

March 10, 2005

U.S. Nuclear Regulatory Commission  
Region I  
Nuclear Materials Safety Branch  
475 Allendale Road  
King of Prussia, PA 19406-1415

03032954

**RE:** Radioactive Material License #24-04206-13MD (Philadelphia Nuclear Pharmacy)

***Please Expedite Licensing Action***

Dear License Reviewer:

Please amend the above-referenced radioactive materials license as follows:

- Replace Appendix F of the current license application with the data contained in Attachment A. New, as well as improved existing, unit and bulk dose shielding have been put into service. In addition, we request that future submittals regarding unit and bulk dose shielding be required only if changes to shielding will increase the radiation levels at the surface of the container. All data will be maintained on file and available for inspection.

All primary shields will be shipped in packaging that meets the requirements of Title 49 Code of Federal Regulations.

- Update Appendix E of the current license application with the information provided in Attachment B. In addition, we request that future submittals be limited to changes to labeling that will cause a change to radioactive markings or labeled activity, other than position and size of symbols and wording.

All other items relating to this radioactive material license remain unchanged at this time.

REC'D IN LAT 3/14/2005

136605  
NMSS/RGNI MATERIALS-002

Please contact April Chance at (314) 654-7960 if you have any questions and/or require supplemental information regarding this request. Your prompt review and approval of this licensing action is greatly appreciated.

Sincerely,



Kay M. Yoder

Director, Radiation, Environment, Health & Safety – Mallinckrodt Inc.

#### Attachments

cc: P. Chhita, Nuclear Pharmacy Manager/RSO (Philadelphia, PA)  
A. Chance, Manager, Radiological Affairs (Hazelwood, MO)  
J. Schuh, Manager, EHS, Pharmacy Operations (Hazelwood, MO)

**ATTACHMENT A  
RADIATION PROFILE DATA**

<b>Nuclide</b>	<b>Maximum Activity per Carrier (mCi)</b>	<b>Carrier</b>	<b>Maximum Radiation Field@ Surface (mR/hr)</b>
Technetium-99m	1000	Syringe	5
Technetium-99m	1500	Vial	2.5
Gallium-67	16	Syringe	65
Gallium-67	30	Vial	20
Thallium-201	9	Syringe	10
Thallium-201	16	Vial	8
Iodine-131	44	Vial	90
Iodine-131	630	Vial	475
Xenon-133	150	Vial	15

## ATTACHMENT B SAMPLE LABELS

TC - 99M MYOVIEW (TETROFOSMIN) It em: R489AD Lot: 40100	<b>TC - 99M MYOVIEW (TETROFOSMIN)</b>		
	Procedure: <b>MYOCARDIAL IMAGING</b>		
	Activity: <b>15 mCi @ 07:30 4 MAR 2005 FRI</b>		
	Vol: <b>0.78 ml</b>	Use By: <b>11:15 4 MAR 2005 FRI</b>	Dispensed: <b>3 MAR 2005 THU</b>
	Conc: <b>19.35 mCi / ml</b>	Issued: <b>4 MAR 2005 FRI</b>	
	<b>ST MARYS NUCLEAR CARDIOLOGY, LANGHORNE, PA</b>		
	ATTN: MARY NUCLEAR MEDICINE NEWTON ROAD LANGHORNE, PA 19047	PE: <b>M.D. USE</b>	Weight: <b>0</b>
	Dr: <b>NEIL PROSHAM, M.D.</b>	Dr: <b>NEIL PROSHAM, M.D.</b>	Key: <b>0</b>
License: <b>PO: NONE</b>	PROCEDURE INSTRUCTIONS	Rx: <b>00264260</b>	
MDC: <b>NONE</b>			
<b>MALLINCKRODT</b> (610) 532-2248	Price: \$	Mfg: <b>AMERSHAM</b>	
19 INDEPENDENCE COURT FOLCROFT, PA 19032	Mfg State: <b>PA</b>		
RPH: <b>MIKE F HAIGH</b>			

