

August, 2 2007

NMSB2

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

03032952

RE: Material License #24-04206-15MD (Milford, CT)

2007 AUG - 6 AM 10:34
RECEIVED
REGION I

Dear License Reviewer:

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

1. Amend Item 9.H 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 the list of Authorized Nuclear Pharmacists for the above referenced radioactive material license to the following:

Thu N. Dang, R.Ph.	Michael J. Loiseau, R.Ph.
Richard S. Hylinski, R.Ph.	John P. Minella, R.Ph.
John J. Keenan, R.Ph.	Val V. Nassiri, R.Ph.

Mr. Hylinski, Mr. Keenan, and Mr. Minella are currently listed as ANPs on this license (24-04206-15MD).

Mr. Dang is listed as an ANP on our Bethlehem, Pennsylvania license 24-04206-17MD, included as Attachment A.

Mr. Nassiri is listed as an ANP on our Pine Brook, New Jersey license 24-04206-14MD, included as Attachment B.

140912

NMSS/RGN1 MATERIALS-002

Mr. Loiseau is listed as an ANP on our Wilkes-Barre, Pennsylvania license 24-04206-16MD, included as Attachment C.

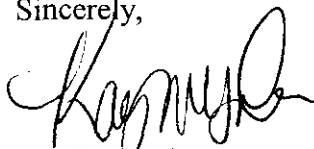
Documentation of registration with the Connecticut Department of Consumer Protection as licensed pharmacists for each individual is included as Attachment D.

Please delete all other names listed as ANPs for this license: Steven Alvey, Margaret Anderson, Jacqueline E. Anglin-Dixon, Brian Auger, Terry Austin, Christine Basilone, Wendy Lou Baumering, Quent Besing, Amy Bettle, Thomas Brady, John Briggs, Barry Brown, Nancy Cahill, Robert Chandler, Padmesh Chhita, Harold Cleveland, Matthew Coccaro, Daniel Coffman, Cheryl Cordum, Brian Cox, William Crawford, Dennis Davis, Vicky Davis, Rodney Detrow, Kenneth DeTurk, Vincent DiSpigno, Greg Edquist, Oliver Emberger, Allen Fazekas, Joseph Fery, Thomas Firman, James Flynn, Lori Follis (DeVos), Joseph Gatton, Rudolph Gilliam, Bonnie Gindling, Margaret Glennon, Christine Goetting (Sureus), Kelly Hall, David Hart, David Hartter, Elaine Haynes, Michael Hess, Henry Jahn, Homan Jarrar, Lucie Kawaguchi, Michael Klug, Scott Knishka, Raymond Komosinski, Lisa Koss (Leonard), Timothy Layne, Sam Shen-Shin Ling, Paul Lukas, David Lutes, Thomas Mabis, John Manzi, Brad Martin, John Martin, Deborah McDowell (Cashabaugh), Thomas McKean, Barbara Missal, Richard Nickel, Michael Palmer, Amit Parikh, Neal Patel, Craig Petzold, Karen Pieszala, David Poydence, Charles Reed, Debra Ross, Michael Rossi, Warren Salomon, Barbara Scavullo, Richard Schafer, David Schmitt, Steven Schultz, David Senko, Aly Sharaf, Nakia McArthur Shaw, Mary Sue Shrum, James Sorensen, Gary Spence, Michael Stipanovich, Wayne Toal, Sally DuAnn Vanderslice, Deborah Vanerka (Wierzba), Thomas Viering, Tracey Villa, Anthony Volpe, Donald Warner, Todd Warren, Genevieve Watanabe, Randall Watt, Larry Weidner, Henry Weilgosz, Jeff Williams, Jason Willman, Brian Wong, and Richard Wride.

