the decaying Molybdenum Mo99 atoms form Technetium Tc 99m. This means that only 78% of the activity remains after 24 hours; 60% remains after 48 hours, etc. All units have a minimum of 38mm, 1.5 inches (= 6 half-value layers) of lead surrounding the activity. Since the Molybdenum Mo99 is constantly decaying to fresh Technetium Tc 99m, it is possible to elute the generator at any time. (See Table 3.)

Table 3. Molybdenum Mo99 Decay Chart Half-Life 66.0 Hours

Days	Percent Remaining	Days	Percent Remaining
0	100	8	13
1	78	9	10
2	60	10	8
3	47	11	6
4	36	12	5
5	28	13	4
6	22	14	3
7	17		

Generator elutions may be made at any time, but the amount of Technetium Tc 99m available will depend on the interval from the last elution. Approximately 47% of maximum Technetium Tc 99m is reached after 6 hours and 96% after 24 hours.

The elution vial shield has a wall thickness of 7.9mm, 0.31 inches, and reduces transmitted Technetium Tc 99m radiation essentially to zero. To correct for physical decay of Tc 99m, the fractions that remain at selected intervals of time are shown in Table 4.

Table 4. Physical Decay Chart: Technetium Tc 99m Half-Life 6.02 Hours

Hours	Percent Remaining	Hours	Percent Remaining
0*	100.0	7	44.7
1	89.1	8	39.8
2	79.4	9	35.5
3	70.8	10	31.6
4	63.1	11	28.2
5	56.2	12	25.1
6	50.1		

*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 choroid plexus, thyroid gland, salivary glands, and stomach. However, in contrast to the iodide ion, the pertechnetate ion is released unchanged from the thyroid gland.

After intravascular administration it remains in the circulatory system for sufficient time to permit blood pool, organ perfusion, and major vessel studies. It gradually equilibrates with the extracellular space. A fraction is promptly excreted via the kidneys.

Following the administration of Sodium Pertechnetate Tc 99m Injection 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 a fractional turnover rate of 0.015/min in normal individuals, 0.021/min in patients without any sac and 0.027/min in patients with inflamed 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 Injection 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 the detection of vesico-ureteral reflux.
- Nasolacrimal Drainage System Imaging

Sodium Pertechnetate Tc 99m Injection is used IN CHILDREN as an agent for:

- Brain Imaging (including cerebral radionuclide angiography)
- Thyroid Imaging
- Blood Pool Imaging
- 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 Injection 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.

PRECAUTIONS:

General

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 ensure minimum radiation exposure to occupational workers.

Since the eluate does not contain an antimicrobial agent, it should not be used after 12 hours from the time of TECHNELITE™, Technetium Tc 99m Generator elution.

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.

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

No animal studies have been performed to evaluate carcinogenic potential or whether Sodium Pertechnetate Tc 99m affects 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 reproduction capacity. Sodium Pertechnetate Tc 99m Injection should be given to a pregnant woman only if clearly needed.

Ideally examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers

Sodium Pertechnetate Tc 99m is excreted in human milk during lactation; therefore formula feedings should be substituted for breast feeding.

This radiopharmaceutical preparation should not be administered to pregnant or lactating women unless expected benefits to be gained outweigh the potential risks.

Pediatric Use

See INDICATIONS and DOSAGE AND ADMINISTRATION sections. Also see the description of additional risks under WARNINGS.

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

DOSAGE AND ADMINISTRATION: Sodium Pertechnetate Tc 99m Injection is usually administered by intravascular injection but can be given orally. For imaging the urinary bladder and ureters (direct isotopic cystography), the Sodium Pertechnetate Tc 99m Injection is administered by direct instillation aseptically into the bladder via a urethral catheter, following which the catheter is flushed with approximately 200ml 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. When imaging the nasolacrimal drainage system, instill the Sodium Pertechnetate Tc 99m Injection by the use of a device such as a micropipette or similar method which will ensure the accuracy of the dose.

The suggested dose range employed for various diagnostic indications in the average ADULT PATIENT (70kg) is:

Vesico-ureteral Imaging	18.5 to 37MBq (0.5 to 1mCi)
Brain Imaging	370 to 740MBq (10 to 20mCi)
Thyroid Gland Imaging	37 to 370MBq (1 to 10mCi)
Salivary Gland Imaging	37 to 185MBq (1 to 5mCi)
Placenta Localization	37 to 111 MBq (1 to 3mCi)
Blood Pool Imaging	370 to 1110MBq (10 to 30mCi)
Nasolacrimal Drainage System	Max. 3.7MBq (100μCi)

The recommended dosage range in PEDIATRIC PATIENTS is:

Vesico-ureteral Imaging	18.5 to 37MBq (0.5 to 1mCi)
Brain Imaging	5.18 to 10.36MBq (140 to 280μCi)/kg body weight
Thyroid Gland Imaging	2.22 to 2.96MBq (60 to 80μCi)/kg body weight
Blood Pool Imaging	5.18 to 10.36MBq (140 to 280μCi)/kg body weight

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

NOTE: Up to one (1) gram of pharmaceutical grade potassium perchlorate in a suitable base or capsule may be given prior to administration of Sodium Pertechnetate Tc 99m Injection. When Sodium Pertechnetate Tc 99m Injection is used in children for brain or blood pool imaging, the administration of potassium perchlorate is especially important in order 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 of the dose.

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 crystal clear and contain no particulate matter. Do not use an eluate of the TECHNELITE™, Technetium Tc 99m Generator later than one (1) working day after elution (12 hours).

RADIATION DOSIMETRY

The estimated absorbed radiation doses[2] to an average ADULT patient (70kg) from an intravenous injection of a maximum dose of 1110MBq (30 millicuries) of Sodium Pertechnetate Tc 99m Injection distributed uniformly in the total body of subjects not pretreated with blocking agents such as pharmaceutical grade potassium perchlorate are shown in Table 5. For placenta localization studies, when a maximum of 111MBq (3 millicuries) is used, it is assumed to be uniformly equilibrated between maternal and fetal tissues.

Table 5. Absorbed Radiation Doses (Adults)

Tissue	mGy/1110MBq (rads/30 millicuries) Resting Population	Active Population	mGy/111MBq (rads/3mCi)
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)	—
Whole-Body	4.2 (0.42)	3.3 (0.33)	—
Placenta	—	—	0.5 (0.05)
Fetus	—	—	0.5 (0.05)

In pediatric patients, the maximum radiation doses of 185MBq (5 millicuries) of Sodium Pertechnetate Tc 99m Injection administered to a neonate (3.5kg) for brain or blood pool imaging with radionuclide angiography are shown in Table 6. In pediatric patients, an average 30 minute exposure to 37MBq (1 millicurie) of Sodium Pertechnetate Tc 99m Injection following instillation for direct cystography,

results in an estimated absorbed radiation dose of approximately 0.30mGy (30 millirads) to the bladder wall and 0.04 to 0.05mGy (4 to 5 millirads) to the gonads.[3]

Table 6. Absorbed Radiation Doses (Pediatric)

Tissue	Absorbed Radiation Doses mGy/ 37MBq	(rads/ 1mCi)	mGy/ 185MBq	(rads/ 5mCi)
Thyroid (without perchlorate)	46.0	(4.6)	230.0	(23.0)
Thyroid (with perchlorate)	9.7	(0.97)	48.5	(4.85)
Large Bowel (with perchlorate)	19.0	(1.9)	95.5	(9.55)
Testes	1.0	(0.10)	5.1	(0.51)
Ovaries	2.2	(0.22)	11.0	(1.10)
Whole-Body	1.5	(0.15)	7.6	(0.76)

[2]Modified from: Summary of Current Radiation Dose Estimates to Normal Humans from 99m-Tc as Sodium Pertechnetate. MIRD Dose Estimates Report No. 8. J. Nucl. Med. **17(1)**: 74-77, 1976.
[3]Conway, JJ, *et al*. Direct and indirect radionuclide cystography. J. Urol. **113**: 689-693 May 1975.

Table 7. Absorbed Radiation Dose from Dacryoscintigraphy Using Sodium Pertechnetate Tc 99m

Target Organ	Absorbed Dose mGy/ 3.7MBq	(mrad/ 100μCi)
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	402.0
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 drainage system. MIRD Dose Estimate Report No. 8, J. Nucl Med. 17: 74-77, 1976.

