mcd
1375

pharmaco nuclear inc.
100 NORTH EUCLID AVENUE • SUITE 900
ST. LOUIS, MISSOURI 63108
(314) 367-9300

July 10, 1981
RE. Control No. 07466

Mr. Joseph Del Medico
Material Licensing Branch
Division of Fuel Cycle and Material Safety
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Del Medico:

With response to your letter date June 23, 1981 the following information and statements are made:

1. The used generators we will provide clients will not be altered nor adulterated by us. Our use of them is in strict accordance with manufacturer's instructions.

2. In addition to the original manufacturer's labeling, attached to the generator will be a Pharmaco Nuclear label delineating the original assay along with the assay at the time of shipment by us.

3. All information, instructions and procedures originally provided to us by the manufacturer with the generator will be sent with the used generator.

Enclosed please find the manufacturer's "Operating Instructions Booklet" NRP-196 and auxillary labels they provide. Also enclosed are two samples of our prescription labels.

We will provide these items with each used generator delivered.

Sincerly,

William C. McHugh

William C. McHugh Ph.D.
Manager

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Form PI-12

pharmaco nuclear inc.

100 N. EUCLID - Suite 900
ST. LOUIS, MO 63108
PHONE: (314) 367-9300

CAUTION

RADIOACTIVE MATERIAL

SODIUM PERTECHNETATE Tc 99m

_____ millicuries
Total Activity

_____ millicuries/ml
Activity Concentration

_____
Time/Date Calibrated

Generator Lot Number _____

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

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ospital _____
R Doctor _____ Date _____
Radionuclide _____
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lume Dispensed _____
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spensed By _____ R Ph.
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Sodium Pertechnetate Tc 99m