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 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: R. Hylinski, R.Ph., Radiation Safety Officer (Milford, CT)
A. Chance, Manager, Radiological Affairs (Hazelwood, MO)

ATTACHMENT A
U.S. NRC License 24-04206-17MD

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 1. Mallinckrodt, Inc. 2. 675 McDonnell Boulevard P.O. Box 5840 St. Louis, Missouri 63134		In accordance with the letter dated April 26, 2006, ✓ 3. License No. 24-04206-17MD is amended in its entirety to read as follows: 4. Expiration Date: February 28, 2014 5. Docket No. 030-33157
6. Byproduct, source, and/or special nuclear material A. Any byproduct material with atomic numbers 1 through 83, except molybdenum-99, technetium-99m, iodine-131 and xenon-133 B. Yttrium 90 C. Molybdenum 99 D. Technetium 99m E. Iodine 131 F. Xenon 133 G. Any byproduct material listed in 10 CFR 31.11(a) H. Any byproduct material authorized under 10 CFR 35.65(a) I. Depleted Uranium	7. Chemical and/or physical form A. Any B. Any C. Any D. Any E. Any F. Any G. Prepackaged units for <u>in vitro</u> diagnostic tests H. Sealed sources (North American Scientific Models MED 3550 and CAL 2702) I. Metal	8. Maximum amount that licensee may possess at any one time under this license A. 0.5 curies per radionuclide and 1 curie total B. 1 curie C. 200 curies D. 200 curies E. 5 curies F. 7 curies G. 20 millicuries H. 300 millicuries I. 600 kilograms

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License No.
24-04206-17MDDocket No.
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9. Authorized use:

- A. - F. Preparation, including compounding of iodine 131, 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. Redistribution of 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. Redistribution of xenon-133 for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
- G. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11 provided the packaging and labeling remain unchanged.
- H. Calibration and checking of the licensee's instruments. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74 to authorized recipients and to authorized recipients for non-medical use.
- 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 2299 Brodhead Road, Suites H and I, Bethlehem, Pennsylvania.
11. 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:

Allen Ayala
Christine Basilone
Wendy Lou Baumering
Quent Besing
Christine A. Bortz
Thomas Brady
Christopher Brunner
Padmesh Chhita
William Crawford
Thu Dang
Dennis Davis

Rudolph Gilliam
Bonnie Gindling
Kelly Hall
David Hart
Shanna Henninger
Richard Hylinski
John Keenan
Michael Klug
Lisa Koss (Leonard)
Timothy Layne

Richard Nickel
Amit Parikh
Neal Patel
Payal Patel
Craig Petzold
Karen Pieszala
David Poydence
Debra Ross
Aly Sharaf
Mary Sue Shrum

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James Dawson
Kerry Eberly
Thomas Firman
James Flynn
Lori Follis (DeVos)
Joseph Gatton

David Lutes
Brad Martin
John Martin
Matthew Mauro
Berry Joe Means
John Minella

Gary Spence
Wayne Toal
Sally DuAnn Vanderslice
Deborah Vanerka (Wierzbna)
Jason Willman
Richard Wride

12. The Radiation Safety Officer (RSO) for this license is Kerry Eberly, R.Ph.
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), 40.36(b), and 70.25(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 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.
- 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.

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- 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 five 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 five 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.
18. The licensee is authorized to hold radioactive 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 it:
- 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 and 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 material for three years. The record must include the date of the 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.

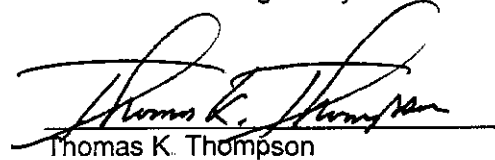
**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License No.
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19. The licensee is authorized to retrieve, receive and dispose of radioactive waste from its customers limited to radiopharmacy supplied syringes and vials and their contents.
20. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
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 July 11, 2003 [ML032020148] ✓
B. Letter dated September 11, 2003 [ML032690128] ✓
C. Letter dated October 1, 2003 [ML032890442] ✓
D. Letter dated January 23, 2004 [ML040430631] ✓
E. Letter dated May 9, 2005 [ML051430332] ✓
F. Letter dated May 13, 2005 [ML051430335] ✓

