

August 3, 2009

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

RE: Material License #24-04206-10MD (Warren, MI Radiopharmacy)

Please Expedite Review

Dear License Reviewer:

Please amend the radioactive materials license above to reflect the following changes:

1. Amend to name **Debra Ross, R.Ph.** as Authorized Nuclear Pharmacist. Ms. Ross is currently listed as ANP on NRC license# 24-04206-08MD included as Attachment A.

Amend to name **Joseph Remesz-Guerrette, R.Ph.** as Authorized Nuclear Pharmacist. Mr. Remesz-Guerrette is currently listed as ANP on NRC license# 24-04206-15MD included as Attachment B.

Amend to name **Brian Osterberg, R.Ph.** as Authorized Nuclear Pharmacist. Mr. Osterberg is currently listed as ANP on Florida license# 1937-3 included as Attachment C.

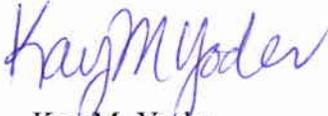
Documentation of registration with the Michigan Board of Pharmacy for each individual is included as Attachment D.

2. Remove **Brenda Ochylski, R.Ph.** as Authorized Nuclear Pharmacist.
3. Remove **Sara Vogler, R.Ph.** as Authorized Nuclear Pharmacist effective 8/17/2009.

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

Attachments

cc: M. Klug, R.Ph., RSO (Detroit, MI)
A. Chance, Manager, Radiological Affairs (Hazelwood, MO)

ATTACHMENT A
NRC LICENSE# 24-04206-08MD

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

<p style="text-align: center;">Licensee</p> <p>1 Mallinckrodt Inc.</p> <p>2 675 McDonnell Boulevard</p> <p style="padding-left: 20px;">P O Box 5840</p> <p style="padding-left: 20px;">St. Louis, MO 63134</p>	<p>In accordance with letter dated June 17, 2009,</p> <p>3 License number 24-04206-08MD is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date July 31, 2017</p> <hr/> <p>5 Docket No. 030-18546</p> <p style="padding-left: 20px;">Reference No</p>
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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 byproduct material with atomic numbers 3 through 83 except molybdenum-99, iodine-131, technetium-99m, Yttrium-90 and xenon-133	A. Any form initially distributed in accordance with a specific license issued pursuant to 10 CFR 32.72 or equivalent Agreement State regulations	A. 700 millicuries per nuclide total possession not to exceed 1 curie
B. Molybdenum-99	B. Any molybdenum-99/technetium-99m generator initially distributed in accordance with a specific license issued pursuant to 10 CFR 32.72 or equivalent Agreement State regulations	B. 200 curies
C. Technetium-99m	C. Any	C. 200 curies
D. Xenon-133	D. Any	D. 6 curies
E. Iodine-131	E. Any	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

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

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030-18546

Amendment No. 38

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|---|--|--------------------|
| G. Any byproduct material authorized under 10 CFR 35.65 | G. Any sealed source listed in 10 CFR 35.65 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. Yttrium-90 | I. Any | I. 1 curie |
| J. Thallium-201 | J. Any | J. 2 curies |
| K. Indium-111 | K. Any | K. 500 millicuries |
| L. Fluorine-18 | L. Any | L. 4 curies |
| M. Gallium-67 | M. Any | M. 1 curie |
| N. Iodine-123 | N. Any | N. 500 millicuries |

9. Authorized Use:

- A. through E., I. and J through N. Preparation and distribution of radioactive drugs including redistribution of unused molybdenum-99/technetium-99m to authorized recipients on accordance with 10 CFR 32.72.
- F. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11 provided the packaging and labeling remain unchanged
- G. 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 or under equivalent licenses of Agreement States
- H. Shielding for Mo-99/Tc-99m generators.