_____ millicuries
Total Activity

_____ millicuries/ml
Activity Concentration

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Time/Date Calibrated

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Total Activity

_____ millicuries/ml
Activity Concentration

_____
Time/Date Calibrated

_____
Generator Lot No

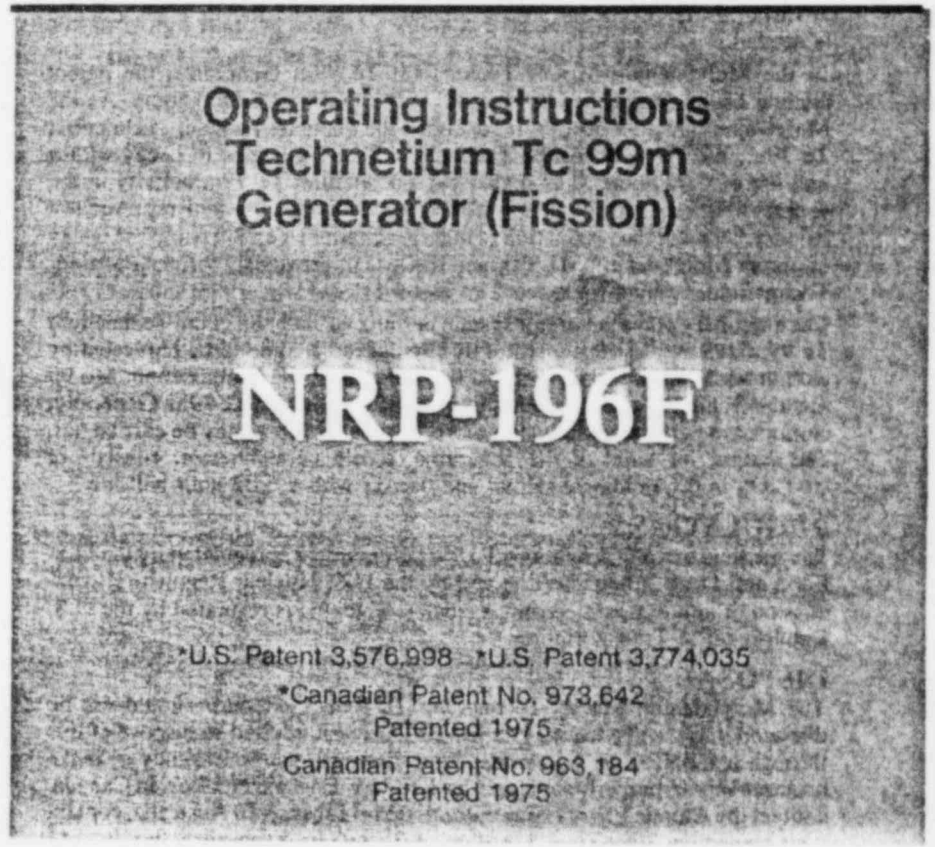
CAUTION RADIOACTIVE MATERIAL

February 1981

1575

New England Nuclear®

Technetium Tc 99m Generator (Fission)*



Marketed by

New England Nuclear
Medical Diagnostics Division
601 Treble Cove Rd., North Billerica, MA 01862

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(In Massachusetts and International 617-482-9595)

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Canada: NEN Canada, 2453 46th Avenue, Lachine, Que. H8T 3C9 Tel. 514-636-4971
Europe: NEN Chemicals GmbH, Postfach 401240 6072 Dreieich, W. Germany,
Tel. (06103) 85034 order entry (06103) 81013

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Printed in U.S.A.

Technetium Tc 99m Generator Operating Instructions

RATIONALE

A radioisotope generator is a device for separating a daughter nuclide from its parent. For nuclear medicine applications, this usually involves separating a shorter-lived daughter from a much longer-lived parent. The use of short-lived nuclides for diagnosis is quite desirable, as it generally decreases radiation burden to the patient while simultaneously increasing the diagnostic information available to the physician. The generator concept is a practical method of making short-lived radionuclides available to the medical community at distances far from the production facility and at the time the nuclide is needed.

In the Molybdenum Mo 99-Technetium Tc 99m Generator, the parent nuclide Molybdenum Mo 99 decays with a half-life of 66.0 hours. As the Molybdenum Mo 99 decays, it generates the daughter nuclide, Technetium Tc 99m. As it is formed, the Technetium Tc 99m begins to decay with a half-life of 6.02 hours. The maximum Technetium Tc 99m activity in the generator is reached 23 hours after a previous elution, and represents a balance between the production of new Technetium Tc 99m (from the decay of parent Molybdenum Mo 99), and the loss of previously formed daughter Technetium Tc 99m (as a result of its own decay).

The chemistry of the generator system permits virtually all of the Technetium Tc 99m existing in the generator at any particular time to be harvested by elution with sterile saline, while at the same time, the Molybdenum Mo 99 remains behind to continue generating more Technetium Tc 99m. Generally, elutions are performed daily, but more frequent elutions may be carried out. The output, or yield of the generator, sterile pertechnetate, consists of $^{99m}TcO_4^-$ in physiological saline, and decays with a 6.02 hour half-life.

REGULATIONS

The medical use of Technetium Tc 99m Generators is regulated by the U.S. Food and Drug Administration and by the U.S. Nuclear Regulatory Commission or appropriate licensing agencies. Shipping is regulated by the U.S. Department of Transportation.

DISPOSAL

The Molybdenum Mo 99-Technetium Tc 99m Generator should not be disposed into routine trash systems. You are best advised to dispose of this through a USNRC or Agreement State licensed disposal agency or make arrangements to properly ship them back to New England Nuclear. In Canada, contact the Atomic Energy Commission Board License. In Australia, contact your respective State Health Authority for proper disposal methods.

December 1980

New England Nuclear
601 Treble Cove Road
North Billerica, Massachusetts 01862

Technetium Tc 99m Generator (Fission)

FOR DIAGNOSTIC USE

DESCRIPTION: Sodium pertechnetate Tc 99m as eluted according to the operating instructions from the NEN Molybdenum Mo 99-Technetium Tc 99m Generator is in isotonic saline solution as a sterile non-pyrogenic diagnostic radiopharmaceutical suitable for intravenous administration. The pH is 4.5-7.0

PHYSICAL CHARACTERISTICS

Technetium Tc 99m decays by isomeric transition with a physical half-life of 6.02 hours. (SOURCE: Martin, M.J., Nuclear Data Project, Oak Ridge National Laboratory, March 1976.) Photons that are useful for imaging studies are listed in Table 1.