HOW SUPPLIED: Du Pont Radiopharmaceutical's TECHNELITE™, Technetium Tc 99m Generator is available in the following quantities of radioactivity: 8.3, 16.6, 25.0, 33.3, 50.0, 66.6, 83.3, and 100.0GBq (225, 450, 675, 900, 1350, 1800, 2250, and 2700 millicuries) of Mo99 on the calibration date (as specified on the product lot identification label affixed to the generator). Each generator is supplied with the following standard components:

1 Collect Needle Seal Vial (placed in generator dust cover)
6 Eluant Charge Vials
6 Eluate Collection Vials
1 Package Insert
10 Radiation Labels (Collection Vial)
10 Radiation Labels (Eluting Shield)
1 Molybdenum Mo99 Activity Record

First order generators are shipped with the following accessory components:

2 Eluting Shields
Extra quantities of these components may be obtained at the customer's request.

STORAGE: Controlled room temperature, 15°C - 30°C (59°F-86°F).

EXPIRATION: The expiration time of the Sodium Pertechnetate Tc 99m Injection is not later than 12 hours after elution. (If the eluate is to be used to reconstitute a kit for the preparation of a Technetium Tc 99m radiopharmaceutical, the kit should not be used after 12 hours from time of Generator elution or after six hours from the time of reconstitution of the kit.)

The expiration date of the TECHNELITE™, Technetium Tc 99m Generator is a maximum of thirteen days after calibration.

ELUTION INSTRUCTIONS – TOTAL ELUTION METHOD

1. Waterproof gloves should be worn during elution.
2. Remove dust (clear plastic) cover of generator which contains the sterile collect needle seal vial with bacteriostat.
3. Perform all subsequent operations aseptically.
4. Remove silicone needle seal from eluant charge well. Discard as radioactive waste.
5. Remove flip-off seal and swab septum of eluant charge vial with a bactericide (such as 70% isopropyl alcohol), allow to dry, and insert the vial into charge well. Vial should be firmly inserted to assure puncture of septum.
6. Open elution shield base and insert an eluate collection vial from which the flip-off seal has been removed. Screw base back on securely. Swab the exposed vial septum with a bactericide.
7. Remove vented needle cover from collect well. Discard as radioactive waste.
8. Insert shielded eluate collection vial in collect well. Elution should commence within 30 seconds and can be visually checked by the appearance of bubbles in the eluant charge vial.**
   **NOTE: If bubbles do not appear in the eluant charge vial within 30 seconds, either one of the vials has not been properly placed on its needle or the eluate vial has no vacuum. Remove the eluate collection vial to prevent vacuum loss; then remove and reinsert the charge vial. Reinsert the eluate collection vial and if elution does not commence, use a second shielded collection vial.
   Caution: Tampering with the internal components could compromise sterility and present a radiation hazard. This generator should not be dismantled.
9. To assure proper yield and functioning, elution must proceed to completion as evidenced by emptying of the charge vial. Allow generator to elute for at least 3 minutes after the charge has been drained, or for a total of 6 minutes.
10. After elution has been completed, remove shield containing the collection vial. Remove the collect needle seal vial from the generator top cover, and using a bactericide, swab the septum of the collect needle seal vial and insert over the collect needle. The eluant vial is sterile and should stay in place until the next elution, functioning as a seal for the needles within the charge well.
11. Fill out and attach the appropriate supplied pressure sensitive radioactivity labels to the elution shield containing the filled eluate collection vial. Do not use an eluate of the Technetium Tc 99m Generator later than 1 working day after the time of elution (12 hours).
12. Use a shielded syringe when introducing the Sodium Pertechnetate Tc 99m solution into mixing vials.
13. Maintain adequate shielding during the life of the radioactive preparation by using a lead vial shield and cover, and use a shielded syringe for withdrawing and injecting the preparation.

ASSAY INSTRUCTIONS FOR THE TECHNELITE™, TECHNETIUM Tc 99m GENERATOR ELUATE

The TECHNELITE™, Technetium Tc 99m Generator Eluate may be assayed using an ionization chamber dose calibrator. The manufacturer's instructions for operation of the dose calibrator should be followed for measurement of Technetium Tc 99m and Molybdenum Mo99 activity in the generator eluate. The Molybdenum

99/Technetium 99m ratio should be determined at the time of elution prior to administration, and from that ratio, the expiration time (up to 12 hours) of the eluate mathematically determined. Each eluate should meet or exceed the purity requirements of the current United States Pharmacopeia; that is, not more than 0.0056MBq (0.15 microcurie) of Molybdenum 99 per 37MBq (1 millicurie) of Technetium 99m per administered dose at the time of administration.

RADIOMETRIC MOLYBDENUM TEST PROCEDURE

This method is based on the fact that most Technetium Tc 99m radiation can be readily shielded and only the more energetic gamma rays from Molybdenum Mo99 (739KeV and 778KeV) are counted in the 550-850KeV energy range. A simulated Molybdenum Mo99 source utilizing Cesium Cs 137 dissolved in hard plastic is supplied upon request in the geometry of the Technetium Tc 99m Eluate Collection Vial. The entire eluate may be assayed for Molybdenum Mo99 activity as follows:

1. Du Pont Radiopharmaceutical's Cesium Cs 137 reference source which has the same geometry as the generator eluate must be used to standardize the well counter.
2. Determine the background after setting the window to the 550-850KeV energy range.
3. Count the Technetium Tc 99m eluate in its lead shield (thereby shielding out Technetium Tc 99m) by placing over the well or probe.
4. Count the Cs 137 reference source in the same shield geometry for the same time period.
5. Compute Molybdenum Mo99 activity in the eluate as follows:

$$\frac{\mu Ci\ Molybdenum\ Mo99\ (total)}{} = \frac{\mu Ci\ simulated\ Mo99 \times net\ cpm\ Eluate}{net\ cpm\ simulated\ Mo99\ reference\ source}$$

Divide this number by the mCi of Technetium Tc 99m. This result (μCi Mo99/mCi Tc 99m) can be converted to MBq Mo99/MBq Tc 99m by multiplying by 10^{-3}. The U.S. Pharmacopeia and the U.S. Nuclear Regulatory Commission or equivalent Agreement State regulations specify a limit of 0.00015MBq Molybdenum Mo99 per MBq of Technetium Tc 99m (0.15μCi Mo99/mCi Tc 99m) at the time of administration to each patient.

COLORIMETRIC ALUMINUM ION TEST PROCEDURE

Du Pont Radiopharmaceutical's offers an Aluminum Ion Indicator Kit as an accessory to permit monitoring the aluminum ion in each eluate. It is based on a colorimetric reaction performed on a paper strip impregnated with indicator. A bottle of aluminum ion standard is included. Complete information is available on request.

DISPOSAL: All components shipped with the TECHNELITE™, Technetium Tc 99m Generator should be monitored for contamination prior to disposing into routine trash systems. The Technetium Tc 99m should not be disposed of into routine trash systems. The generator should be disposed through a USNRC or Agreement State licensed disposal agency or by a method approved by the appropriate regulatory authority. Spent generators should be returned; **complete return instructions are provided regularly with generator shipments and are also available on request.**

The U.S. Nuclear Regulatory Commission has approved this generator for distribution to persons licensed to use byproduct material pursuant to Title 10 CFR Part 35 §35.57 and §35.200, to persons who hold an equivalent license issued by an Agreement State, and, outside the United States, to persons authorized by the appropriate authority.

Du Pont Radiopharmaceutical Division
The Du Pont Merck Pharmaceutical Co.
331 Treble Cove Road
Billerica, MA, USA 01862
For Ordering Call Toll-Free: 800-225-1572 All other business: 800-362-2668
(In Massachusetts and International, call 508-667-9531)

U.S. Patent 5,109,160

Du Pont Radiopharmaceutical Division
The Du Pont Merck Pharmaceutical Co.

DU PONT
PHARMA

513069

Printed in U. S. A.

NRC FORM 218
(4-78)
NRCM 0240

U.S. NUCLEAR REGULATORY COMMISSION

DATE 8/28/92

TELEPHONE OR VERBAL CONVERSATION RECORD

TIME ☐ A.M. ☐ P.M.

☐ INCOMING CALL ☐ OUTGOING CALL ☐ VISIT

PERSON CALLING	OFFICE/ADDRESS	PHONE NUMBER	EXTENSION
Sheri Arredondo			

PERSON CALLED	OFFICE/ADDRESS	PHONE NUMBER	EXTENSION
Francis Roy	DuPont Merck		

CONVERSATION

SUBJECT Control # 116746

SUMMARY

He will send in evidence of FDA approval when they get in.

REFERRED TO:

☐ ADVISE ME OF ACTION TAKEN.