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

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SUPPLEMENTARY SHEET**

License Number
24-04206-08MD

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CONDITIONS

- 10 License material shall be used only at the licensee's facilities located at 1827 Belt Way Drive, Overland, Missouri.
11. The Radiation Safety Officer for this license is Jerrod Brown, R Ph
12. Licensed material shall be used by, or under the supervision of:
- A. A pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2) and (4), or
- B. Authorized nuclear pharmacists:**
- | | | |
|------------------------|------------------------|-----------------|
| Dennis Davis | Chau Bosgraaf | |
| Debra (Debrowiak) Ross | Andrew J. Farrow | Joseph M. Huber |
| Todd Kliche | David Wright Persinger | Fred Gattas |
| David McLeland | Stephen Pugh | Jerrod Brown |
| Kyle Oelrichs | Jonathan Vaught | Adam Rahman |
| Joseph Blair | | |
13. 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 a period of 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 on the test sample. If the test reveals 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

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- 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.
14. Sealed sources containing licensed material shall not be opened
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. The licensee may transport licensed material in accordance with the provisions of 10CFR Part 71, "Packaging and Transportation of Radioactive Material."
17. 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.
18. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements and representations in application dated February 15, 2007.
19. 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. Application dated February 15, 2007; and

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- B. Letters dated June 21, 2007, July 19, 2007, June 17, 2008, July 3, 2008, February 10, 2009, March 31, 2009, May 28, 2009 and June 11, 2009.

FOR THE U S NUCLEAR REGULATORY COMMISSION

Date JUL 08 2009

By

James R. Mullauer, M.H.S.
Materials Licensing Branch
Region III

ATTACHMENT B
NRC LICENSE# 24-04206-15MD

Official Use Only - Security-Related Information

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

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Amendment No. 18

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.

<p align="center">Licensee</p> <p>1. Mallinckrodt, Inc.</p> <p>2. 675 McDonnell Boulevard P.O. Box 5840 St. Louis, Missouri 63134</p>	<p>In accordance with the letter dated April 17, 2009,</p> <p>3. License number 24-04206-15MD is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date March 31, 2013</p> <hr/> <p>5. Docket No. 030-32952 Reference No.</p>
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| <p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material with atomic numbers 1 through 83, except molybdenum 99, technetium 99m, iodine 131, xenon 133, and yttrium 90</p> <p>B. Molybdenum 99</p> <p>C. Technetium 99m</p> <p>D. Iodine 131</p> <p>E. Xenon 133</p> <p>F. Yttrium 90</p> <p>G. Any Byproduct material permitted by 10 CFR 31.11</p> <p>H. Any Byproduct material permitted by 10 CFR 35.65(a)</p> <p>I. Depleted Uranium</p> | <p>7. Chemical and/or physical form</p> <p>A. Any, except sealed sources</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Any</p> <p>F. Any</p> <p>G. Prepackaged Kits for <u>in vitro</u> diagnostic tests</p> <p>H. Sealed Sources</p> <p>I. Metal</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 500 millicuries per radionuclide and 1 curie total (See Condition 13)</p> <p>B. 200 curies</p> <p>C. 200 curies</p> <p>D. 999 millicuries</p> <p>E. 4 curies</p> <p>F. 1 curie</p> <p>G. 20 millicuries</p> <p>H. 300 millicuries</p> <p>I. 999 kilograms</p> |
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9 Authorized use:

- A through F. Preparation and distribution of radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
- B and C. Redistribution of used and unused molybdenum 99/technetium 99m generators to authorized recipients for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients

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- G. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11 provided the packaging and labeling remain unchanged.
- H. Redistribution for medical use of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74. Redistribution for non-medical use of sealed sources that have been registered either with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with a Commission or Agreement State specific license authorizing distribution to persons specifically authorized by a Commission or Agreement State license to receive, possess and use the devices.
- I. Shielding for molybdenum-99/technetium-99m generators.

