Fax

To:	Colleen Casey	**From:**	Roland Sawyer
Fax:	630-829-9782	**Pages:**	3 including cover
Phone:		**Date:**	12 December 2005
Re:	Amendment Request	**CC:**	

Urgent **For Review** **Please Comment** **Please Reply** **Please Recycle**

Colleen,

Attached is the package insert for the BMS generator as requested. Page 1 of the insert gives the description and chemical form that appears to be essentially the same as ours. The NDA's are listed on page 2 in the section "How Supplied".

Please feel free to give me a call if there are any questions.

Thanks,

Roland Sawyer (Chip)

Manager EH&S / RSO

Maryland Heights Plant

Tyco Healthcare Mallinckrodt

314-654-7644 office / 314-267-0723 cellular

DESCRIPTION: Sodium Pertechnetate Tc 99m Injection, as eluted according to the elution instructions with Bristol-Myers Squibb Medical Imaging, Inc. 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).

Bristol-Myers Squibb Medical Imaging, Inc. 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 eluent 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	88.07	140.5

[1]Kocher, David C., "Radioactive Decay Data Tables," DOE/TIC-11026, 100 (1981).

513160-0903 Bristol-Myers Squibb Medical Imaging March 2003

TechneLite®

Technetium Tc 99m Generator

FOR DIAGNOSTIC USE

EXTERNAL RADIATION

The specific gamma ray constant for Technetium Tc 99m is 5.4 micro-coulombs/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 0.25 cm 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: Ensure 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 eluent charge vial.

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

Shield Thickness lead (Pb) cm	Coefficient of Attenuation
0.017	10^{-1}
0.08	10^{-2}
0.16	10^{-3}
0.25	10^{-4}
0.33	10^{-5}

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 88.6% 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 89 mm, 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	88	9	10
2	80	10	8
3	71	11	6
4	63	12	5
5	56	13	4
6	52	14	3
7	47		

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 shielding has a wall thickness of 7.8 mm, 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 signs of inflammation and 0.027/min in patients with inflamed conjunctivae 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: (1) 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.

Geriatric Use

Clinical studies of TechneLite® did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in response between the elderly and

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younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

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 200 mL of sterile saline directly into the bladder. The dosage employed varies with each diagnostic procedure. If the oral route is elected, the patient should fast for at least six (6) hours before and two (2) hours after administration. 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 80uCi)/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 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 (70 kg) 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	—	—	0.6 (0.06)
Fetus	—	—	0.5 (0.05)

In pediatric patients, the maximum radiation dose of 185MBq (5 millicuries) of Sodium Pertechnetate Tc 99m Injection administered to a neonate (3.5 kg) for brain or blood pool imaging with radionuclide angiography are shown in Table 6. In pediatric patients, an average 30 minute exposure to 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 Estimate Report No. 8. *J. Nucl. Med.* 17(1): 74-77, 1976.

[3]Conway, J.J. et al: Direct and indirect radionuclide cystography. *J. Urol.* 113: 589-595 May 1975.

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

Target Organ	Absorbed Dose mGy/ 3.7MBq	(mrad/ 100µCi)
Eye Lens:		
If lacrimal fluid turnover is 15%/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: Bristol-Myers Squibb Medical Imaging TECHNELITE®, Technetium Tc 99m Generator is available in the following quantities of radioactivity: 18.5 (NDC #11994-090-10), 27.6 (NDC #11994-090-27), 37.0 (NDC #11994-090-36), 46.3 (NDC #11994-090-46), 55.5 (NDC #11994-090-55), 64.8 (NDC #11994-090-64), 74.0 (NDC #11994-090-73), 92.5 (NDC #11994-090-92), 111.0 (NDC #11994-090-01), 129.5 (NDC #11994-090-02), 148.0 (NDC #11994-090-03), 166.5 (NDC #11994-090-04), 185.0 (NDC #11994-090-05), 222.0 (NDC #11994-090-06), 277.5 (NDC #11994-090-07), 370.0 (NDC #11994-090-09), 462.5 (NDC #11994-090-10), 555.0 GBq (NDC #11994-090-11), 666.0 GBq (NDC #11994-090-12) (500, 750, 1000, 1250, 1500, 1750, 2000, 2500, 3000, 3500, 4000, 4500, 5000, 6000, 7500, 10,000, 12,500, 15,000 18,000 mCi) of Mo99 on the calibration date (date of manufacture) 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
6 Eluant Charge Vials (may be supplied separately)
6 Eluate Collection Vial (may be supplied separately)
1 Package Insert
6 Radiation Labels (Collection Vial)
6 Radiation Labels (Elution Shield)
1 Molybdenum Mo99 Activity Record (optional)

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 20° to 25°C (68° to 77°F) [See USP].

