

June 22, 2007

U.S. Nuclear Regulatory Commission, Region III
Nuclear Materials Safety Branch
2443 Warrenville Road
Ste. 210
Lisle, IL 60532-4352

A
030-32515

RE: Material License #24-04206-12MD (Kansas City, MO)

Dear License Reviewer:

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

1. Amend Item 9.I to delete the phrase "Calibration and checking of the licensee's instruments" and read as follows:

"Redistribution of sources to specifically authorized recipients. Pursuant to 10 CFR 32.74, the licensee is authorized to redistribute sources to persons licensed pursuant to 10 CFR 35.65(a) or under equivalent licenses of Agreement States."

Mallinckrodt does not perform instrument calibrations.
2. Amend Item 6.I to read:

"Any byproduct material authorized under 10 CFR 35.65(a)"
3. Please amend the list of Authorized Nuclear Pharmacists (ANPs) for the above referenced radioactive material license to the following:

| | |
|---------------------------|---------------------------|
| Chau Bosgraaf R.Ph. | Todd Kliche', R.Ph. |
| Danielle Burroughs, R.Ph. | David McLeland R.Ph. |
| Dennis Davis, R.Ph. | Brenda C. Ochylski, R.Ph. |
| Andrew Farrow, R.Ph. | David Persinger, R.Ph. |
| Fred Gattas, R.Ph. | Stephen Pugh, R.Ph. |
| Joseph M. Huber, R.Ph. | Debra Ross, R.Ph. |
| Adam Kautzner, R.Ph. | Barbara Scavullo R.Ph. |

316340
JUN 25 2007

Mr. Davis, Mr. Huber, Ms. Ochylski (formerly Schultz), Mr. Persinger, Mr. Pugh, Ms. Ross, and Ms. Scavullo are currently listed as ANPs on this license.

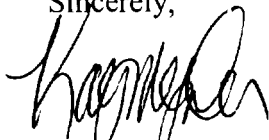
Ms. Bosgraaf, Ms. Burroughs, Mr. Farrow, Mr. Gattas, Mr. Kautzner, Mr. Kliche', and Mr. McLeland are listed as ANPs on U.S. NRC License 24-04206-08MD, included as Attachment A for your convenience.

Documentation of registration with the Missouri Board of Pharmacy for each individual is included as Attachment B.

Name change documentation for Ms. Ochylski is included as Attachment C.

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.

cc: D. Persinger, R.Ph., RSO (Kansas City, MO Nuclear Pharmacy)
A. Chance, Manager, Radiological Affairs (Hazelwood, MO)

Mr. Davis, Mr. Huber, Ms. Ochylski (formerly Schultz), Mr. Persinger, Mr. Pugh, Ms. Ross, and Ms Scavullo are currently listed as ANPs on this license.

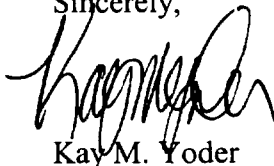
Ms. Bosgraaf, Ms. Burroughs, Mr. Farrow, Mr. Gattas, Mr. Kautzner, Mr. Kliche', and Mr. McLeland are listed as ANPs on U.S. NRC License 24-04206-08MD, included as Attachment A for your convenience.

Documentation of registration with the Missouri Board of Pharmacy for each individual is included as Attachment B.

Name change documentation for Ms. Ochylski is included as Attachment C.

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,

A handwritten signature in black ink, appearing to read 'Kay M. Yoder', is written over the word 'Sincerely,'.