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at 180 Pepe's Farm Road, Milford, Connecticut.
- 11. The Radiation Safety Officer for this license is Richard Hylinski, R.Ph.
- 12. Licensed material shall be used by, or under the supervision of:
 - A. A pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2)(i) or (4).
 - B. Authorized nuclear pharmacists: Ayoola O. Aladesanmi, Kerry Eberly, Thu N. Dang, Joseph Remesz-Guerrette, R.Ph., Richard Hylinski, John Keenan, Michael J. Loiseau, David McLeland, Val V. Nassiri, Kerry P. Pallien, Elisabeth Pietronigro, Blessen Varghese, or Henry Wielgosz
- 13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
- 14. This license does not authorize commercial distribution of licensed material to persons exempt from licensing pursuant to 10 CFR 30.14 through 30.21, inclusive, or equivalent regulations of any Agreement State.
- 15. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months or at the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.

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- 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 the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
 - C. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.
 - D. 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 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 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals 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.
 - F. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
 - G. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.
16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
17. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

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18. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
- A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
 - B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and
 - C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.
19. The licensee is authorized to retrieve, receive and dispose of radioactive waste from its customers limited to radiopharmacy supplied syringes and vials and their contents.
20. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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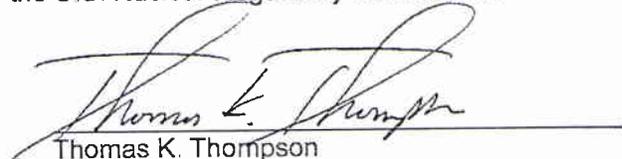
21. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated October 28, 2002 [ML023080091]
- B. Letter dated February 24, 2003 [ML030690006]
- C. Letter dated September 11, 2003 [ML032690114]
- D. Letter dated October 1, 2003 [ML032890442]
- E. Letter dated May 9, 2005 [ML051430332]
- F. Letter dated May 13, 2005 [ML051430335]
- G. Letter dated September 26, 2005 [ML052790622]

For the U.S. Nuclear Regulatory Commission

Date May 4, 2009

By



Thomas K. Thompson
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

Monday, May 4, 2009 07:22:48

ATTACHMENT C
FLORIDA LICENSE# 1937-3

STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

RADIOACTIVE MATERIALS LICENSE

Pursuant to Chapter 404, Florida Statutes, and Chapter 64E-5 Florida Administrative Code (F.A.C.), and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to receive, acquire, possess and transfer the radioactive material(s) designated below and to use such radioactive material(s) for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the state of Florida, Department of Health now or hereafter in effect and to any conditions specified below.

<p style="text-align: center;">Licensee</p> <p>1. Name: MALLINCKRODT, INC.</p>	<p>3 License Number: 1937-3</p> <p>is hereby renewed in its entirety with reference to application, attestation, and correspondence dated July 7, 2009.</p>
<p>2. Address: 675 McDonnell Boulevard Hazelwood, MO 63042</p>	<p>4. Expiration Date: 7/31/2014</p> <p>5. Category: 3B</p>

6. Radioactive Material (element and mass number)	7. Chemical And/Or Physical Form	8. Maximum Quantity Licensee May Possess At Any One Time
A. Molybdenum 99	A. Any molybdenum/ technetium 99m generator manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to section 64E-5.210, F.A.C., or a specific license issued to a manufacturer by the U.S. Nuclear Regulatory Commission (NRC) or an agreement state pursuant to equivalent regulations	A. 200 Curies
B. Any radioactive material authorized under section 64E-5.617, F.A.C.	B. Any sealed source listed in section 64E-5.617, F.A.C.	B. 200 millicuries total for all sources authorized under subitem 6.B.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