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

Radiation	Mean %/ Disintegration	Mean Energy (keV)
Gamma-2	88.96	140.5

EXTERNAL RADIATION

The specific gamma ray constant for Technetium Tc 99m is 0.8R/mCi-hr. at 1cm. The first half-value thickness is 0.2mm of lead (Pb). To facilitate control of radiation exposure from millicurie amounts of Technetium Tc 99m, the use of a 2.5mm 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.

Table 2. Radiation Attenuation By Lead Shielding

Shield Thickness lead (Pb) mm	Coefficient of Attenuation
0.2	0.5
0.8	10^{-1}
1.6	10^{-2}
2.5	10^{-3}
3.3	10^{-4}

To facilitate correction for physical decay of Technetium Tc 99m, the fractions of initial activity that remain at selected intervals after the time of calibration 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 choroid plexus, thyroid gland, salivary glands, and stomach. 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.

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; and blood pool imaging including radionuclide angiography.

Sodium pertechnetate Tc 99m is used IN CHILDREN as an agent for: brain imaging including cerebral radionuclide angiography; thyroid imaging; and blood pool imaging including radionuclide angiography.

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.

This radiopharmaceutical preparation should not be administered to patients who are pregnant or to nursing mothers unless the expected benefits to be gained outweigh the potential hazards.

CAUTION: It is recommended that elution vial shields be used when eluting generators, shielded syringes be used when preparing formulations, and appropriate vial shields be used for the formulations.

Store at room temperature (15°-30°C). Avoid Freezing.

PRECAUTIONS: Sodium pertechnetate Tc 99m, like any radioactive agent, must be handled with care. Appropriate safety measures should be used to minimize external radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to the patients in a manner consistent with proper patient management.

The USNRC and USP have established a limit of 0.15 microcurie of Molybdenum Mo 99 per millicurie of Technetium Tc 99m at the time of administration to each patient. Routine testing for molybdenum breakthrough should be performed by the user. Please refer to the Technetium Tc 99m Generator Operating Instructions for the Radiometric Molybdenum Test Procedure. These instructions are enclosed with each generator.

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.

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.

The expiration date of the Technetium Tc 99m Generator is thirteen days after calibration.

ADVERSE REACTIONS: None known.

DOSAGE AND ADMINISTRATION: Sodium pertechnetate Tc 99m is usually administered by intravascular injection, but can be given orally. The dosage employed varies with each diagnostic procedure.

The suggested intravenous dose range employed for various diagnostic indications are as follows:

IN AVERAGE ADULT(70kg) PATIENTS:

Brain imaging:	10 to 20mCi
Thyroid gland imaging:	1 to 10mCi
Salivary gland imaging:	1 to 5mCi
Placenta localization:	1 to 3mCi
Blood pool imaging:	10 to 30mCi

IN PEDIATRIC PATIENTS:

Brain imaging: 140-280μCi/kg body weight
A minimum dose of 3-5mCi should be employed if cerebral radionuclide angiography is performed as part of the brain imaging procedure.

Thyroid gland imaging: 60-80μCi/kg body weight.

Blood pool imaging: 140-280μCi/kg body weight.
A minimum dose of 3-5mCi should be employed if radionuclide angiography is performed as part of the blood pool imaging procedure.

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 children 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.

RADIATION DOSIMETRY

The estimated absorbed radiation doses (modified from: Summary of Current Radiation Dose Estimates to Normal Humans from ^{99m}Tc as Sodium Pertechnetate, MIRD Dose Estimate Report No. 8. J. Nucl. Med. *17* (1):74-7. (1976).) to an average patient (70kg) from an intravenous injection of a maximum dose of 20 millicuries of Technetium Tc 99m distributed uniformly in the total body of subjects not pretreated with blocking agents such as reagent grade potassium perchlorate are shown in Table 4. For placental localization studies, when a maximum dose of 3 millicuries is used, it is assumed to be uniformly equilibrated between maternal and fetal tissues.

