

March 10, 2005

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

03035461

RE: Radioactive Material License #24-04206-22MD (Altoona 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.

05 MAR 14 09:41

RECEIVED
REGION I

136615
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: E. Hunt, Nuclear Pharmacy Manager (Altoona, PA)
T. Hays, Radiation Safety Officer (Altoona, PA)
A. Chance, Manager, Radiological Affairs (Hazelwood, MO)
J. Schuh, Manager, EHS, Pharmacy Operations (Hazelwood, MO)

**ATTACHMENT A
RADIATION PROFILE DATA**

Nuclide	Maximum Activity per Carrier (mCi)	Carrier	Maximum Radiation Field@ Surface (mR/hr)
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) Item: R489AD Lot: 12267	TC - 99M MYOVIEW (TETROFOSMIN) Procedure: MYOCARDIAL IMAGING Activity: 15 mCi @ 08:00 4 MAR 2005 FRI	
	Vol: 0.62 ml	Use By: 13:30 4 MAR 2005 FRI Dispensed: 4 MAR 2005 FRI Issued: 3 MAR 2005 THU
	Conc: 24.3648 mCi / ml	<small>1099 & 0.18 UCI/CI T099 & EXPIRATION</small>
	WINDBER MEDICAL CENTER	
	NUCLEAR MEDICINE 600 SOMERSET AVE WINDBER, PA 15963	Pt: M.D. USE Weight: [REDACTED] Dr: LAWRENCE M. MCNIESH, M.D.
	License: PO: 33440 NDC:	PROCEDURE INSTRUCTIONS Rx: 00089725
MALLINCKRODT (814) 471-2750 656 INDUSTRIAL DRIVE EBENSBURG, PA 15931 RPH: ERIC L HUNT	Price: \$ Mfg: AMERSHAM Mfg State: PA	
RX ONLY	 RADIOACTIVE MATERIAL	CAUTION 

TC - 99M MYOVIEW (TETROFOSMIN) Item: R489AD Lot: 12267	TC - 99M MYOVIEW (TETROFOSMIN) Procedure: MYOCARDIAL IMAGING Activity: 15 mCi @ 08:00 4 MAR 2005 FRI	
	Vol: 0.62 ml	Use By: 13:30 4 MAR 2005 FRI Dispensed: 4 MAR 2005 FRI Issued: 3 MAR 2005 THU
	Conc: 24.3648 mCi / ml	<small>1099 & 0.18 UCI/CI T099 & EXPIRATION</small>
	WINDBER MEDICAL CENTER	
	NUCLEAR MEDICINE 600 SOMERSET AVE WINDBER, PA 15963	Pt: M.D. USE Weight: [REDACTED] Dr: LAWRENCE M. MCNIESH, M.D.
	License: PO: 33440 NDC:	PROCEDURE INSTRUCTIONS Rx: 00089725
MALLINCKRODT (814) 471-2750 656 INDUSTRIAL DRIVE EBENSBURG, PA 15931 RPH: ERIC L HUNT	Price: \$ Mfg: AMERSHAM Mfg State: PA	
RX ONLY	 RADIOACTIVE MATERIAL	CAUTION 



TC-99M MYOVIEW (TETROFOSMIN) Rx: 00089725
 MYOCARDIAL IMAGING
 15 mCi @ 08:00 4 MAR 2005 FRI
 MALLINCKRODT/656 INDUSTRIAL DRIVE
 EBENSBURG
 (814) 471-2750
 Pt: M.D. USE



THE U.S. NUCLEAR REGULATORY COMMISSION HAS
 APPROVED DISTRIBUTION OF THIS
 RADIOACTIVE MATERIAL TO PERSONS LICENSED TO
 USE OF PRODUCT MATERIAL LISTED IN PARAGRAPH
 35.100, 200 & 300 OF 10 CFR PART 35
 AND TO PERSONS HOLDING AN EQUIVALENT
 LICENSE ISSUED BY AN AGREEMENT STATE.