For the U. S. Nuclear Regulatory Commission

Date May 17, 2006

By

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

Wednesday, May 17, 2006 10:43:26 AM

ATTACHMENT B
U.S. NRC License 24-04206-14MD

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 the letter dated May 14, 2007,	
1. Mallinckrodt Inc.		3. License No. 24-04206-14MD	
2. 675 McDonnell Boulevard P.O. Box 5840 St. Louis, Missouri 63134		is amended in its entirety to read as follows:	
		4. Expiration Date: March 31, 2013	
		5. Docket No. 030-32951	
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 1 through 83, except molybdenum 99, technetium 99m, iodine 131, xenon 133, and yttrium 90	A. Any, except sealed sources	A. 500 millicuries per radionuclide and 1 curie total	
B. Molybdenum 99	B. Any	B. 200 curies	
C. Technetium 99m	C. Any	C. 200 curies	
D. Iodine 131	D. Any	D. 1 curie	
E. Xenon 133	E. Any	E. 6 curies	
F. Yttrium 90	F. Any	F. 1 curie	
G. Any byproduct material listed in 10 CFR 31.11	G. Prepackaged units for <i>in vitro</i> diagnostic tests	G. 20 millicuries	
H. Any byproduct material authorized under 10 CFR 35.65(a)	H. Sealed sources	H. 300 millicuries	
I. Depleted Uranium	I. Metal	I. 999 kilograms	

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SUPPLEMENTARY SHEET**License No.
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9. Authorized use:

- A - 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 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.
- G. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11 provided the packaging and labeling remained unchanged.
- H. Calibration and checking of the licensee's instruments. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74 to authorized recipients and to authorized recipients for non-medical use.
- 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 26 Chapin Road, Unit 1110, Pine Brook, New Jersey.

11. 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:

Danielle Burroughs (King)
Denise Callender
Padmesh Chhita
Bonnie Ciechanowicz (Gindling)
Gertrude Etta

Thomas Firman
Neal Khazana (Patel)
Brad Martin
Val Nassiri
Hoang T. Nguyen

Payal Patel
Yogesh Patel
Barbara Scavullo
Zury-Lin Sheng
Jason Willman

12. The Radiation Safety Officer (RSO) for this license is Hoang T. Nguyen, R. Ph.

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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) and 10 CFR 40.36(b) for establishing decommissioning financial assurance.
14. This license does not authorize 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 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.
- 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 five years.

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16. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.
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 five 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.
18. The licensee is authorized to hold radioactive 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 it:
 - 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 material for three years. The record must include the date of the 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."

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License No.
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28

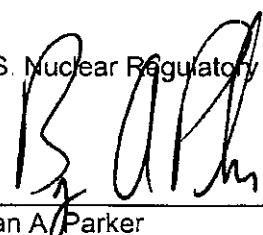
21. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U. S. Nuclear Regulatory Commission's regulations shall govern 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 [ML023080077]
- B. Letter dated February 24, 2003 [ML030690024]
- C. Letter dated September 11, 2003 [ML032690068]
- D. Letter dated October 1, 2003 [ML032890442]
- E. Letter dated May 9, 2005 [ML051430332]
- F. Letter dated May 13, 2005 [ML051430335]
- G. Letter dated August 12, 2005 [ML052340302]
- H. Letter dated March 27, 2006 [ML060890428]

For the U. S. Nuclear Regulatory Commission

Date June 14, 2007

By


Bryan A. Parker
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

Thursday, June 14, 2007 1:56:42 PM

Attachment C
U.S. NRC License 24-04206-16MD

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 the letter dated August 1, 2006,
1. Mallinckrodt, Inc.		3 License No. 24-04206-16MD
2. 675 McDonnell Boulevard P O Box 5840 St. Louis, Missouri 63134		is amended in its entirety to read as follows:
		4. Expiration Date: June 30, 2014
		5. Docket No. 030-32971
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 1 through 83, except molybdenum 99, technetium 99m, iodine 131, xenon 133, and yttrium 90	A. Any	A. Not to exceed 500 millicuries per radionuclide and 1 curie total
B. Molybdenum 99	B. Any	B. 200 curies
C. Technetium 99m	C. Any	C. 200 curies
D. Iodine 131	D. Any	D. 2.5 curies
E. Xenon 133	E. Any	E. 4 curies
F. Yttrium 90	F. Any	F. 1 curie
G. Any byproduct material listed by 10 CFR 31.11(a)	G. Prepackaged units for <u>in vitro</u> diagnostic tests	G. 20 millicuries
H. Any byproduct material authorized under 10 CFR 35.65(a)	H. Sealed sources	H. 100 millicuries
I. Depleted uranium	I. Metal	I. 600 kilograms

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License No.
24-04206-16MDDocket No.
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9. Authorized use:

- A. - F. Preparation and distribution of radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72 and to authorized recipients for non-medical use.
- B. & C. Redistribution of 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.
- G. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11 provided the packaging and labeling remain unchanged.
- H. Calibration and checking of the licensee's instruments. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74 to authorized recipients and to authorized recipients for non-medical use.
- I. Shielding for molybdenum-99/technetium-99m generators.

