UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

August 4, 2006

Docket No. 03032971 License No. 24-04206-16MD
Control No. 139215

April Chance
Manager, Radiation Health and Safety
Mallinckrodt, Inc.
675 McDonnell Boulevard
PO Box 5840
St. Louis, MO 63134

SUBJECT: MALLINCKRODT, INC., LICENSE AMENDMENT, CONTROL NO. 139215

Dear Ms. Chance:

This refers to your license amendment request. Enclosed with this letter is the amended license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

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

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material;** then **Toolkit Index Page.** Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

Original signed by Elizabeth Ullrich

Elizabeth Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 23

cc:
Michael Loiseau, R.Ph., Radiation Safety Officer

DOCUMENT NAME: G:\Docs\Mailed\Lic Cvr Letter\l24-04206-16.139215.08082006.wpd

SUNSI Review Complete: DLawyer
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NAME	DLawyer/DRL		EUllrich/EU					
DATE	08/04/2006		8/4/2006					

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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 August 1, 2006, 3. License No. 24-04206-16MD 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

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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 Gernerd	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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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©)(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

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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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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 ***Original signed by Elizabeth Ullrich***

Elizabeth Ullrich
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406