Example Unit Dose Labels

TC - 99M SODIUM PERTECHNETATE Item: R005AD Lot: 12258	TC - 99M SODIUM PERTECHNETATE Procedure: FOR RADIOPHARMACEUTICAL USE Activity: 50 mCi @ 10:00 4 MAR 2005 FRI	
	Vol: 1.05 ml	Use By: 01:22 5 MAR 2005 SAT Dispensed: 4 MAR 2005 FRI Issued: 4 MAR 2005 FRI
	Conc: 47.796 mCi / ml	<small>1099 & 0.18 UCI/CI T099 & EXPIRATION</small>
	MOUNT NITTANY MEDICAL CENTER	
	ATTN NUC MED DEPT 1800 EAST PARK AVENUE STATE COLLEGE, PA 16803	Pt: M.D. USE Weight: [REDACTED] Dr: ARI R. GESELOWITZ, M.D.
	License: PO: 062044 NDC:	PROCEDURE INSTRUCTIONS Rx: 00089682
MALLINCKRODT (814) 471-2750 656 INDUSTRIAL DRIVE EBENSBURG, PA 15931 RPH: ERIC L HUNT	Price: \$ Mfg: ALTOONA Mfg State: PA	
RX ONLY	 RADIOACTIVE MATERIAL	CAUTION 

TC-99M SODIUM PERTECHNETATE Rx: 00089682
 FOR RADIOPHARMACEUTICAL USE
 50 mCi @ 10:00 4 MAR 2005 FRI
 MALLINCKRODT/656 INDUSTRIAL DRIVE
 EBENSBURG
 (814) 471-2750
 Pt: M.D. USE



TC - 99M SODIUM PERTECHNETATE Item: R005AD Lot: 12258	TC - 99M SODIUM PERTECHNETATE Procedure: FOR RADIOPHARMACEUTICAL USE Activity: 50 mCi @ 10:00 4 MAR 2005 FRI	
	Vol: 1.05 ml	Use By: 01:22 5 MAR 2005 SAT Dispensed: 4 MAR 2005 FRI Issued: 4 MAR 2005 FRI
	Conc: 47.796 mCi / ml	<small>1099 & 0.18 UCI/CI T099 & EXPIRATION</small>
	MOUNT NITTANY MEDICAL CENTER	
	ATTN NUC MED DEPT 1800 EAST PARK AVENUE STATE COLLEGE, PA 16803	Pt: M.D. USE Weight: [REDACTED] Dr: ARI R. GESELOWITZ, M.D.
	License: PO: 062044 NDC:	PROCEDURE INSTRUCTIONS Rx: 00089682
MALLINCKRODT (814) 471-2750 656 INDUSTRIAL DRIVE EBENSBURG, PA 15931 RPH: ERIC L HUNT	Price: \$ Mfg: ALTOONA Mfg State: PA	
RX ONLY	 RADIOACTIVE MATERIAL	CAUTION 

THE U.S. NUCLEAR REGULATORY COMMISSION HAS
 APPROVED DISTRIBUTION OF THIS
 RADIOACTIVE MATERIAL TO PERSONS LICENSED TO
 USE OF PRODUCT MATERIAL LISTED IN PARAGRAPH
 35.100, 200 & 300 OF 10 CFR PART 35
 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

3/10/2005, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment 24-04206-22 MD
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

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 136615.
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 : Program Code: 02500
 and : Status Code: 0
 Regional Licensing Sections : Fee Category: 3C 2B
 : Exp. Date: 20101130
 : Fee Comments: _____
 : Decom Fin Assur Req'd: N
 : ::

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
 Applicant/Licensee: MALLINCKRODT INC.
 Received Date: 20050314
 Docket No: 3035461
 Control No.: 136615
 License No.: 24-04206-22MD
 Action Type: Amendment

2. FEE ATTACHED
 Amount: /
 Check No.: _____

3. COMMENTS

Signed Rebecca Hurd
 Date 3/21/05

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 _____