ACTION REQUESTED

Wait till Oct ~~Roy~~ then call to see if they have approval yet.

INITIALS

DATE

ACTION TAKEN

INITIALS

DATE 116746

OFFICIAL RECORD COPY

The Du Pont Merck Pharmaceutical Company
Radiopharmaceutical Division
331 Treble Cove Road
N. Billerica, MA 01862
(508) 667 9531

June 17, 1992

030-11164

United States Nuclear Regulatory Commission
Region I
Attn: Francis M. Costello, Chief
Research, Development & Decommissioning Section
Division of Radiation Safety and Safeguards
475 Allendale Road
King of Prussia, PA 19406

DU PONT
MERCK

Log July 1
Remitter
Check No. 408146
Amount $370
Fee Category 3D
Type of Fee AMD
Date Check Rec'd 7/1
Date Completed 7/1
By JBrown

Reference: Materials License No. 20-00320-16MD

Gentlemen:

This is a request for an amendment to the above-referenced license to update the information on a new Technetium Tc-99m Generator originally submitted to your office with our renewal application dated December 28, 1988.

By the start of the 4th Quarter 1992, the Radiopharmaceutical Division would like to introduce a new Tc-99m generator to the nuclear medicine marketplace. This new generator works in the same manner as the existing model LP-5 and is essentially the same as described in the renewal application for the unit using shields "B" and "C" (Note: Shield A has been dropped and will not be introduced into the product line). The new unit was not launched as planned back in 1989 due to the need for extensive engineering development of the manufacturing process.

This new generator has been assigned a product name "Technelite™". The Technelite™ unit incorporates additional shielding in its design and will be manufactured as a terminally sterilized device.

Attached to this cover letter is a revised Technical Report with the specifications and engineering drawings of the new Technelite™ generator using either shield "B" or shield "C".

I have also enclosed for your review a copy of the following:

1. The revised Technelite™ package insert
2. Artwork/markings on surface of generator can
3. Generator can label
4. Label for 5.8 ml eluant vial
5. Label for 20 m eluant vial
6. Label for eluate collection vial

The radiation labels for the technetium eluate vials and lead shield do not require any revision. These labels will remain as submitted to your office in the license renewal application dated December 28, 1988.

RECEIVED
'91 JUN 26 A10:41
U.S. NRC
FEE MGMT. BRANCH

116746

June 17, 1992

Francis M. Costello, Chief
U.S.N.R.C. Region I
475 Allendale Road
King of Prussia, PA 19406

A check is enclosed in the amount of $310.00 in payment of the amendment processing fee as specified for Fee Category 3D in the regulations of Title 10 CFR Part 170 Section 170.31.

We request the LP-5 unit continue on this license in addition to the new Technelite™ generator with shields B and C. Please contact me if you require any additional information.

Sincerely,

Francis E Roy Jr.

Francis E. Roy, Jr.
Health Physicist

Telephone: (508) 671-8242

Toll Free: 1-800-362-2668, ext. 8242

The Du Pont Merck Pharmaceutical Company
Radiopharmaceutical Division

Technical Report on Technelite™ Tc-99m Generator Shields
(Revised 6/16/92)

"B" and "C" Shields

PURPOSE

New designs of the Du Pont Merck Pharmaceutical Company's Tc-99m Generator have been developed from the LP-5 design (currently in use) that utilize one of two generator shields that have a common top. The primary reason for the new designs is to allow steam sterilization of the Mo-99 generator column while attached to the top shield.

The secondary reasons for the new designs are to eliminate the auxiliary lead sleeves used in shipping, and to optimize the shielding to reduce the package shipping weight while maintaining a low transport index (TI), box reading and generator can reading.

This is possible because the curie content of the generators at shipping time range from a low of 225 millicuries to a high of 5750 millicuries. This is the same range now shipped in the LP-5 generator shield. The larger activity generators can be better shielded with the large "C" shield, while less shielding is needed for the low millicurie generators.

All of the generators with the new shields are well below the maximum TI limit of 10.0. The TI's for the range of use are shown in Tables 1 and 2.

The box readings, in a 14 inch cube box, are ≤ 60% of the maximum box surface reading limit of 200 millirem/hour.

The ranges of use of Tables 1 and 2 for the Technelite™ generator shields B and C overlap so that lower TI's can be attained for certain international transport requirements or when requested by customers.

Specific generator data is shown in Table 3. The new generators with shields B and C are compared with the presently used LP-5 with and without the auxiliary sleeve. The millicurie content of the new generators is at or within 5% of the highest millicurie content of the range of use.

Figure 1 and 2, attached, show the generator assembly drawings of the Technelite™ generators with shields B and C. The outer can remains the same and the only differences between generators is the shield and insert to hold the shield in place.

DESIGN CHANGES

There are 4 major changes incorporated into the new Technelite ™ generator shield design.

a) Top plug of the generator
b) Length of the internal cavity of the shield
c) Thickness of lead, and package weight of the generators
d) Shipping sleeves used in package

These will be discussed below:

a) Top plug: The LP-5 shield has a simple top plug with grooves for the column needles in the shield body with a close fit to prevent beaming. The new generator top has a three piece shield assembly. The shield assembly encapsulates the generator column and needle assemblies which includes a supportive plastic platform. This assembly is designated as the generator core unit and is autoclaved during the manufacturing process. The generator top or core unit is the same for both shields B and C (Figure 2)

b) The length of internal cavity: The glass column containing the alumina has been shortened from 3" to 2", and the internal cavity of the shields has been shortened from 3.5 inches to 2.5 inches. This change decreases the height of the shields.

c) Thickness of the lead shields: Below is a comparison of the lead thickness of the LP-5 generator with the proposed Technelite™ generator shields B and C.

	Inches of lead			
Model	Side	Top	Bottom	Pkg. Weight
Current Use: LP-5 + Sleeve	2.18"	1.92"	2.03"	41 pounds
Current Use: LP-5	1.68"	1.92"	2.03"	31 pounds
Proposed: B	1.85"	2.63"	1.65"	29 pounds
Proposed: C	2.20"	2.63"	2.21"	39 pounds

d) The lead sleeve used in the LP-5 unit package for shipping has been eliminated. The new shields (B and C) include the extra lead as part of the Technelite™ generator shield, resulting in an increase in the generator diameter.

TABLE 1
T.I. CHART - GENERATOR SHIELD "B"
RANGE OF USE

GENERATOR SIZE @ CALIBRATION DATE MC		TIME OF SHIPPING							
		0 DAYS PRECALIB.		1 DAY PRECALIB.		2 DAYS PRECALIB.		3 DAYS PRECALIB.	
SIZE DESIGNATION	MCI	MCI	T.I.	MCI	T.I.	MCI	T.I.	MCI	T.I.
F1	225	225	0.3	289	0.4	373	0.5	479	0.6
F2	450	450	0.6	579	0.7	745	1.0	958	1.2
F3	675	675	0.9	868	1.1	1118	1.4	1438	1.8
F4	900	900	1.2	1158	1.5	1490	1.9	1917	2.4
F6	1350	1350	1.7	1737	2.2	2236	2.8	2675	3.4
F8	1800	1800	2.3	2316	2.9	2981	3.7	3834	4.8
F10	2250	2250	2.8	2863	3.6	3726	4.7	4739	5.9
F12	2700	2700	3.4	3474	4.3	4471	5.6	5750	7.2

TABLE 2
*T.I. CHART - GENERATOR SHIELD "C"
RANGE OF USE

GENERATOR SIZE @ CALIBRATION DATE MC		TIME OF SHIPPING							
		0 DAYS PRECALIB.		1 DAY PRECALIB.		2 DAYS PRECALIB.		3 DAYS PRECALIB.	
SIZE DESIGNATION	MCI	MCI	T.I.	MCI	T.I.	MCI	T.I.	MCI	T.I.
F1	225	225	0.2	289	0.2	373	0.2	479	0.3
F2	450	450	0.3	579	0.3	745	0.4	953	0.5
F3	675	675	0.4	868	0.5	1118	0.6	1438	0.8
F4	900	900	0.5	1158	0.6	1491	0.8	1919	1.0
F6	1350	1350	0.7	1737	0.9	2236	1.2	2675	1.4
F8	1800	1800	1.0	2316	1.2	2981	1.6	3834	2.0
F10	2250	2250	1.2	2863	1.5	3726	2.0	4739	2.5
F12	2700	2700	1.4	3471	1.8	4471	2.4	5750	3.0