Kay M. Yoder

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

cc: D. Persinger, R.Ph., RSO (Kansas City, MO Nuclear Pharmacy)
A. Chance, Manager, Radiological Affairs (Hazelwood, MO)

Licensee: Mallinckrodt, Inc.
License No. 24-04206-12MD
Docket No. 030-32515
Amendment No.: 16
Control No: 316340

LICENSING ACTION

This certifies that to the best of my knowledge, this licensing action in response to request dated June 22, 2007, was performed in accordance with current NRC regulations, policies and guidance.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

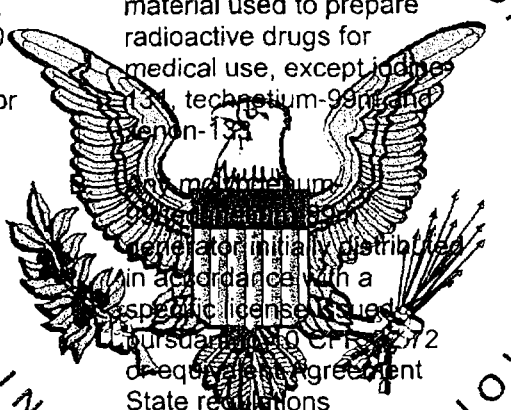
Kevin G. Null
Sr. Health Physicist

Kevin G. Null 8/28/07

ATTACHMENT A
U.S. NRC LICENSE # 24-04206-08MD
ST. LOUIS, MO

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10 Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material 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 regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954 as amended and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below

| | | | |
|--|--|---|--|
| Licensee | | In accordance with letter dated November 20, 2006, | |
| 1 Mallinckrodt Inc | | 3 License number 24-04206-08MD is amended in its entirety to read as follows: | |
| 2 675 McDonnell Boulevard P O. Box 5840 St. Louis, MO 63134 | | 4. Expiration date March 31, 2007 | |
| | | 5 Docket No. 030-18546 Reference No | |
| 6 Byproduct, source, and/or special nuclear material | 7 Chemical and/or physical form | 8 Maximum amount that licensee may possess at any one time under this license | |
| A Any unsealed byproduct material, except iodine-131, technetium-99m, Yttrium-90 and xenon-133 used to prepare radioactive drugs for medical use | A Any unsealed byproduct material used to prepare radioactive drugs for medical use, except iodines 131, technetium-99m and xenon-133 | A 700 millicuries | |
| B Molybdenum-99 | B Molybdenum-99 | B 200 curies | |
|  | | | |
| C Technetium-99m | C Unsealed | C 200 curies | |
| D Xenon-133 | D Unit dose containers of gas or gas in solution initially distributed in accordance with a specific license issued pursuant to 10 CFR 32.72 or equivalent Agreement State regulations | D 5 curies | |

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number
24-04206-08MD

Docket or Reference Number
030-18546

Amendment No. 28

- | | | |
|---|--|--|
| 6 Byproduct, source, and/or special nuclear material | 7 Chemical and/or physical form | 8. Maximum amount that licensee may possess at any one time under this license |
| E Iodine-131 | E Any form initially distributed in accordance with a specific license issued pursuant to 10 CFR 32.72 or equivalent Agreement State regulations | E 5 Curies |
| F Any byproduct material listed in 10 CFR 31.11(a) | F Prepackaged units for <u>in vitro</u> diagnostic tests | F 20 millicuries |
| G Any byproduct material authorized under 10 CFR 35.65(a) | G Any sealed source listed in 10 CFR 35.65(a) that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to 10 CFR 32.74 or equivalent Agreement State regulations | G 300 millicuries |
| H Uranium (depleted in the isotope Uranium-235) | H Metal encased in stainless steel | H 400 kilograms |
| I Rhenium-186 | I Rhenium | I 4 curies |
| J Iodine-125 | J Therapeutic seed sources as listed in 10 CFR 35.400(f) | J 4 curies |
| K Yttrium-90 | K Unsealed for preparation of radiopharmaceuticals for medical use | K 1 curie |