6. Radioactive Material (element and mass number)	7. Chemical And/Or Physical Form	8. Maximum Quantity Licensee May Possess At Any One Time
C. Xenon 133	C. Unit dose containers of gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by the Food and Drug Administration (FDA) or an active (i.e., not withdrawn, terminated or on "clinical hold") "Investigational New Drug Application" (IND) that has been accepted by the FDA	C. 7 Curies
D. Technetium 99m	D. Any form described in sections 64E-5.626 and 64E-5.627, F.A.C.	D. 200 Curies
E. Iodine 131	E. Any form described in section 64E-5.626, 64E-5.627 and 64E-5.630, F.A.C.	E. 999 millicuries
F. Any radioactive material except iodine 131 and technetium 99m, described in section 64E-5.626, F.A.C.	F. Any form described in section 64E-5.626, F.A.C.	F. 100 millicuries total possession limit
G. Any radioactive material except iodine 131, and technetium 99m, described in section 64E-5.627, F.A.C.	G. Any form described in section 64E-5.627, F.A.C.	G. 5 Curies total possession limit
H. Any radioactive material except iodine 131 described in section 64E-5.630, F.A.C.	H. Any form described in section 64E-5.630, F.A.C.	H. 1,500 millicuries total possession limit

License Number: 1937-3
Amendment No.: 38
Control Number: 20090709-1032

LICENSEE COPY

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Category: [3B]

Expiration Date: 7/31/2014a

STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

6. Radioactive Material (element and mass number)	7. Chemical And/Or Physical Form	8. Maximum Quantity Licensee May Possess At Any One Time
I. Any radioactive material listed in sections 64E-5.206(7) and (8), F.A.C.	I. Prepackaged in vivo and in vitro diagnostic test kits	I. 20 millicuries total for in vivo kits and 20 millicuries total for in vitro kits
J. Uranium 238	J. Depleted metal	J. 993 pounds

9. AUTHORIZED USES

- A. Production of technetium 99m pertechnetate. Redistribution of unused generators and associated depleted uranium shielding to authorized recipients in accordance with statements, representations and procedures contained in the application dated March 25, 2004, and statements or representations identified in Condition 24.
- B. To be used for instrument calibration. Redistribution of sources to specifically authorized recipients. Pursuant to section 64E-5.210, F.A.C., the licensee is authorized to redistribute sources to persons licensed pursuant to section 64E-5.601, F.A.C., or under equivalent licenses of the NRC or an agreement state.
- C. For dispensing, distributing or redistributing prepared radiopharmaceuticals to authorized recipients. For distribution as calibration or reference standard to authorized recipients.
- D. For dispensing, distributing or redistributing prepared radiopharmaceuticals to authorized recipients. For distribution as calibration or reference standard to authorized recipients. For use of technetium 99m pertechnetate for processing with reagent kits in preparing radiopharmaceuticals.
- E. – H. For dispensing, distributing or redistributing prepared radiopharmaceuticals to authorized recipients. For distribution as calibration or reference standard to authorized recipients.
- I. Redistribution to general and specific licensees in accordance with statements, representations and procedures contained in the application dated March 25, 2004, and statements or representations identified in Condition 24.
- J. To be used as shielding for molybdenum 99/technetium 99m generators.

CONDITIONS

- 10. The authorized place of use is the licensee's facility located at 5135 Adanson, Suite 900, Orlando, Florida, 32804.

License Number: 1937-3
Amendment No.: 38
Control Number: 20090709-1032

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Category: [3B]
Expiration Date: 7/31/2014a

STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

11. Failure to comply with the provisions of this license is a felony of the third degree pursuant to section 404.161, Florida Statutes. Also, violations may warrant an administrative fine of up to \$1,000.00 per violation per day, pursuant to section 404.162, Florida Statutes.
12. A. Licensed material shall be used by, or under the supervision and in the physical presence of at least one of the below listed nuclear pharmacists. Licensed material may also be used by, or under the supervision and in the physical presence of a visiting nuclear pharmacist. A visiting nuclear pharmacist may work for up to 60 days each calendar year, provided the licensee's management approves, in writing, each visiting nuclear pharmacist; the licensee maintains a copy of that individual's licensure from the Florida Board of Pharmacy as a nuclear pharmacist; and the licensee maintains a record of each visitation. Copies of these records shall be maintained for 5 years after the visiting nuclear pharmacist's last visit.