RX ONLY



TC-99M MYOVIEW (TETROFOSMIN) Rx: 00264260  
MYOCARDIAL IMAGING  
15 mCi @ 07:30 4 MAR 2005 FRI  
MALLINCKRODT/19 INDEPENDENCE COURT  
FOLCROFT, PA 19032  
(610) 532-2248  
Pt: M.D. USE



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RX ONLY



THE U.S. NUCLEAR REGULATORY COMMISSION HAS  
APPROVED DISTRIBUTION OF THIS  
RADIOACTIVE MATERIAL TO PERSONS LICENSED TO  
USE BY PRODUCT MATERIAL LISTED IN PARAGRAPH  
36.100, 200 & 300 OF 10 CFR PART 36  
AND TO PERSONS HOLDING AN EQUIVALENT  
LICENSE ISSUED BY AN AGREEMENT STATE.

*Example Unit Dose Labels*

TC - 99M SODIUM PERTECHNETATE It em: FROESAB Lot: 40103	<b>TC - 99M SODIUM PERTECHNETATE</b>		
	Procedure: <b>FOR RADIOPHARMACEUTICAL USE</b>		
	Activity: <b>200 mCi @ 12:00 4 MAR 2005 FRI</b>		
	Vol: <b>1.93 ml</b>	QS <b>3.75</b>	Use By: <b>22:34 4 MAR 2005 FRI</b>
	Conc: <b>08 53.3333 mCi / ml</b>		Dispensed: <b>4 MAR 2005 FRI</b>
	<b>PRESBYTERIAN HOSP</b>		
	ATTN: NUC MED 5TH FLOOR R 2583 51 NORTH 39TH STREET PHILADELPHIA, PA 19104	PE: <b>M.D. USE</b>	Weight: <b>0</b>
	Dr: <b>M.D. USE</b>	Dr: <b>M.D. USE</b>	Key: <b>0</b>
License: <b>370011807</b>	PROCEDURE INSTRUCTIONS	Rx: <b>00264258</b>	
PO: <b>175003</b>			
MDC: <b>NONE</b>			
<b>MALLINCKRODT</b> (610) 532-2248	Price: \$	Mfg: <b>MH PLANT</b>	
19 INDEPENDENCE COURT FOLCROFT, PA 19032	Mfg State: <b>MD</b>		
RPH: <b>MIKE F HAIGH</b>			

RX ONLY



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FOR RADIOPHARMACEUTICAL USE  
200 mCi @ 12:00 4 MAR 2005 FRI  
MALLINCKRODT/19 INDEPENDENCE COURT  
FOLCROFT, PA 19032  
(610) 532-2248  
Pt: M.D. USE



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36.100, 200 & 300 OF 10 CFR PART 36  
AND TO PERSONS HOLDING AN EQUIVALENT  
LICENSE ISSUED BY AN AGREEMENT STATE.

*Example Bulk Dose Labels*

This is to acknowledge the receipt of your letter/application dated

3/16/2005, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment 24-04206-13MD  
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 136605.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.

(FOR LFMS USE)  
INFORMATION FROM LTS

BETWEEN:

License Fee Management Branch, ARM  
and  
Regional Licensing Sections

: Program Code: 02500  
: Status Code: 0  
: Fee Category: 3C 3P 2B  
: Exp. Date: 20050831  
: Fee Comments: \_\_\_\_\_  
: Decom Fin Assur Req'd: N  
:.....

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED  
Applicant/Licensee: MALLINCKRODT, INC.  
Received Date: 20050304  
Docket No: 3032954  
Control No.: 136605  
License No.: 24-04206-13MD  
Action Type: Amendment

2. FEE ATTACHED  
Amount: /  
Check No.: \_\_\_\_\_

3. COMMENTS

Signed Rebecca J. Jundt  
Date 3/17/2005

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /\_/)

1. Fee Category and Amount: \_\_\_\_\_

2. Correct Fee Paid. Application may be processed for:  
Amendment \_\_\_\_\_  
Renewal \_\_\_\_\_  
License \_\_\_\_\_

3. OTHER \_\_\_\_\_  
\_\_\_\_\_

Signed \_\_\_\_\_  
Date \_\_\_\_\_