**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
24-04206-08MDDocket or Reference Number
030-18546

Amendment No 28

9 Authorized Use:

- A through E and K Preparation and distribution of radioactive drugs (includes Mo-99/Tc-99m generators) to authorized recipients
- F Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11 provided the packaging and labelling remain unchanged
- G Instrument calibration. Redistribution of sources to specifically authorized recipients. Pursuant to 10 CFR 32.74, the licensee is authorized to redistribute sources to persons licensed pursuant to 10 CFR **35.65(a)** or under equivalent licenses of Agreement States.
- H Shielding for Mo-99/Tc-99m generators.
- I For possession incident to the preparation of Rhenium-186 labeled monoclonal antibodies in accordance with Food and Drug Administration IND Number 3197 for transfer to St. Louis University Medical Center, NRC Byproduct Material License No. 24-00196-07.
- J For distribution of repackaged sealed sources manufactured pursuant to 10 CFR 32.74 and redistribution of sealed sources manufactured pursuant to 10 CFR 32.74. Sealed sources must be registered either with NRC under 10 CFR 32.210 or an Agreement State and distributed or redistributed to persons specifically authorized by an NRC or an Agreement State License to receive, possess, and use the sealed sources.

Pursuant to 10 CFR 32.72 and 32.74, the licensee is authorized to distribute the byproduct material described in Items 6 and 7A. This portion of this license is pursuant to Sections 35.100, 35.200 and 35.300 of 10 CFR Part 35 for under equivalent licenses of Agreement States.

10. License material shall be used only at the licensee's facilities located at 1827 Belt Way Drive, Overland, Missouri

- 11 A Licensed material shall be used by, or under the supervision of:

- (1) a pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2) and (4), or

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

 License Number
24-04206-08MD

 Docket or Reference Number
030-18546

Amendment No 28

 (2) **authorized nuclear pharmacists:**

 Dennis Davis
Debra (Debrowiak) Ross
Jason Willman
Adam Kautzner ✓
David McLeland ✓

 Chau Nguyen Bosgraaf ✓
Barbara Scavullo
Joseph M. Huber
David Wright Persinger
Stephen Pugh

 Brenda C. Ochylski
Andrew J. Farrow ✓
Danielle S. Burroughs ✓
Fred Gattas ✓
Todd Kliche ✓

B The Radiation Safety Officer for this license is Adam Kautzner, R Ph

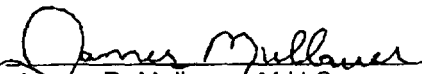
- 12 A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by NRC under 10 CFR 32.210 or by an Agreement State.
- B. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by NRC under 10 CFR 32.210 or by an Agreement State prior to the transfer, a sealed source received from another person shall not be put into use until tested.
- C. Sealed sources need not be tested if they are in storage and are not being used. However, when they are removed from storage for use or transferred 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 more than 10 years without being tested for leakage and/or contamination.
- D. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material. If the test results reveal the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.
- E. Tests for leakage and/or contamination shall be performed by the licensee or other persons specifically licensed by the Commission or an Agreement State to perform such services. In addition, the licensee is authorized to collect leak test samples for analysis by persons specifically licensed by the Commission or an Agreement State to perform such services.
- 13 Sealed sources containing licensed material shall not be opened.
- 14 The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.
- 15 The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
24-04206-08MDDocket or Reference Number
030-18546

Amendment No 28

- 16 The licensee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash provided:
- A. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate survey meter 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.
- B. A record of each 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 byproduct 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.
- 17 Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements and representations in letter dated November 7, 1996.
- 18 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 Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Applications dated March 6, 1996 (excluding items 10.9 and 10.15), and
- B. Letters dated November 24, 1996 (with attachments and Appendix A), March 10, 1997 (with attachments), August 24, 1999 (with attachments), January 27, 2001, May 1, 2001, October 11, 2001, September 8, 2002, January 27, 2003, September 11, 2003, May 9, 2005 (excluding Attachment 10) and May 13, 2005.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date **DEC 22 2006**By 
James R. Mullauer, M.H.S.
Materials Licensing Branch
Region III

ATTACHMENT B
MISSOURI BOARD OF PHARMACY REGISTRATIONS