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 fourteen days post-manufacture.

ELUTION INSTRUCTIONS -- TOTAL ELUTION METHOD

1. Waterproof gloves should be worn during elution.
2. Remove dust (clear plastic) cover of generator.
3. Perform all subsequent operations aseptically.
4. Remove silicone needle seal from eluant charge vial. **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 by hinged door and insert an eluate collection vial from which the flip-off seal has been removed. Secure door 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 elution vial into 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. The 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 drain 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. Obtain the collect needle seal vial and invert 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. **Upon initiating the next elution, discard the empty eluant vial as radioactive waste.**
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 cap, 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 and from that ratio, the expiration time (up to 12 hours) of the eluate is 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.

RADIOCHEMIC 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 containing 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. A 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:

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

Divide the 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^{-6}. 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 (0.15 µCi Mo99/mCi Tc 99m) at the time of administration to each patient.

COLORIMETRIC ALUMINUM ION TEST PROCEDURE

Bristol-Myers Squibb Medical Imaging, Inc. 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 may be returned; **complete return instructions are provided regularly with generator shipments and are also available on request.**

This radioactive drug is approved for distribution to persons licensed pursuant to the Code of Massachusetts Regulations 105 CMR 120.500 for the uses listed in 105 CMR 120.532 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.

Bristol-Myers Squibb Medical Imaging
331 Treble Cove Road
N. Billerica, MA 01862 USA
For Ordering Call Toll-Free: 800-225-1572 All other business: 800-362-2666
(In Massachusetts and International, call 978-667-9531)

U.S. Patent 5,109,160

Bristol-Myers Squibb Medical Imaging

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PAGE 2

Fax

To:	Colleen Casey	**From:**	Roland Sawyer
Fax:	630-829-9782	**Pages:**	2 including cover
Phone:		**Date:**	12 December 2005
Re:	Amendment Request	**CC:**	

Urgent **For Review** **Please Comment** **Please Reply** **Please Recycle**

Colleen,

Attached is the amendment request, the hard copy is in the mail today. I appreciate the quick response and turn around and all of your assistance.

Please feel free to give me a call if there are any questions.

Thanks,

Roland Sawyer (Chip)

Manager EH&S / RSO

Maryland Heights Plant

Tyco Healthcare Mallinckrodt

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tyco Healthcare

Mallinckrodt

Building 100

Mallinckrodt Inc.
2703 Wagner Place
Maryland Heights, MO 63043

December 13, 2005

Materials Licensing Section
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road STE 210
Lisle, Illinois 60532-4352

RE: License 24-04206-05MD
Docket Number (030-10801)

Dear Patty,

Currently in Section 7 of license 24-04206-05MD, Mallinckrodt Inc is limited to shipping DTE generators manufactured under NDA No. 17-243.

Due to a production hold at the Maryland Heights facility on DTE generators, Bristol Myers Squibb (BMS) is currently backfilling Mallinckrodt customers with generators. Two customers located in Alaska are having difficulty receiving BMS generators. This is due to BMS not having a Preferred Customer Status with Alaskan Airlines. This is commonly known in the airline industry as PAL#. BMS has requested that Maryland Heights drop ship two generators per week (one to each customer) to the Alaska hospitals.

This request is to amend the above listed license to include the ability to redistribute these two generators to the Alaska hospitals until Mallinckrodt is back in production. Maryland Heights intends to receive the BMS generators, perform appropriate receipt surveys after breaking the security seal. Upon proper receipt, a new security seal will be applied, and Maryland Heights will remanifest the packages as the shipper. At no time will any of the manufacturers generator labeling or shipping package labeling be altered. Additionally, based on the two customer's standing orders, our license limit of 19.5 Curies at time of shipment will not be exceeded.

BMS is authorized to initially distribute in accordance with a specific license issue pursuant to 10 CFR 32.72 or equivalent Agreement State regulations.

If you have any questions concerning this request please feel free to contact me at (314) 654-7644 (office) or 314-267-0723 (cell).

Sincerely,

Roland E Sawyer,
Manager EH&S / RSO
Tyco/Healthcare/Mallinckrodt
Maryland Heights Facility