tyco
Healthcare

Mallinckrodt

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

Tele: 314 654-2000
www.mallinckrodt.com

March 10, 2005

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

RE: Material License #24-04206-17MD 03033157

'05 MAR 11 P2:21
RECEIVED
REGION 1

Dear License Reviewer:

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

1. Amend to name James Dawson, R.Ph. as an Authorized Nuclear Pharmacist. Mr. Dawson was previously named as an Authorized Nuclear Pharmacist to Ohio License 02500250072, issued to the Mallinckrodt facility in Columbus, Ohio. This license is attached for your convenience. In addition, the Pennsylvania Board of Pharmacy recognizes Mr. Dawson as a Registered Pharmacist.

All other items relating to our radioactive material license and established Radiation Safety Program remain unchanged at this time.

Please contact April Chance, Manager, Radiological Affairs at (314) 654-7960 for further information regarding this matter. Your prompt review and approval of this license modification is greatly appreciated.

Sincerely,

Kay M. Yoder
Director, Environmental, Health & Safety – Imaging

Attachment

cc: T. Layne, Nuclear Pharmacy Manager (Bethlehem, PA)
C. Brunner, Radiation Safety Officer (Bethlehem, PA)
A. Chance, Manager, Radiological Affairs (Hazelwood, MO)
J. Schuh, Manager, EHS, Pharmacy Operations (Hazelwood, MO)

136603
NMSS/RGNI MATERIALS-002

ATTACHMENT
OHIO LICENSE 02500250072

Amendment No. 11

OHIO DEPARTMENT OF HEALTH
LICENSE FOR RADIOACTIVE MATERIAL

Pursuant to Chapter 3748 of the Ohio Revised Code, and in reliance on statements and representations made by the licensee, a license is hereby issued authorizing the licensee named herein to receive, acquire, possess, and transfer radioactive material as designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the applications of Chapter 3748 of the Ohio Revised Code and all rules promulgated thereunder. This license shall be deemed subject to all applicable rules, regulations and orders of the Ohio Department of Health now or hereinafter in effect and to any conditions specified below.

LICENSEE	LICENSE NUMBER
1. Mallinckrodt, Inc.	3. 02500250072
2. 675 McDonnell Boulevard St. Louis, Missouri 63134	EXPIRATION DATE 4. February 1, 2009
	BUREAU DOCKET NUMBER 5. AC-12-11-97

6. RADIOACTIVE MATERIAL	7. CHEMICAL AND/OR PHYSICAL FORM	8. MAXIMUM QUANTITY THAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE
A. Any radioactive material identified in 10 CFR 35.100	A. Any radiopharmaceutical form	A. 3.7 GBq (100 mCi)
B. Any radioactive material identified in 10 CFR 35.200, except Technitium-99m, Xenon-133, Iodine-131, and Thallium-201	B. Any radiopharmaceutical form	B. 18.5 GBq (0.5 Ci)
C. Any radioactive material identified in 10 CFR 35.300 except Iodine -131 and Yttrium-90	C. Any radiopharmaceutical form	C. 3.7 GBq (100 mCi)
D. Xenon-133	D. Unit dose containers of gas or gas in solution	D. 74 GBq (2.0 Ci)
E. Iodine-131	E. Any radiopharmaceutical form	E. 33.3 GBq (900 mCi)
F. Thallium – 201	F. Thallous Chloride	F. 74 GBq (2.0 Ci)
G. Yttrium-90	G. Any form	G. 185 GBq (5.0 Ci)
H. Technetium-99m	H. Any form listed in Sections 10 CFR 35.100 and 10 CFR 35.200	H. 7.4 TBq (200 Ci)
I. Iodine-125 as identified in 10 CFR 35.400	I. Liquid form for use in the GliaSite brachytherapy device	I. 351.5 GBq (9.5 Ci)
J. Molybdenum-99	J. Any Mo-99/Tc-99m generator, manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to rule 3701:1-46-43 of the Ohio Administrative Code.	J. 7.4 TBq (200 Ci)
K. Any radioactive material listed in rule 3701:1-46-11 of the Ohio Administrative Code	K. Prepackaged units for in vitro diagnostic tests	K. 740 MBq (20 mCi)
L. Any radioactive material authorized under 10 CFR 35.57	L. Any sealed source listed in 10 CFR 35.57(a), that has been manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to rule 3701:1-46-44 of the Ohio Administrative Code.	L. 11.1 GBq (33 mCi)

OHIO DEPARTMENT OF HEALTH LICENSE FOR RADIOACTIVE MATERIALS SUPPLEMENTARY SHEET	Page 2 of 4 License Number: 02500250072 Bureau Docket Number: AC-12-11-97 Amendment No. 11

6. RADIOACTIVE MATERIAL	7. CHEMICAL AND/OR PHYSICAL FORM	8. MAXIMUM QUANTITY THAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE
M. Cobalt-57	M. Sealed Source(s)	M. As needed, no single source to exceed 1.1 GBq (30 mCi)
N. Radioactive material with atomic numbers between 3 – 83, inclusive	N. Sealed source leak test samples	N. As needed
O. Uranium (depleted in the isotope Uranium-235)	O. Metal	O. 200 kilograms