*TI is mr/hr at 1 meter from surface of package

TABLE 3

T.I. @ 1 METER FROM SURFACE OF BOX

SHIELD	mCi	SIDE 1	SIDE 2	TOP	BOTTOM	SIDE 3	SIDE 4
LP-5 & Sleeve	2712	3.478 +/- .110	3.339 +/- .40	3.493 +/- .57	1.939 +/- .15	3.549 +/- .20	3.410 +/- .336
LP-5	1386	3.864 +/- .051	3.458 +/- .05	1.461 +/- .111	.778 +/- .027	3.694 +/- .122	3.758 +/- .314
"B"	3765	3.86 +/- .04	3.86 +/- .04	1.42 +/- .04	2.69 +/- .05	3.86 +/- .04	3.86 +/- .04
"C"	6020	2.86 +/- .14	2.86 +/- .14	1.96 +/- .03	1.18 +/- .02	2.86 +/- .14	2.86 +/- .14

BOX READINGS, MR/HR AT CONTACT (14 INCH CUBE)

SHIELD	mCi	SIDE 1	SIDE 2	TOP	BOTTOM	SIDE 3	SIDE 4
LP-5 & Sleeve	2712	88.4 +/- 3.5	87.7 +/- 3.9	80.5 +/- 7.1	81.4 +/- 6.9	87.2 +/- 3	86.6 +/- 3
LP-5	1386	95.2 +/- 4.8	95.3 +/- 4.6	33.5 +/- 5.9	33.5 +/- 4.0	96.1 +/- 3.8	94.6 +/- 2.6
"B"	3765	105 +/- 5	100 +/- 5	86 +/- 5	90 +/- 5	105 +/- 5	100 +/- 5
"C"	6020	85 +/- 5	85 +/- 5	123 +/- 5	50 +/- 5	80 +/- 5	85 +/- 5

GENERATOR CAN READING

SHIELD	MILLICURIES	SIDE	TOP	BOTTOM
LP-5 (4" dia. can)	2712	1.35 +/- .6 R/hr	.115 +/- .015 R/hr	.10 +/- .02 R/hr
"B" (5" dia. can)	3765	.42 +/- .02	.088 +/- .002	.112 +/- .002
"C" (5" dia. can)	6020	.36 +/- .02	.168 +/- .002	.101 +/- .002

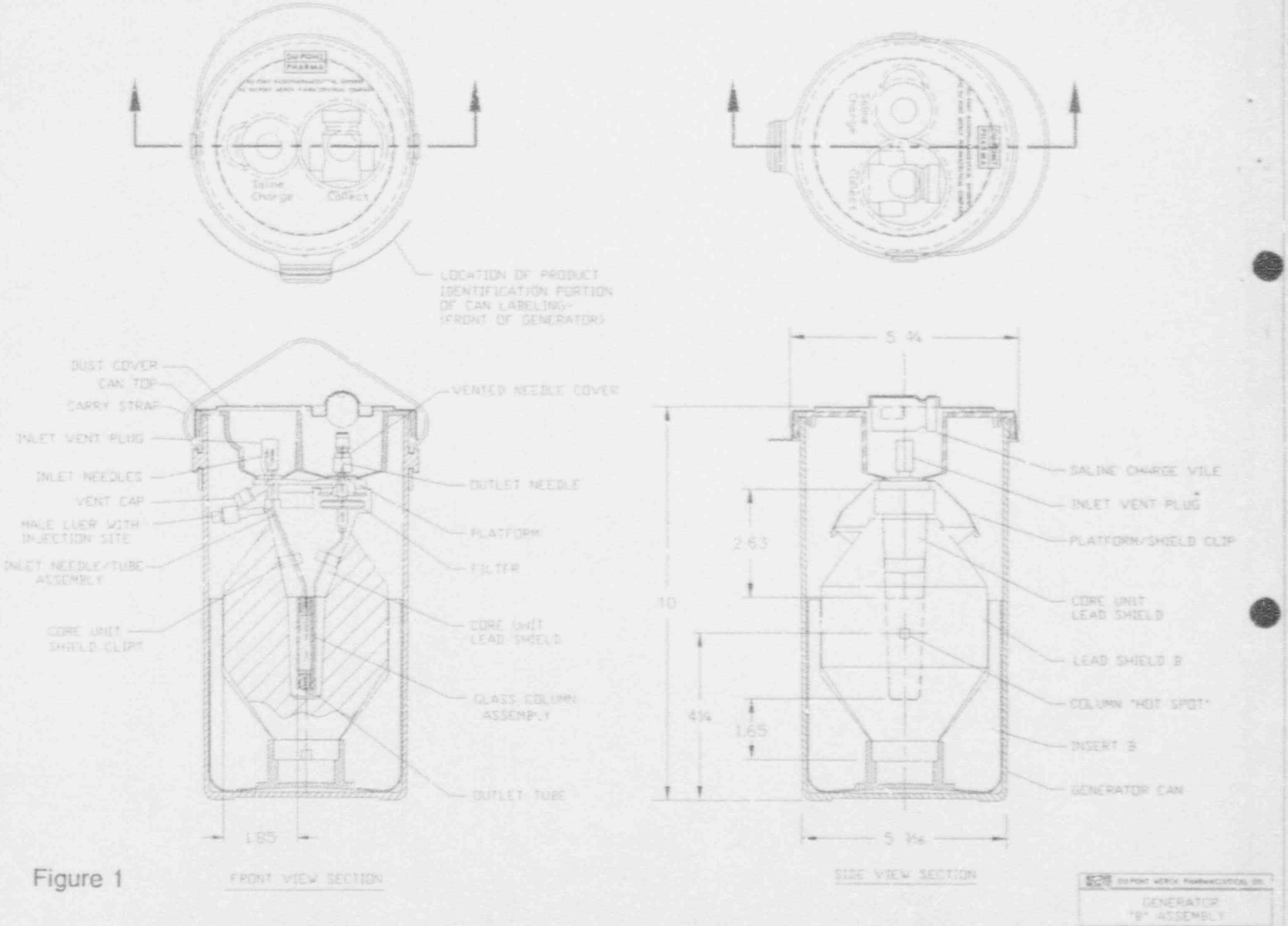

DUPONT PHARMA
Saline Charge
Collect
LOCATION OF PRODUCT IDENTIFICATION PORTION OF CAN LABELING (FRONT OF GENERATOR)
DUST COVER
CAN TOP
CARRY STRAP
INLET VENT PLUG
INLET NEEDLES
VENT CAP
MALE LUER WITH INJECTION SITE
INLET NEEDLE/TUBE ASSEMBLY
CORE UNIT SHIELD CLIPS
VENTED NEEDLE COVER
OUTLET NEEDLE
PLATFORM
FILTER
CORE UNIT LEAD SHIELD
GLASS COLUMN ASSEMBLY
OUTLET TUBE
1.85
FRONT VIEW SECTION
5 3/4
10
2.63
4 1/4
1.65
5 1/16
SALINE CHARGE VIAL
INLET VENT PLUG
PLATFORM/SHIELD CLIP
CORE UNIT LEAD SHIELD
LEAD SHIELD B
COLUMN "HOT SPOT"
INSERT B
GENERATOR CAN
SIDE VIEW SECTION
GENERATOR "B" ASSEMBLY

