

**tyco**

**Healthcare**

**Mallinckrodt**

Mallinckrodt Inc.  
675 McDonnell Boulevard  
P.O. Box 5840  
St. Louis, MO 63134

Tele: 314 654-2000  
www.mallinckrodt.com

RECEIVED  
REGION 1

February 28, 2005

'05 MAR -2 AM 10:06

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

RE: Material License #24- 04206-13MD 03032954

Dear License Reviewer:

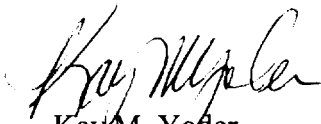
Please amend the above referenced material license to reflect the following modification:

1. Increase the maximum possession limit for Iodine-131 (Items 6.D-8.D) to 5 Curies. Customer demands for nuclear medicine products containing Iodine-131, particularly custom capsules and oral solutions, has significantly increased warranting the need for Mallinckrodt to adjust our current license limits.

Air monitoring and bioassay practices will continue as described in the current license.

All other items relating to our established Radiation Safety Program remain unchanged at this time. Please contact April Chance, Manager, Radiological Affairs, at (314) 654-7960 for additional information to support this request. Thank you for your prompt assistance regarding this matter.

Sincerely,



Kay M. Yoder

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

Attachments

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

136549  
NMSS/RGNI MATERIALS-002

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

2/28/2005, 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** 136599.  
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 3P 2B  
 : Exp. Date: 20050831  
 : Fee Comments: \_\_\_\_\_  
 : Decom Fin Assur Reqd: N  
 : ::

LICENSE FEE TRANSMITTAL

A. REGION 1

1. APPLICATION ATTACHED  
 Applicant/Licensee: MALLINCKRODT, INC.  
 Received Date: 20050302  
 Docket No: 3032954  
 Control No.: 136599  
 License No.: 24-04206-13MD  
 Action Type: Amendment

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

3. COMMENTS  
 Signed *Robert J. Ford*  
 Date 3/17/05

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 \_\_\_\_\_