CONDITIONS

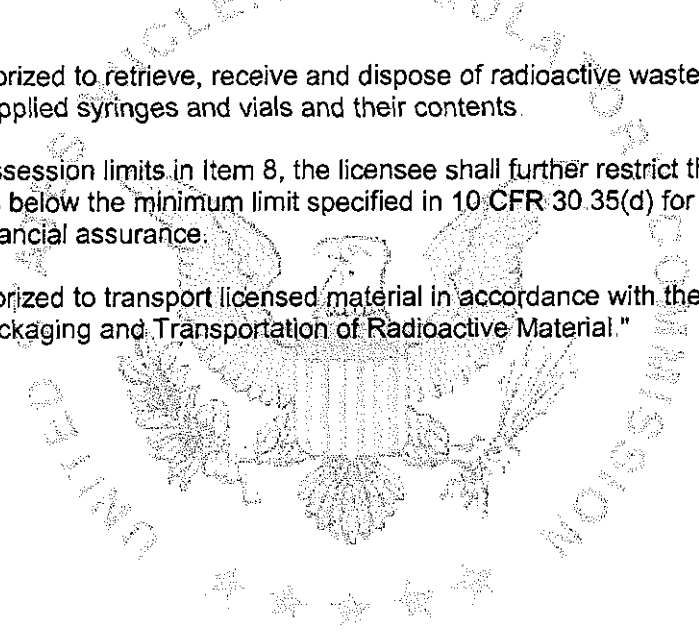
- 10. Licensed material may be used or stored only at the licensee's facilities located at 300 Laird Street, Wilkes-Barre, Pennsylvania.
- 11. The Radiation Safety Officer (RSO) for this license is Michael Loiseau, R.Ph.
- 12. Licensed material shall be used by, or under the supervision of:
 - A. A pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2)(I) or (4).
 - B. Authorized Nuclear Pharmacists:

Brandon Baker	John Keenan	David Poydence
Christine Basilone-Treolo	Timothy Layne	Kirk Price
Padmech Chhita	Michael Loiseau	Robert Schork
Kerry Eberly	Brad Martin	Zury Lin Sheng
Andrew Gerner	Berry Means	Gary Spence
Michael Haigh	Michael Mezeivtch	Michael Stipanovich
Todd Hays	Karen Pieszala	Henry Wielgosz
Kerry Iannielli	Cynthia Posey	
- 13. 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.

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030-32971Amendment No.
23

14. 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 the U. S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of 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 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 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.
- E. 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.
- F. Records of leak test results shall be kept in units of microcuries and shall be maintained for five years.
15. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
16. 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 five 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.
17. The licensee is authorized to hold radioactive 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 it:
- 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

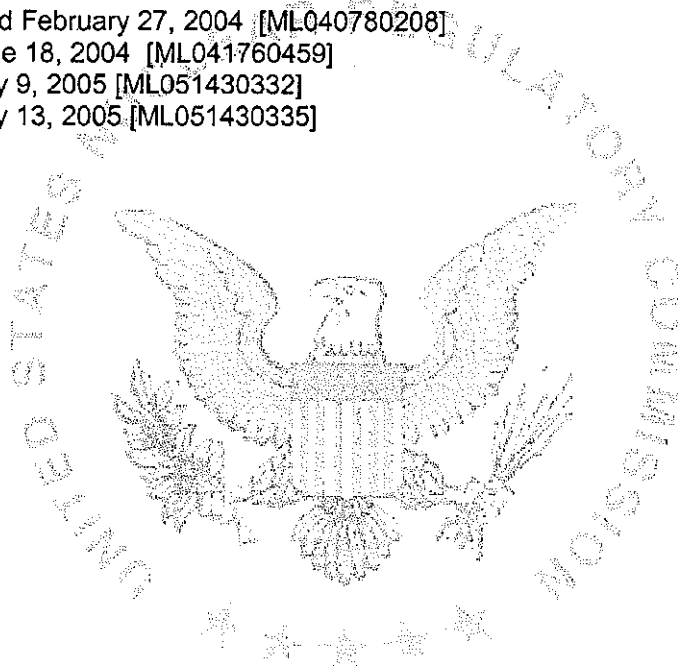
**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License No.
24-04206-16MDDocket No.
030-32971Amendment No.
23