Figure 1

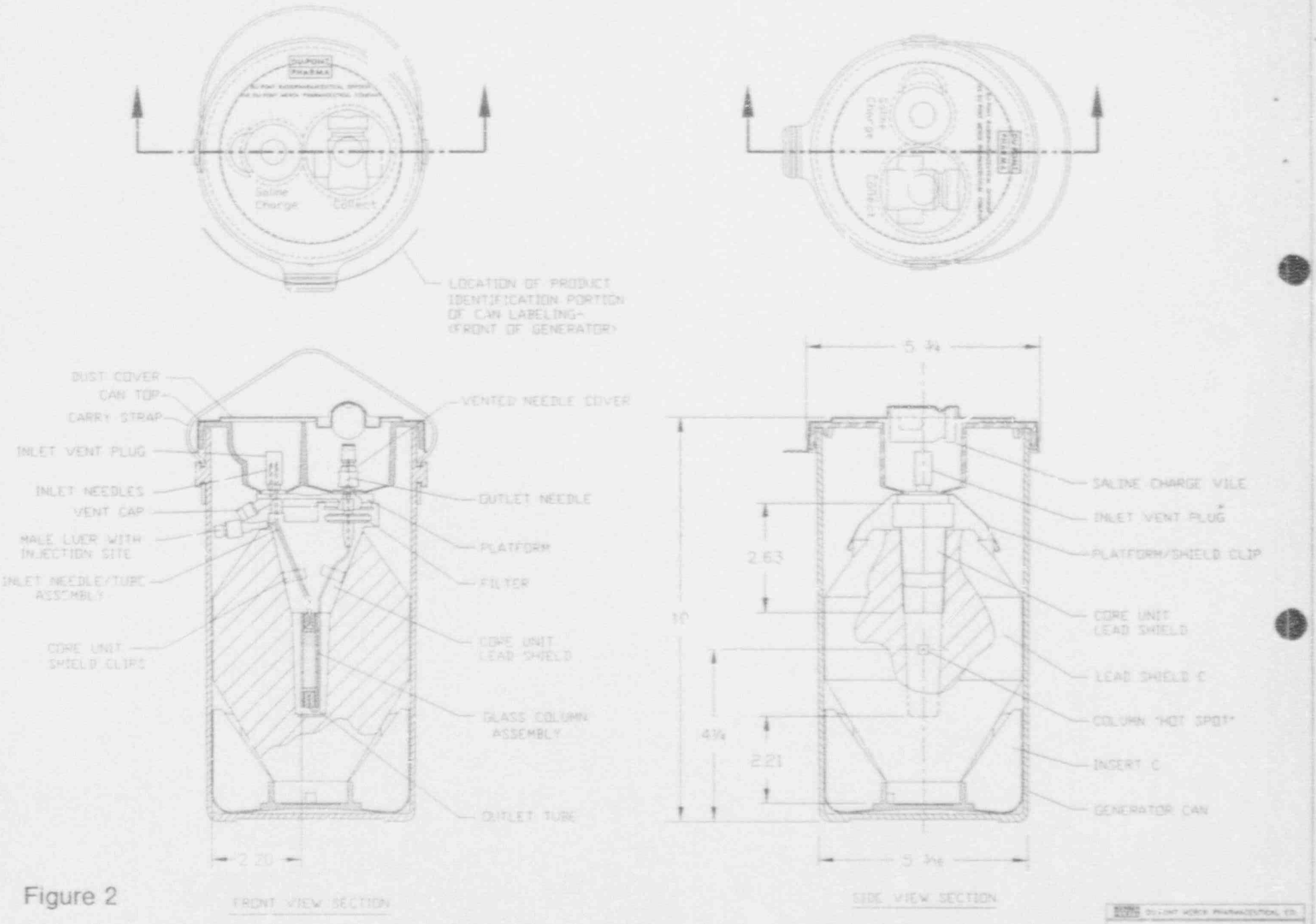
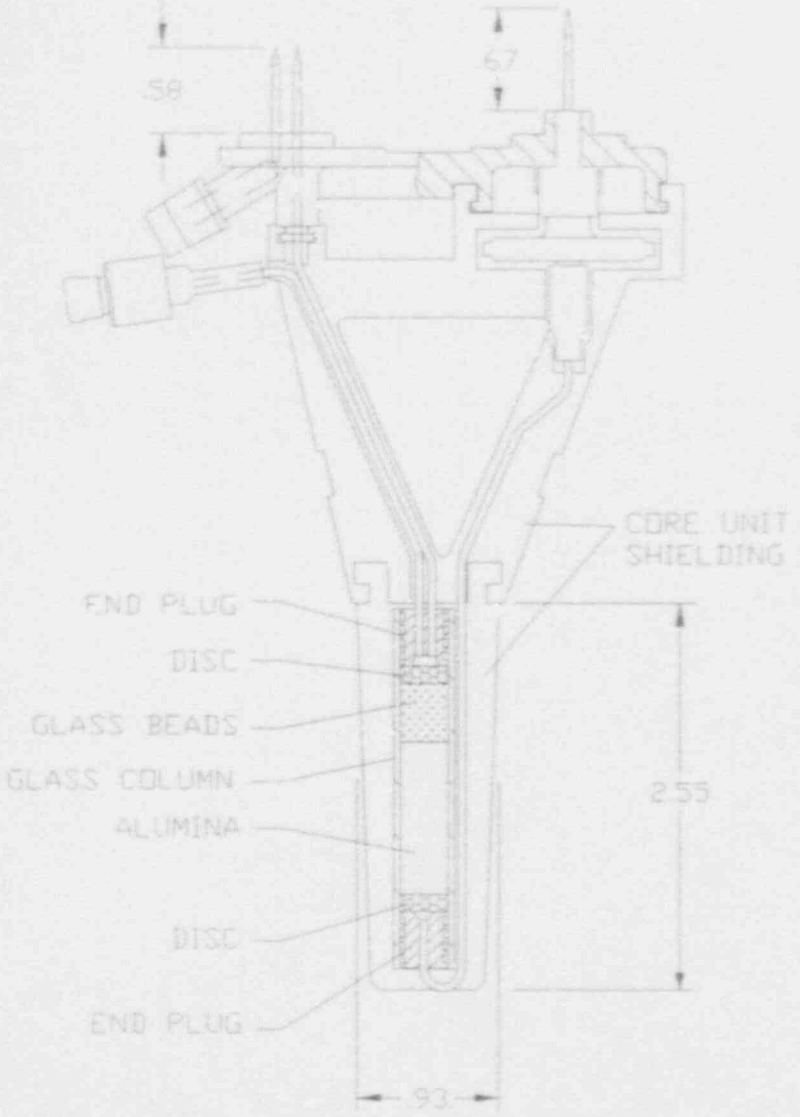
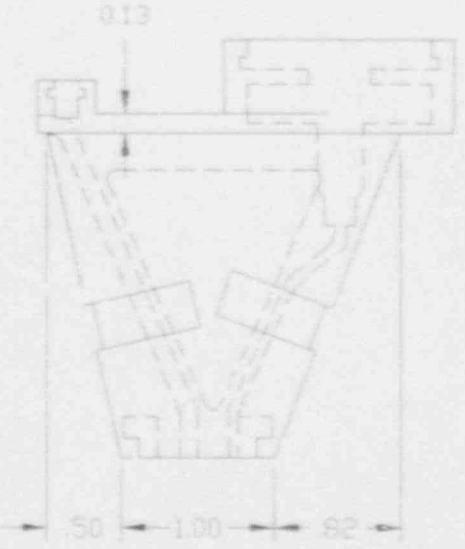

Saline Charge
Collect
LOCATION OF PRODUCT IDENTIFICATION PORTION OF CAN LABELING- (FRONT OF GENERATOR)
DUST COVER
CAN TOP
CARRY STRAP
INLET VENT PLUG
INLET NEEDLES
VENT CAP
MALE LUER WITH INJECTION SITE
INLET NEEDLE/TUBE ASSEMBLY
CORE UNIT SHIELD CLIPS
VENTED NEEDLE COVER
OUTLET NEEDLE
PLATFORM
FILTER
CORE UNIT LEAD SHIELD
GLASS COLUMN ASSEMBLY
OUTLET TUBE
2.20
FRONT VIEW SECTION
5 3/4
10
2.63
4 1/4
2.21
5 3/16
SALINE CHARGE VILE
INLET VENT PLUG
PLATFORM/SHIELD CLIP
CORE UNIT LEAD SHIELD
LEAD SHIELD C
COLUMN "HOT SPOT"
INSERT C
GENERATOR CAN
SIDE VIEW SECTION
GENERATOR "C" ASSEMBLY