<u>Authorized Users</u>	<u>Authorized Users</u>
Peter Ancona, R.Ph. Robert Armstrong, R.Ph. David Bock, R.Ph. Dennis Davis, R.Ph. Carol Gammage, R.Ph. William Gray, R.Ph. Lawrence Rush, R.Ph. Zobeida Torras, R.Ph. John Scott Warner, R.Ph. Henry Wielgosz, R.Ph.	Darrell R. Harvey, R.Ph. Ryan Kazmierczak, R.Ph. Lisa Leonard Koss, R.Ph. Ronald E. Kraus, R.Ph. Marc Mesadieu, R.Ph. David McLeland, R.Ph. Kirk Price, R.Ph. Uzuazomaro E. Ubogu, R.Ph. Brian Osterberg, R.Ph.

- B. The radiation safety officer is Ryan Kazmierczak, R.Ph.
13. Radioactive material transported on public thoroughfares shall be packaged, prepared for shipment, and transported in accordance with Title 49, Code of Federal Regulations and Chapter 64E-5, F.A.C.
14. Pursuant to section 64E-5.210, F.A.C., the licensee is authorized to distribute the radioactive material described in Items 6, and 7 of this license to persons licensed pursuant to section 64E-5.601, F.A.C., or under equivalent licenses of the NRC or an agreement state, for the uses indicated below:
- A. Unused molybdenum 99/technetium 99m, rubidium 81/krypton 81m, tin 113/indium 113m or yttrium 87/strontium 87m generators and associated depleted uranium shielding may be redistributed to persons licensed pursuant to section 64E-5.627, F.A.C.

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14. B. Any form listed in each section, radioactive materials described in sections 64E-5.626, 64E-5.627, 64E-5.630 and 64E-5.632, F.A.C., may be redistributed to persons licensed pursuant to that section.
15. Sealed sources containing licensed material shall not be opened.
16. Radiopharmaceuticals shall be assayed in a dose calibrator to accurately measure the activity of the radiopharmaceutical before administration. Instruments utilized in the assay of pure alpha or beta-emitting radiopharmaceuticals shall be calibrated in accordance with the dose calibrator's or drug manufacturer's instructions. The licensee shall maintain copies of these procedures for inspection by the department.
17. The licensee shall assure that each sealed source is tested for leakage or contamination and follow the appropriate actions as required by section 64E-5.1303, F.A.C. Licensed material shall be tested at least every 6 months. The test sample (smear) shall be taken by the licensee using an approved leak test kit. Analysis of the test sample shall be performed by individuals who are licensed by the department, NRC, agreement state, or licensing state to provide these services. The licensee is required to retain leak test records containing the manufacturer's name, model and serial number of each sealed source tested, identity of each sealed source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries, the date of the test and signature of the radiation safety officer or designee. The records shall be maintained for 3 years for inspection by the department.
18. The licensee shall conduct a physical inventory and inspection at least every 6 months to account for all sealed sources received and possessed under this license as required by section 64E-5.1304, F.A.C. Inventory records shall be maintained for 3 years from the date of the inventory for inspection by the department, and shall include the manufacturer's name, model and serial numbers of each sealed source, the identity of each sealed source radionuclide and its estimated activity, the location of each sealed source, the date of the inventory and the signature of the radiation safety officer(s) or designee.
19. The licensee shall notify the Bureau of Radiation Control within 48 hours of any misadministration of licensed material that occurred as a result of activities conducted under the authority of this license. Records of these misadministrations shall be maintained indefinitely for inspection by the department.
20. The licensee shall elute generators and process radioactive material with reagent kits in accordance with instructions furnished by the manufacturer on the label attached to, or in, the leaflet or brochure that accompanies the generator or reagent kit; otherwise reagent kits must be prepared and compounded from a prescription in accordance with the regulations of the Florida Board of Pharmacy.