Table 4. Radiation Dosimetry

	Absorbed Radiation Dose		
	(rads/20 millicuries)		(rads/3 millicuries)
Tissue	Resting Population	Active Population	
Bladder wall	1.06	1.70	—
Gastrointestinal tract:			
Stomach wall	5.00	1.02	—
Upper large intestine wall	1.36	2.40	—
Lower large intestine wall	1.22	2.20	—
Red marrow	0.38	0.34	—
Testes	0.18	0.18	—
Ovaries	0.44	0.60	—
Thyroid	2.60	2.60	—
Brain	0.28	0.24	—
Whole body	0.28	0.22	—
Placenta	—	—	0.05
Fetus	—	—	0.05

In pediatric patients, the maximum absorbed radiation doses will be obtained when a dose of 5mCi of sodium pertechnetate Tc 99m is administered to a neonate (3.5kg) for brain or blood pool imaging with radionuclide angiography.

The absorbed radiation doses under these circumstances are as follows:

Tissue	Absorbed Radiation Dose (rads/5mCi)	Tissue	Absorbed Radiation Dose (rads/5mCi)
Thyroid (without perchlorate)	23.0	Testes	0.51
Thyroid (with perchlorate)	4.85	Ovaries	1.10
Large Bowel (with perchlorate)	9.55	Whole-body	0.76

HOW SUPPLIED: The NEN Molybdenum Mo 99-Technetium Tc 99m Generator is available in the following quantities of radioactivity: 225, 450, 675, 900, 1350, 1800, 2250 and 2700 millicuries of Mo 99 on the calibration date (as specified on the identification label affixed to the generator). Each generator is supplied with the following standard components:

10 Saline Charge Vials
10 Collection Vials
1 Package Insert
1 Operating Instructions
10 Radiation Labels (Collection Vial)
10 Radiation Labels (Lead Shield)
1 Molybdenum Mo 99 Activity Record

First order generators are shipped with the following accessory components:

2 Eluting Shields
1 Cesium Cs 137 Reference Source Kit

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

DISPOSAL: The Molybdenum Mo 99-Technetium Tc 99m Generator should not be disposed of into routine trash systems. You are best advised to dispose of this through a USNRC or Agreement State licensed disposal agency or make arrangements to properly ship them back to New England Nuclear. In Canada contact the Atomic Energy Commission Board License. In Australia, contact your respective State Health Authority for proper disposal methods.

Spent generators may be returned to NEN collect *via ground transportation only.* Full return instructions are provided regularly with generator shipments and are available on request.

This generator is licensed for use by persons licensed by the U.S. Nuclear Regulatory Commission pursuant to Section 35.14 and 35.100 Group III of 10 CFR 35 or under equivalent licenses of Agreement States.

Catalog Number NRP-196F

Marketed by

New England Nuclear
Medical Diagnostics Division
601 Treble Cove Rd., North Billerica, MA 01862

CALL TOLL-FREE 800-225-1572 Telex: 94-0996
(In Massachusetts and International: 617-482-9595)

Los Angeles: NEN West, 17210 South Gramercy Place, Gardena, California 90247 Tel: 213-321-3311
Canada: NEN Canada, 2453 46th Avenue, Lachine, Que. H8T 3C9 Tel: 514-636-4971
Europe: NEN Chemicals GmbH, Postfach 401240, 6072 Dreieich, W. Germany, Tel: (06103) 85034 Order Entry: (06103) 81013

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Printed in U.S.A.

Spent generators may be returned to NEN collect *via ground transportation only.* Full return instructions are provided regularly with generator shipments and are available on request.

NRP-196F NEN TECHNETIUM Tc 99m GENERATOR CONTENTS:

1. Generator
2. Eluate Collection Vials, sterile, non-pyrogenic, evacuated, 27ml capacity
3. Charge Vials, approximately 5.8ml sterile eluant for NEN Technetium Tc 99m Generator; 20ml sterile eluant available upon request.
4. Eluate labels

Starter Kit (supplied with initial generator order)

a. Two eluting shields

b. One simulated Molybdenum Mo 99 reference source (utilizing Cesium Cs 137 to simulate Molybdenum Mo 99). The reference source is calibrated prior to shipment in terms of Molybdenum Mo 99 and is identical in geometry to the 27ml Eluate Collection Vial.