Figure 2





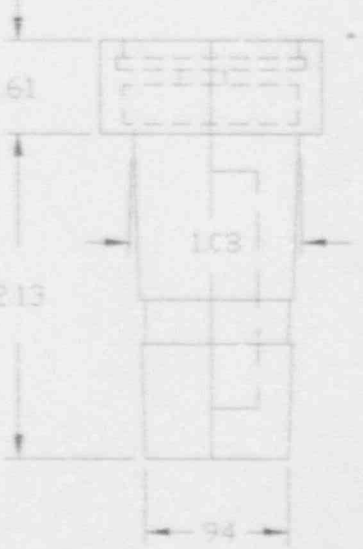


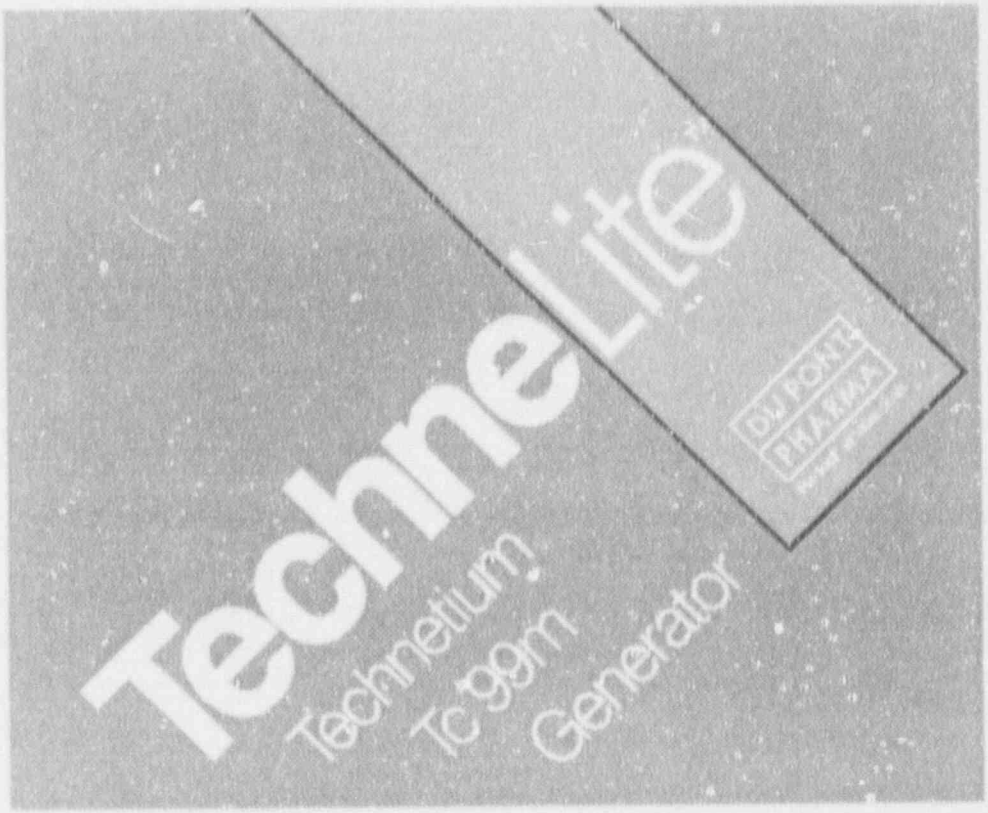
Figure 3

DUPONT MERCK PHARMACEUTICAL CO.

GENERATOR
CORE UNIT ASSEMBLY

January 1992

Du Pont Radiopharmaceutical Division
The Du Pont Merck Pharmaceutical Co.



FOR DIAGNOSTIC USE

DESCRIPTION: Sodium Pertechnetate Tc 99m Injection, as eluted according to the elution instructions with Du Pont Radiopharmaceutical's TECHNELITE™, Technetium Tc 99m Generator, is in Sodium Chloride 0.9% as a sterile, non-pyrogenic, diagnostic radiopharmaceutical suitable for intravenous injection, oral administration, and direct instillation. The pH is 4.5-7.5. The eluate should be clear, colorless, and free from visible foreign material. Each eluate of the TECHNELITE™, Technetium Tc 99m Generator should not contain more than 0.0056MBq (0.15 microcuries) of Molybdenum Mo99 per 37MBq (1 millicurie) of Technetium Tc 99m per administered dose at the time of administration, and not more than 10 micrograms of aluminum per milliliter of the Technetium Tc 99m 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 later than one (1) working day after the elution (12 hours).

Du Pont Radiopharmaceutical's TECHNELITE™, Technetium Tc 99m Generator consists of a column containing fission produced Molybdenum Mo99 adsorbed on alumina. The terminally sterilized and sealed column is enclosed in a lead shield; the shield and other components are sealed in a cylindrical plastic container with an attached handle. Built into the top surface are two recessed wells marked CHARGE and COLLECT. Needles protruding from these two wells accommodate supplied sterile eluant charge vials and sterile eluate collection vials. The eluting solvent consists of Sodium Chloride 0.9%, prepacked into septum-sealed vials.

The eluate collection vial is evacuated, sterile and non-pyrogenic. A sterile 0.22 micrometer bacteriological filter is incorporated between the column outlet and the collection vials. During and subsequent to elution, the eluate collection vial should be kept in a radiation shield. The Generator is shipped with a silicone needle seal over the charge needle and a vented needle cover over the collect needle. A sterile vial containing bacteriostat is supplied for the customer to aseptically reseal the collect needle after each elution.

PHYSICAL CHARACTERISTICS

Technetium Tc 99m decays by isomeric transition with a physical half-life of 6.02 hours.[1] Photons that are useful for imaging studies are listed in Table 1.

Table 1. Principal Radiation Emission Data – Technetium Tc 99m

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

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

EXTERNAL RADIATION

The specific gamma ray constant for Technetium Tc 99m is 5.4 microcoulombs/Kg-MBq-hr (0.78 R/mCi-hr) at 1cm. The first half-value thickness is 0.017cm of lead (Pb). To facilitate control of radiation exposure from millicurie amounts of Technetium Tc 99m, for example: the use of a 0.25cm thick standard radiation elution lead shield will attenuate the radiation emitted by a factor of about

1000. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of lead is shown in Table 2.

NOTE: Because the generator is well contained and essentially dry, there is little likelihood of contamination due to damage in transit. The most probable source of leakage resulting from damage in transit is the nonradioactive eluant charge vial.

Table 2. Radiation Attenuation of Technetium Tc 99m by Lead Shielding

Shield Thickness lead (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 Mo99 decays to Technetium Tc 99m with a Molybdenum Mo99 half-life of 66 hours. The physical decay characteristics of Molybdenum Mo99 are such that only 86.8% of the decaying Molybdenum Mo99 atoms form Technetium Tc 99m. This means that only 78% of the activity remains after 24 hours; 60% remains after 48 hours, etc. All units have a minimum of 38mm, 1.5 inches (~ 6 half-value layers) of lead surrounding the activity. Since the Molybdenum Mo99 is constantly decaying to fresh Technetium Tc 99m, it is possible to elute the generator at any time. (See Table 3.)

Table 3. Molybdenum Mo99 Decay Chart Half-Life 66.0 Hours

Days	Percent Remaining	Days	Percent Remaining
0	100	8	13
1	78	9	10
2	60	10	8
3	47	11	6
4	36	12	5
5	28	13	4
6	22	14	3
7	17		

Generator elutions may be made at any time, but the amount of Technetium Tc 99m available will depend on the interval from the last elution. Approximately 47% of maximum Technetium Tc 99m is reached after 6 hours and 95% after 24 hours.

The elution vial shield has a wall thickness of 7.9mm, 0.31 inches, and reduces transmitted Technetium Tc 99m radiation essentially to zero. To correct for physical decay of Tc 99m, the fractions that remain at selected intervals of time are shown in Table 4.

Table 4. Physical Decay Chart: Technetium Tc 99m Half-Life 6.02 Hours

Hours	Percent Remaining	Hours	Percent Remaining
0*	100.0	7	44.7
1	89.1	8	39.8
2	79.4	9	35.5
3	70.8	10	31.6
4	63.1	11	28.2
5	56.2	12	25.1
6	50.1		

*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 choroid plexus, thyroid gland, salivary glands, and stomach. However, in contrast to the iodide ion, the pertechnetate ion is released unchanged from the thyroid gland.

After intravascular administration it remains in the circulatory system for sufficient time to permit blood pool, organ perfusion, and major vessel studies. It gradually equilibrates with the extracellular space. A fraction is promptly excreted via the kidneys.

Following the administration of Sodium Pertechnetate Tc 99m Injection 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 a fractional turnover rate of 0.015/min in normal individuals, 0.021/min in patients without any sac and 0.027/min in patients with inflamed 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 Injection 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 the detection of vesico-ureteral reflux.
- Nasolacrimal Drainage System Imaging

Sodium Pertechnetate Tc 99m Injection is used IN CHILDREN as an agent for:

- Brain Imaging (including cerebral radionuclide angiography)
- Thyroid Imaging
- Blood Pool Imaging
- 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 Injection 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.

PRECAUTIONS:

General

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 ensure minimum radiation exposure to occupational workers.

Since the eluate does not contain an antimicrobial agent, it should not be used after 12 hours from the time of TECHNELITE™, Technetium Tc 99m Generator elution.

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.

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

No animal studies have been performed to evaluate carcinogenic potential or whether Sodium Pertechnetate Tc 99m affects 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 reproduction capacity. Sodium Pertechnetate Tc 99m Injection should be given to a pregnant woman only if clearly needed.

Ideally examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers

Sodium Pertechnetate Tc 99m is excreted in human milk during lactation; therefore formula feedings should be substituted for breast feeding.