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21. A. The licensee shall perform a test to detect and quantify the activity of molybdenum 99 contamination in each elution of technetium 99m from a molybdenum 99/technetium 99m generator and in each extraction or separation of technetium 99m from molybdenum 99 not contained in a generator.
- B. The licensee shall not distribute technetium 99m for human use if the technetium 99m contains more than 0.15 microcurie of molybdenum 99 per millicurie of technetium 99m at the time of administration. The expiration date and time shown on the package label shall be such that the limits above are not exceeded for any single patient dose. The limits for molybdenum 99 contamination represent maximum values and molybdenum 99 contamination should be kept as low as reasonably achievable below these limits.
- C. The licensee shall establish written procedures for personnel performing tests to detect and quantify molybdenum 99 contamination. These procedures shall include all necessary calculations and steps to be taken if activities of molybdenum 99 in excess of the limits specified in paragraph B, above, are detected.
- D. Personnel performing tests to detect and quantify molybdenum 99 contamination shall be given specific training in performing these tests prior to conducting such tests.
- E. (1) The licensee shall maintain for inspection by the department, records of the results of each test performed to detect and quantify molybdenum 99 contamination and records of training given to personnel performing these tests.
- (2) Records described in paragraph E.(1), above, shall be maintained for 3 years following the performance of the tests and the training of personnel.
22. The licensee is authorized to collect and dispose of radioactive waste in the form of contaminated syringes, needles, vials and unused doses, except for materials described in section 64E-5.632, F.A.C., from their customers only when these materials were originally supplied by the licensee. This condition does not authorize the receipt of any other forms of radioactive waste.
23. Individuals involved in operations which utilize, at any one time or over a 3 month period, radioiodine in an unsealed form that exceeds the activities specified in table 1 of the U.S. Nuclear Regulatory Commission (NRC) Regulatory Guide 8.20 shall have bioassays performed at the following frequency and follow the corresponding actions:
- A. (1) A bioassay shall be taken within 72 hours of initial use of radioiodine and every 2 weeks thereafter, except for personnel compounding therapeutic iodine 131 capsules shall be tested every week. When radioiodine use is on an infrequent basis (less than every 2 weeks), a bioassay shall be taken within 10 days of the last day of use.

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23. A. (II) The licensee shall take the corresponding actions according to the action levels listed below:
- (a) If the thyroid burden at the time of measurement exceeds 0.12 microcurie of iodine 125 or 0.04 microcurie of iodine 131, the following actions shall be taken:
- (1) An investigation of the operations involved, including air and other facility surveys, shall be carried out to determine the cause(s) of exposure and to evaluate the potential for further exposures;
 - (2) If the investigation indicates that further work in the area might result in the worker to exceed the applicable limits established in sections 64E-5.304, 64E-5.310, or 64E-5.311, F.A.C., the licensee shall restrict the worker from further exposure until the source of exposure is discovered and corrected;
 - (3) Corrective actions that will eliminate or lower the potential for further exposures shall be implemented;
 - (4) A repeat bioassay shall be taken within 2 weeks of the previous measurement and shall be evaluated within 24 hours after the measurement in order to confirm the presence of internal radioiodine and to obtain an estimate of its effective half-life for use in estimating dose commitment; and
 - (5) Notification reports must be provided as required by sections 64E-5.345, and 64E-5.347, F.A.C., and as required by conditions of the license.
- (b) If the thyroid burden at any time exceeds 0.5 microcurie of iodine 125 or 0.14 microcurie of iodine 131, the following actions shall be taken:
- (1) Carry out all steps described in A.(II)(a) of this condition;
 - (2) As soon as possible, refer the case to appropriate medical consultation for recommendations regarding therapeutic procedures that may be carried out to accelerate removal of radioactive iodine from the body; and
 - (3) Carry out repeated measurements at approximately one week intervals at least until the thyroid burden is less than 0.12 microcurie of iodine 125 or 0.04 microcurie of iodine 131.