DESCRIPTION

The NEN Technetium Tc 99m Generator consists of an alumina column loaded with Molybdenum Mo 99, with a means for convenient aseptic elution of the daughter nuclide, Technetium Tc 99m. The column is enclosed in a lead shield; the shield and other components are sealed in a cylindrical plastic container with a built-in handle. Built into the top surface are two recessed wells marked CHARGE and COLLECT. Needles protruding from these two wells accommodate supplied sterile eluting solvent vials and sterile eluate collection vials. The eluting solvent consists of 0.9% sodium chloride solution, prepacked into septum-sealed vials.

The eluate collection vial is evacuated, sterile and nonpyrogenic. A sterile 0.2 micron 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 the supplied lead shield. The saline charge vial is vented during elution by means of a loop containing a sterile plug. NEN's generator is shipped with sterile seal vials over both the eluting and charge needles. The sterile seal vial over the elute needle contains a bacteriostat, and should be aseptically replaced immediately following each elution.

FEATURES

Convenience

NEN's Technetium Tc 99m generator is shipped ready for use. There is no assembly required. Remove generator from shipping carton by handle. Remove shrink-fit, peel-off top. Deposit generator into supplemental lead shield. Remove sterile seal vials which cover both the eluting and charge needles. Start elution. Elution is a simple two-step operation: aseptically insert a saline

charge vial; aseptically insert a shielded eluate collection vial. Elution proceeds to completion without further manipulation.

Quality Control

Each generator is eluted subsequent to manufacture, and the eluate is submitted to tests for sterility, non-pyrogenicity, Molybdenum Mo 99 breakthrough, alumina breakthrough and flow characteristics. Routine testing for aluminum ion, radionuclidic impurities other than Molybdenum Mo 99 and pH is also conducted.

Radiation Safety

All units have a minimum of 38mm, 1.5 inches (~6 half-value layers) of lead surrounding the activity. The elution vial shield has a wall thickness of 7.9mm, 0.31 inches, and reduces transmitted Technetium Tc 99m radiation essentially to zero.

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 non-radioactive saline charge vial.

ELUTION INSTRUCTIONS - TOTAL ELUTION METHOD

1. Remove top of generator container by pulling plastic tab.
2. Perform all subsequent operations aseptically.
3. Remove needle seal from saline charge well.
4. Remove flip-off seal and swab septum of saline charge vial with a bactericide (such as 70% alcohol) and insert the vial into charge well. Vial should be firmly inserted to assure puncture of septum.
5. 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.
6. Remove needle seal from collect well.
7. 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 saline charge vial.**

   **Note: If bubbles do not appear in the saline charge vial within 30 seconds, either one of the vials has not been properly placed on its needle or the eluate collection 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.

8. To assure proper yield and functioning, elution must proceed to completion as evidence by emptying of the charge vial. Allow generator to elute for as least 3 minutes after the charge vial has been drained, or for a total of 6 minutes.

   Note: If for any reason the eluate collection vial is removed prior to complete elution, insert a second shielded vial to complete the elution. Failure to observe this procedure may result in a low yield on the subsequent generator elution.

9. After elution has been completed, remove shield containing the collection vial. Using a bactericide, swab the septum of the needle seal vial containing bacteriostat and reinsert over the elute needle. The saline charge vial is sterile and should stay in place until the next elution, functioning as a seal for the needle within the charge well.

10. Invert the shielded collection vial several times to insure thorough mixing.
11. Attach one of the supplied pressure sensitive radioactivity labels to the elution shield containing the filled eluate collection vial.

ASSAY INSTRUCTIONS FOR THE TECHNETIUM Tc 99m GENERATOR ELUATE

The Technetium Tc 99m Generator Eluate may be assayed by 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 activity in the generator eluate.