- B. Removes and 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 material for three years. The record must include the date of the 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.
18. 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.
19. 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.
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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23

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 February 27, 2004 [ML040780208]
- B. Letter dated June 18, 2004 [ML041760459]
- C. Letter dated May 9, 2005 [ML051430332]
- D. Letter dated May 13, 2005 [ML051430335]



For the U. S. Nuclear Regulatory Commission

Date August 4, 2006


By


Elizabeth UllrichCommercial and R&D Branch
Division of Nuclear Materials Safety
Region I

King of Prussia, Pennsylvania 19406

Friday, August 04, 2006 7:17:58 AM

Attachment D
Connecticut Department of Consumer Protection
Pharmacists Licenses

 State of Connecticut Department of Consumer Protection

Online Lookup Detail
THU N DANG

Name and Address

Name

THU N DANG

Address

BETHLEHEM PA 18017

Credential Information

Credential	License Type	Effective Date	Expiration Date	Status	Schedule 1	Schedule 2	Sche
PCT.0010741	PHARMACIST	06/06/2007	01/31/2008	ACTIVE			

Schedules are only applicable to Controlled Substance Practitioner Registrations.
For information on any consumer complaints or agency discipline, if applicable, for this credential holder, please email a request to drug.control@ct



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Online Lookup Detail

RICHARD S HYLINSKI

Name and Address

Name

RICHARD S HYLINSKI

Address

CHESHIRE CT 06410

Credential Information

Credential	License Type	Effective Date	Expiration Date	Status	Schedule 1	Schedule 2	Sche
PCT.0005096	PHARMACIST	02/01/2007	01/31/2008	ACTIVE			

Schedules are only applicable to Controlled Substance Practitioner Registrations.

For information on any consumer complaints or agency discipline, if applicable, for this credential holder, please email a request to drug.control@ct



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 State of Connecticut Department of Consumer Protection

Online Lookup Detail
JOHN J KEENAN

Name and Address

Name

JOHN J KEENAN

Address

WANTAGH NY 11793

Credential Information

Credential	License Type	Effective Date	Expiration Date	Status	Schedule 1	Schedule 2	Sche
PCT.0007883	PHARMACIST	02/01/2007	01/31/2008	ACTIVE			

Schedules are only applicable to Controlled Substance Practitioner Registrations.

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 State of Connecticut Department of Consumer Protection

Online Lookup Detail
MICHAEL J LOISEAU

Name and Address

Name

MICHAEL J LOISEAU

Address

ARCHBALD PA 18403-1579

Credential Information

Credential	License Type	Effective Date	Expiration Date	Status	Schedule 1	Schedule 2	Sche
PCT.0009999	PHARMACIST	02/01/2007	01/31/2008	ACTIVE			

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 State of Connecticut Department of Consumer Protection

Online Lookup Detail

JOHN P MINELLA

Name and Address

Name

JOHN P MINELLA

Address

WESTPORT CT 06880

Credential Information

Credential	License Type	Effective Date	Expiration Date	Status	Schedule 1	Schedule 2	Sche
PCT.0006917	PHARMACIST	02/01/2007	01/31/2008	ACTIVE			

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 State of Connecticut Department of Consumer Protection

Online Lookup Detail

VAL V NASSIRI

Name and Address

Name

VAL V NASSIRI

Address

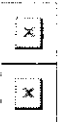
PELHAM NY 10803

Credential Information

Credential	License Type	Effective Date	Expiration Date	Status	Schedule 1	Schedule 2	Schedule 3
PCT.0010689	PHARMACIST	03/05/2007	01/31/2008	ACTIVE			
PTP.0000256	TEMPORARY PERMIT TO PRACTICE PHARMACY	01/19/2007	03/05/2007	CLOSED			

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For information on any consumer complaints or agency discipline, if applicable, for this credential holder, please email a request to drug.control@ct.gov



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

8/2/2007, and to inform you that the initial processing which includes an administrative review has been performed.

☒ ATTEND. 24-04206-15MD
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** 140912.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.