This radiopharmaceutical preparation should not be administered to pregnant or lactating women unless expected benefits to be gained outweigh the potential risks.

Pediatric Use

See INDICATIONS and DOSAGE AND ADMINISTRATION sections. Also see the description of additional risks under WARNINGS.

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

DOSAGE AND ADMINISTRATION: Sodium Pertechnetate Tc 99m Injection is usually administered by intravascular injection but can be given orally. For imaging the urinary bladder and ureters (direct isotopic cystography), the Sodium Pertechnetate Tc 99m Injection is administered by direct instillation aseptically into the bladder via a urethral catheter, following which the catheter is flushed with approximately 200ml 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. When imaging the nasolacrimal drainage system, instill the Sodium Pertechnetate Tc 99m Injection by the use of a device such as a micropipette or similar method which will ensure the accuracy of the dose.

The suggested dose range employed for various diagnostic indications in the average ADULT PATIENT (70kg) is:

Vesico-ureteral Imaging	18.5 to 37MBq (0.5 to 1mCi)
Brain Imaging	370 to 740MBq (10 to 20mCi)
Thyroid Gland Imaging	37 to 370MBq (1 to 10mCi)
Salivary Gland Imaging	37 to 185MBq (1 to 5mCi)
Placenta Localization	37 to 111 MBq (1 to 3mCi)
Blood Pool Imaging	370 to 1110MBq (10 to 30mCi)
Nasolacrimal Drainage System	Max. 3.7MBq (100μCi)

The recommended dosage range in PEDIATRIC PATIENTS is:

Vesico-ureteral Imaging	18.5 to 37MBq (0.5 to 1mCi)
Brain Imaging	5.18 to 10.36MBq (140 to 280μCi)/kg body weight
Thyroid Gland Imaging	2.22 to 2.96MBq (60 to 80μCi)/kg body weight
Blood Pool Imaging	5.18 to 10.36MBq (140 to 280μCi)/kg body weight

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

NOTE: Up to one (1) gram of pharmaceutical grade potassium perchlorate in a suitable base or capsule may be given prior to administration of Sodium Pertechnetate Tc 99m Injection. When Sodium Pertechnetate Tc 99m Injection is used in children for brain or blood pool imaging, the administration of potassium perchlorate is especially important in order 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 of the dose.

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 crystal clear and contain no particulate matter. Do not use an eluate of the TECHNELITE™, Technetium Tc 99m Generator later than one (1) working day after elution (12 hours).

RADIATION DOSIMETRY

The estimated absorbed radiation doses[2] to an average ADULT patient (70kg) from an intravenous injection of a maximum dose of 1110MBq (30 millicuries) of Sodium Pertechnetate Tc 99m Injection distributed uniformly in the total body of subjects not pretreated with blocking agents such as pharmaceutical grade potassium perchlorate are shown in Table 5. For placenta localization studies, when a maximum of 111MBq (3 millicuries) is used, it is assumed to be uniformly equilibrated between maternal and fetal tissues.

Table 5. Absorbed Radiation Doses (Adults)

Tissue	mGy/1110MBq (rads/30 millicuries) Resting Population	Active Population	mGy/111MBq (rads/3mCi)
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)	—
Whole-Body	4.2 (0.42)	3.3 (0.33)	—
Placenta	—	—	0.5 (0.05)
Fetus	—	—	0.3 (0.05)

In pediatric patients, the maximum radiation doses of 185MBq (5 millicuries) of Sodium Pertechnetate Tc 99m Injection administered to a neonate (3.5kg) for brain or blood pool imaging with radionuclide angiography are shown in Table 6. In pediatric patients, an average 30 minute exposure to 37MBq (1 millicurie) of Sodium Pertechnetate Tc 99m Injection following instillation for direct cystography,

results in an estimated absorbed radiation dose of approximately 0.30mGy (30 millirads) to the bladder wall and 0.04 to 0.05mGy (4 to 5 millirads) to the gonads.[3]

Table 6. Absorbed Radiation Doses (Pediatric)

Tissue	Absorbed Radiation Doses mGy/ 37MBq	(rads/ 1mCi)	mGy/ 185MBq	(rads/ 5mCi)
Thyroid (without perchlorate)	46.0	(4.6)	230.0	(23.0)
Thyroid (with perchlorate)	9.7	(0.97)	48.5	(4.85)
Large Bowel (with perchlorate)	19.0	(1.9)	95.5	(9.55)
Testes	1.0	(0.10)	5.1	(0.51)
Ovaries	2.2	(0.22)	11.0	(1.10)
Whole-Body	1.5	(0.15)	7.6	(0.76)

[2]Modified from: Summary of Current Radiation Dose Estimates to Normal Humans from 99m-Tc as Sodium Pertechnetate. MIRD Dose Estimates Report No. 8. *J. Nucl. Med.* **17(1)**: 74-77, 1976.
[3]Conway, JJ, *et al.* Direct and indirect radionuclid- cystography. *J. Urol.* **113**: 689-692 May 1975.

Table 7. Absorbed Radiation Dose from Dacryoscintigraphy Using Sodium Pertechnetate Tc 99m

Target Organ	Absorbed Dose mGy/ 3.7MBq	(mrad/ 100µCi)
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	402.0
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 drainage system. MIRD Dose Estimate Report No. 8, *J. Nucl Med.* **17**: 74-77, 1976.

HOW SUPPLIED: Du Pont Radiopharmaceutical's TECHNELITE™, Technetium Tc 99m Generator is available in the following quantities of radioactivity: 8.3, 16.6, 25.0, 33.3, 50.0, 66.6, 83.3, and 100.0GBq (225, 450, 675, 900, 1350, 1800, 2250, and 2700 millicuries) of Mo99 on the calibration date (as specified on the product lot identification label affixed to the generator). Each generator is supplied with the following standard components:

1 Collect Needle Seal Vial (packed in generator dust cover)
6 Eluant Charge Vials
6 Eluate Collection Vials
1 Package Insert
10 Radiation Labels (Collection Vial)
10 Radiation Labels (Eluting Shield)
1 Molybdenum Mo99 Activity Record

First order generators are shipped with the following accessory components:

2 Eluting Shields
Extra quantities of these components may be obtained at the customer's request.

STORAGE: Generator and eluate are stored at room temperature (15 - 30°C). Avoid freezing.

EXPIRATION: The expiration time of the Sodium Pertechnetate Tc 99m Injection is not later than 12 hours after elution. (If the eluate is to be used to reconstitute a kit for the preparation of a Technetium Tc 99m radiopharmaceutical, the kit should not be used after 12 hours from time of Generator elution or after six hours from the time of reconstitution of the kit.)

The expiration date of the TECHNELITE™, Technetium Tc 99m Generator is a maximum of thirteen days after calibration.

ELUTION INSTRUCTIONS – TOTAL ELUTION METHOD

1. Waterproof gloves should be worn during elution.
2. Remove dust (clear plastic) cover of generator which contains the sterile collect needle seal vial with bacteriostat.
3. Perform all subsequent operations aseptically.
4. Remove silicone needle seal from eluant charge well. Discard as radioactive waste.
5. Remove flip-off seal and swab septum of eluant charge vial with a bactericide (such as 70% isopropyl alcohol), allow to dry, and insert the vial into charge well. Vial should be firmly inserted to assure puncture of septum.
6. Open elution shield base and insert an eluate collection vial from which the flip-off seal has been removed. Screw base back on securely. Swab the exposed vial septum with a bactericide.
7. Remove vented needle cover from collect well. Discard as radioactive waste.
8. Insert shielded eluate collection vial in collect well. Elution should commence within 30 seconds and can be visually checked by the appearance of bubbles in the eluant charge vial.**
   ***NOTE:* If bubbles do not appear in the eluant charge vial within 30 seconds, either one of the vials has not been properly placed on its needle or the eluate vial has no vacuum. Remove the eluate collection vial to prevent vacuum loss; then remove and reinsert the charge vial. Reinsert the eluate collection vial and if elution does not commence, use a second shielded collection vial. **Caution: Tampering with the internal components could compromise sterility and present a Radiation Hazard. This generator should not be dismantled.**
9. To assure proper yield and functioning, elution must proceed to completion as evidenced by emptying of the charge vial. Allow generator to elute for at least 3 minutes after the charge has been drained, or for a total of 6 minutes.
10. After elution has been completed, remove shield containing the collection vial. Remove the collect needle seal vial from the generator top cover, and using a bactericide, swab the septum of the collect needle seal vial and insert over the collect needle. The eluant vial is sterile and should stay in place until the next elution, functioning as a seal for the needle within the charge well.
11. Fill out and attach the appropriate supplied pressure sensitive radioactivity labels to the elution shield containing the filled eluate collection vial. Do not use an eluate of the Technetium Tc 99m Generator later than 1 working day after the time of elution (12 hours).
12. Use a shielded syringe when introducing the Sodium Pertechnetate Tc 99m Solution into mixing vials.
13. Maintain adequate shielding during the life of the radioactive preparation by using a lead vial shield and cover, and use a shielded syringe for withdrawing and injecting the preparation.