9. Authorized Use

A. – I. **Preparation and distribution of radiopharmaceuticals to authorized recipients.**

J. **Elution of Tc-99m Pertechnetate and unused molybdenum-99/technetium-99m generators may be redistributed to persons licensed pursuant to 10 CFR 35.200, as delineated in rule 3701-39-02.1 of the Ohio Administrative Code.**

K. **Redistribution to specific or general licensees.**

L. – M. **Instrument calibration and /or redistribution of sealed sources to authorized recipients.**

N. **In-house analysis of sealed source leak samples.**

O. **Shielding for Mo-99 / Tc-99m generators.**

CONDITIONS

10. Licensed material may only be used at the licensee's facilities located at:

2164 Cloverleaf Street, East
Columbus OH 43232

11. The Radiation Safety Officer or Person in Charge of the radioactive material for this license is:

Amanda Jehl, R.Ph.

12. **Licensed material shall be limited by the procedures outlined in Sections 6, 7, and 8 of this license. Materials may only be used by, or under the supervision of, the below listed individual(s) designated in writing:**

Authorized User(s) / Nuclear Pharmacist(s)

A.	Christine Basilone, R.Ph.	F.	David R. Lutes, R.Ph.	K.	Darlene Rubin, R.Ph.
B.	James M Dawson, R.Ph.	G.	Cynthia Tindall, R. Ph.	L.	Jeffery Smith, R.Ph.
C.	Joseph M. Gatton, R.Ph	H.	Ruth Mary Wetzel, R. Ph.	M.	Lisa L. Koss, R.Ph.
D.	Amanda Jehl, R.Ph.	I.	John Nygard, R.Ph.	N.	Jason Willman, R.Ph.
E.	James Korczynski, R.Ph.	J.	Bradley M. Roff, R.Ph.	O.	Lisa Ann Coats, R. Ph.

13. Sealed Sources

A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six (6) months.

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three (3) months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made within the required leak test interval, a sealed source shall not be put into service until tested.

D. Sealed sources need not be tested if:

1) They contain only a radioactive gas; or

2) The half-life of the radioisotope is 30 days or less; or

3) They contain 3.7 MBq (100 µCi) or less of beta or gamma emitting material or 370 kBq (10 µCi) or less of alpha-emitting material; or

4) They are in storage and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

E. The leak test shall be capable of detecting the presence of 185 Bq (0.005 µCi) of radioactive material on the test sample. If the test reveals the presence of 185 Bq (0.005 µCi) or more of removable contamination, a report shall be filed with the Ohio Department of Health, and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Ohio Department of Health regulations. The report shall be filed within 5 days of the date the leak test result is known with the Bureau of Radiation Protection - Ohio Department of Health, 246 N. High St, Bureau of Radiation Detection / 7th Floor, 35 Bldg., P.O. Box 118, Columbus, Ohio 43216 - 0118. The report shall specify the source involved, the test results, and corrective action taken.

F. The licensee is authorized to collect leak test samples for analysis. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Director, the NRC or an Agreement or NARM licensing state to perform such services.

14. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.

15. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.

16. Radioactive waste may be picked up from licensee's customers and disposed of in accordance with the statements, representations and procedures in renewal application dated October 29, 2003.

17. The licensee is authorized to transport licensed material in accordance with Chapter 3701:1-50 of the Ohio Administrative Code.

18. Radioiodine solution and capsules containing radioiodine solution will be stored within the glove box with the exception of I-131 Tositummomab (Bexxar®). The licensee will follow operations involving I-131 Bexxar® as stated in renewal application dated October 29, 2003.

19. Any proposed changes in packaging, shielding or labeling shall be submitted for review to the Ohio Department of Health, 246 North High Street, Bureau of Radiation Protection / 7th Floor, 35 Bldg. / P.O. Box 118, Columbus OH 43216-0118.

20. The licensee is authorized to hold material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash, provided:

A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

C. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the product material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

21. In addition to the possession limits in item 8, the licensee shall further restrict the possession of sealed source licensed

OHIO DEPARTMENT OF HEALTH LICENSE FOR RADIOACTIVE MATERIALS SUPPLEMENTARY SHEET	Page 4 of 4 License Number: 02500250072 Bureau Docket Number: AC-12-11-97 Amendment No. 11

materials to quantities below the minimum limit specified in Rule 3701:1-40-17(C) of the Ohio Administrative Code for establishing decommissioning financial assurance.

22. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Ohio Department of Health's statutes, rules, and orders shall govern unless statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Renewal application dated October 29, 2003;

B. *Amendment # 11 of license 02500250072; renewed in its entirety.*

For the Ohio Department of Health

DATE: Jan. 20, 2004 BY: _____

Director, Ohio Department of Health

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 04206-17MD
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** 136603.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader

	:	(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: 20140228
	:	Fee Comments: _____
	:	Decom Fin Assur Reqd: N
	::	

LICENSE FEE TRANSMITTAL

A. REGION 1

1. APPLICATION ATTACHED
   Applicant/Licensee: MALLINCKRODT INC.
   Received Date: 20050311
   Docket No: 3033157
   Control No.: 136603
   License No.: 24-04206-17MD
   Action Type: Amendment

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

3. COMMENTS

Signed Melissa Smith
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 _____