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23. B. (I) Bioassays may be performed quarterly, if the following conditions are satisfied:
- (a) The average thyroid burden for each individual working in a given area for which bioassays were performed pursuant to item A.(I), above, was less than 0.12 microcurie of iodine 125, less than 0.04 microcurie of iodine 131 and less than the corresponding proportionate amount of a mixture of these nuclides during the initial 3 month period;
 - (b) (1) If measurements of the concentration of radioiodine in air are required as a condition of the license and the quarterly average concentration does not exceed 25 percent of the value for iodine 125, iodine 131 or a proportionate amount of a mixture of these nuclides as specified Derived Air Concentration (DAC) in table I, column I in the State Of Florida Bureau of Radiation Control, ALIs, DACs, and Effluent Concentrations July 1993 or
 - (2) If a dose determination is performed as a condition of the license and 25 percent of the applicable limits specified in section 64E-5.304, 64E-5.310, or 64E-5.311, F.A.C., are satisfied;
 - (c) The working conditions during the 3 month period with respect to the potential for exposure are representative of working conditions during the period in which the quarterly bioassay frequency is employed, and there is no reasonable expectation that the criteria given in B.(I)(a) and B.(I)(b) will be exceeded; and
 - (d) Bioassays shall be randomly distributed over the quarter and will be done within 1 week after a procedure involving the handling of iodine 125 or iodine 131 to provide a representative assessment of exposure conditions.
- (II) If the thyroid burden exceeds 0.12 microcurie of iodine 125 or 0.04 microcurie of iodine 131, the following actions shall be taken:
- (a) Carry out all steps as described in A.(II)(a) and A.(II)(b) of this condition; and
 - (b) Reinstitute bioassays every 2 weeks for at least the next 3 months before reestablishing quarterly bioassays.

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ATTACHMENT D
MICHIGAN BOARD OF PHARMACY LICENSES



Name and Address

Name : DEBRA ANN ROSS
Address : Ballwin, MO 630214475

Profession and License/Registration Information

Profession : Pharmacy		Type : Pharmacist	
Permanent ID #	Status	Issue Date	Expiration Date
5302028485	Active	07/30/1991	06/30/2010

Complaint(s)

Open Formal Complaints
None

Disciplinary Action

Disciplinary Action
None

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For those licensees/registrants who have actions listed in the **Disciplinary Action** section above, the date the licensee/registrator with their board order is listed for all disciplinary actions subsequent to January 1, 2005. The date of compliance is not listed for disciplinary actions that began prior to that date. You should check with our office to confirm the status of the cases if the date of compliance is

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x

Name and Address

Name : JOSEPH MICHAEL REMESZ-GUERRETTE

Address : Stratford, CT 06614

Profession and License/Registration Information

Profession : Pharmacy

Type : Pharmacist

Permanent ID #

Status

Issue Date

Expiration Date

5302035047

Active

08/17/2007

06/30/2010

Complaint(s)

Open Formal Complaints

None

Disciplinary Action

Disciplinary Action

None

x New Search

x

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Name and Address

Name : BRIAN LEE OSTERBERG

Address : Orlando, FL 32828

Profession and License/Registration Information

Profession : Pharmacy

Type : Pharmacist

Permanent ID #

Status

Issue Date

Expiration Date

5302031396

Active

07/31/1997

06/30/2010

Complaint(s)

Open Formal Complaints

None

Disciplinary Action

Disciplinary Action

None

New Search

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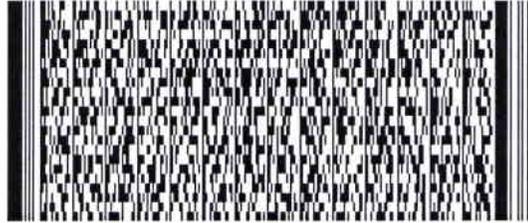
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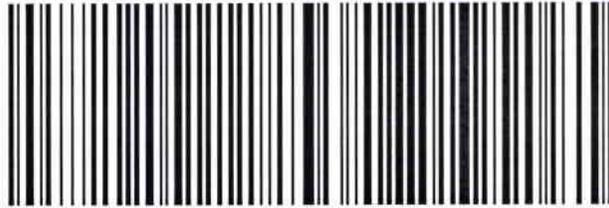


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