ASSAY INSTRUCTIONS FOR THE TECHNELITE™, TECHNETIUM Tc 99m GENERATOR ELUATE

The TECHNELITE™, Technetium Tc 99m Generator Eluate may be assayed using an ionization chamber dose calibrator. The manufacturer's instructions for operation of the dose calibrator should be followed for measurement of Technetium Tc 99m and Molybdenum Mo99 activity in the generator eluate. The Molybdenum

99/Technetium 99m ratio should be determined at the time of elution prior to administration, and from that ratio, the expiration time (up to 12 hours) of the eluate mathematically determined. Each eluate should meet or exceed the purity requirements of the current United States Pharmacopeia; that is, not more than 0.0056MBq (0.15 microcurie) of Molybdenum 99 per 37MBq (1 millicurie) of Technetium 99m per administered dose at the time of administration.

RADIOMETRIC MOLYBDENUM TEST PROCEDURE

This method is based on the fact that most Technetium Tc 99m radiation can be readily shielded and only the more energetic gamma rays from Molybdenum Mo99 (739KeV and 778KeV) are counted in the 550-850KeV energy range. A simulated Molybdenum Mo99 source utilizing Cesium Cs 137 dissolved in hard plastic is supplied upon request in the geometry of the Technetium Tc 99m Eluate Collection Vial. The entire eluate may be assayed for Molybdenum Mo99 activity as follows:

1. Du Pont Radiopharmaceutical's Cesium Cs 137 reference source which has the same geometry as the generator eluate must be used to standardize the well counter.
2. Determine the background after setting the window to the 550-850KeV energy range.
3. Count the Technetium Tc 99m eluate in its lead shield (thereby shielding out Technetium Tc 99m) by placing over the well or probe.
4. Count the Cs 137 reference source in the same shield geometry for the same time period.
5. Compute Molybdenum Mo99 activity in the eluate as follows:

$$\mu\text{Ci Molybdenum Mo99 (total)} = \frac{\mu\text{Ci simulated Mo99} \times \text{net cpm Eluate}}{\text{net cpm simulated Mo99 reference source}}$$

Divide this number by the mCi of Technetium Tc 99m. This result (μCi Mo99/mCi Tc 99m) can be converted to MBq Mo99/MBq Tc 99m by multiplying by 10^{-3}. The U.S. Pharmacopeia and the U.S. Nuclear Regulatory Commission or equivalent Agreement State regulations specify a limit of 0.00015MBq Molybdenum Mo99 per MBq of Technetium Tc 99m (0.15μCi Mo99/mCi Tc 99m) at the time of administration to each patient.

COLORIMETRIC ALUMINUM ION TEST PROCEDURE

Du Pont Radiopharmaceuticals offers an Aluminum Ion Indicator Kit as an accessory to permit monitoring the aluminum ion in each eluate. It is based on a colorimetric reaction performed on a paper strip impregnated with indicator. A bottle of aluminum ion standard is included. Complete information is available on request.

DISPOSAL: All components shipped with the TECHNELITE™, Technetium Tc 99m Generator should be monitored for contamination prior to disposing into routine trash systems. The Technetium Tc 99m should not be disposed of into routine trash systems. The generator should be disposed through a USNRC or Agreement State licensed disposal agency or by a method approved by the appropriate regulatory authority. Spent generators should be returned; **complete return instru[illegible] are provided regularly with generator shipments and are also availa[illegible] request.**

The U.S. Nuclear Regulatory Commission has approved this generator for distribution to persons licensed to use byproduct material pursuant to Title 10 CFR Part 35 §35.57 and §35.200, to persons who hold an equivalent license issued by an Agreement State, and, outside the United States, to persons authorized by the appropriate authority.

Du Pont Radiopharmaceutical Division
The Du Pont Merck Pharmaceutical Co.
331 Treble Cove Road
Billerica, MA, USA 01862
For Ordering Call Toll-Free: 800-225-1572. All other business: 800-362-2668
(In Massachusetts and International, call 508-667-9531)

Du Pont Radiopharmaceutical Division
The Du Pont Merck Pharmaceutical Co.

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Technelite.

Technetium
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Generator

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Technetium
Tc 99m
Generator

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Sterile, Non-Pyrogenic
Diagnostic Agent for Intravenous Injection

TechneLite™

**Molybdenum Mo 99-
Technetium Tc 99m Generator**

CAUTION: Federal (U.S.A.) law prohibits dispensing without prescription.
See Package Insert for dosing information.

CAUTION: This generator should not be dismantled.

Du Pont Radiopharmaceutical Division
The Du Pont Merck Pharmaceutical Co.
Billerica, Massachusetts, U.S.A. 01862

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513037

**CAUTION:
RADIOACTIVE MATERIAL**

Total Activity

Calib. Noon E.T.
Exp. Date
Lot No.

Total Activity

Calib. Noon E.T.
Exp. Date
Lot No.

Molybdenum Mo 99-Technetium Tc 99m Generator

Du Pont Radiopharmaceutical Division
The Du Pont Merck Pharmaceutical Co.
Billerica, Massachusetts, U.S.A. 01862

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PLI

Single Use Approx. 5.8ml

Eluant for Du Pont Radiopharmaceutical's

TechneLite™

Technetium Tc 99m Generator

Sterile Non-Pyrogenic

Each ml contains 9mg Sodium Chloride. To be used exclusively as Eluant for Du Pont Radiopharmaceutical's Tc 99m Generator in accordance with instructions supplied.

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

513004

See Package Insert

The contents of this vial are to be used for a single generator elution. The empty vial must be left on as a generator seal until the next elution.

Marketed by

Du Pont Radiopharmaceutical Division
The Du Pont Merck Pharmaceutical Co.
Billerica, MA, U.S.A. 01862

DU PONT
PHARMA

Lot No.:

Exp. Date:

Single Use 20ml

Eluant for Du Pont Radiopharmaceutical's

TechneLite™

Technetium Tc 99m Generator

Sterile Non-Pyrogenic

Each ml contains
9mg Sodium Chloride. To be used exclusively as Eluant for Du Pont Radiopharmaceutical's Tc 99m Generator in accordance with instructions supplied.

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

513005

See Package Insert

The contents of this vial are to be used for a single generator elution. The empty vial must be left on as a generator seal until the next elution.

Marketed by

Du Pont Radiopharmaceutical Division
The Du Pont Merck Pharmaceutical Co.
Billerica, MA, U.S.A. 01862

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Lot No.:

Exp. Date:

20
15
10
5

Approximate ml

Upon elution vial will contain
Technetium Tc 99m in isotonic
saline for diagnostic use

Sterile Non-Pyrogenic

TechneLite™

Technetium Tc 99m
ELUATE
COLLECTION VIAL
(evacuated)

For use with the
Du Pont Radiopharmaceutical's
Technetium Tc 99m Generator
Only as directed

513041

Du Pont Radiopharmaceutical Division
The Du Pont Merck Pharmaceutical Co.
Billerica, MA, U.S.A. 01862

DU PONT
PHARMA

Lot No.

Exp. Date

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, NRM
AND
REGIONAL LICENSING SECTION

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02512
STATUS CODE: 0
FEE CATEGORY: 3D
EXP. DATE: 19941231
FEE COMMENTS: ----------
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: DU PONT MERCK PHARMACEUTICAL CO.
RECEIVED DATE: 920618
DOCKET NO: 3011164
CONTROL NO.: 116746
LICENSE NO.: 20-00320-16MD
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: $910.00
CHECK NO.: 006110460

3. COMMENTS

SIGNED Rebecca J. Brown
DATE 6/25/92

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

1. FEE CATEGORY AND AMOUNT: 3D $310

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

3. OTHER ----------

This is a Change from info submitted w/ Ren. PKg.

SIGNED [illegible]
DATE 7/1/92

THE ATTACHED DOCUMENTS ARE TO BE PROCESSED AS ONE MATERIALS LICENSING PACKAGE UNDER.....

LICENSE NUMBER: 20-00320 16 MD

DOCKET NUMBER: 030 11164

CONTROL NUMBER: 116746

230028