ELUTION DATA AND DECAY CORRECTIONS

Molybdenum Mo 99 has a half-life of 66.0 hours. This means that only 78% of the activity remains after 24 hours; 60% (0.78 × 0.78) remains after 48 hours, etc. Since the Molybdenum Mo 99 is constantly decaying to fresh Technetium Tc 99m, it is possible to elute the generator at any time. (See section on Rationale and Chart A; also see Product Information for more detailed data.)

Chart A. Molybdenum Mo 99 DECAY CHART
Half-life 66.0 Hours

Days	Fraction Remaining	Days	Fraction Remaining
0	1.00	8	0.13
1	0.78	9	0.10
2	0.60	10	0.08
3	0.47	11	0.06
4	0.36	12	0.05
5	0.28	13	0.04
6	0.22	14	0.03
7	0.17		

Since Technetium Tc 99m has a half-life of only 6.02 hours, it is necessary to correct for the radioactive decay of eluted solution if it is not used promptly after assay. Chart B gives the fraction activity remaining for a 12-hour period following assay.

Chart B. TECHNETIUM Tc 99m DECAY CHART
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

RADIOMETRIC MOLYBDENUM TEST PROCEDURE

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

1. A New England Nuclear Cesium Cs 137 reference source which has the same geometry as the generator eluate must be used to standardize the well counter.
2. Determine 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 geometry) in the same shield geometry for the same time period.
5. Compute Molybdenum Mo 99 activity in the eluate as follows:

$$\frac{\mu\text{Ci Molybdenum}}{\text{Mo 99 (total)}} = \frac{\mu\text{Ci simulated Mo 99} \times \text{net cpm Eluate}}{\text{net cpm simulated Mo 99 reference source}}$$

Divide this number by the mCi of Technetium Tc 99m. The U.S. Pharmacopeia specifies a limit of 0.15μCi Molybdenum Mo 99 per mCi of Technetium Tc 99m at the time of administration to each patient.

CAUTION: New England Nuclear makes available two different Cesium Cs 137 reference sources consisting of a known amount of activity contained within a 5.8cc volume and 20cc volume. It is significant to the accuracy of the Molybdenum Mo 99 determination that the Cesium Cs 137 source be used which corresponds in volume to the eluant utilized to elute the generator. The use of 5.8cc Cesium Cs 137 source to standardize the estimation of Molybdenum Mo 99 in a 20cc eluate, for example, will cause the estimate to be approximately 30% low. This figure may vary depending upon the accuracy of the instrumentation used for the assay.

COLORIMETRIC ALUMINUM ION TEST PROCEDURE

NEN offers an Aluminum Ion Indicator Kit (Catalog No. NRP-122) 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.

NRC FORM 218
(4-76)
NRCM 0240

U.S. NUCLEAR REGULATORY COMMISSION

TELEPHONE OR VERBAL CONVERSATION RECORD

DATE 7/23/81

TIME 3:40 ☐ A.M. ☑ P.M.

☐ INCOMING CALL ☑ OUTGOING CALL ☐ VISIT

PERSON CALLING	OFFICE/ADDRESS	PHONE NUMBER / EXTENSION
Del Medico		
PERSON CALLED	**OFFICE/ADDRESS**	**PHONE NUMBER / EXTENSION**
Dr McHugh	Pharmaco Nuclear Inc	

CONVERSATION

SUBJECT Re ltr dtd 7/10/81

SUMMARY

1. Send of copy of the label that fulfills the requirement of 10 CFR 32.73(a)(5)(ii). This label should include:

   The name of the firm.
   The name of the product.
   The licensing statement.

2. The prescription label submitted with ltr dtd 7/10/81 does not seem very applicable to generators. Please send an example label that has been filled out so that I can see what information the firm intends to provide.

REFERRED TO:

☐ ADVISE ME OF ACTION TAKEN.

ACTION REQUESTED

INITIALS

DATE

ACTION TAKEN

INITIALS

DATE

16

A16

NRC FORM 218 (4-76)