NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 33

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.

PC02500 317446

Licensee

1. Mallinckrodt Inc.

2. 675 McDonnell Boulevard
P.O. Box 5840
St. Louis, MO 63134

In accordance with letter dated **August 21, 2008,**

3. License number 24-04206-08MD is amended in its entirety to read as follows:

4. Expiration date **July 31, 2017**

5. Docket No. 030-18546
Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material with atomic numbers 3 through 83 except molybdenum-99, iodine-131, technetium-99m, Yttrium-90 and xenon-133	A. Any form initially distrubuted 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 in vitro diagnostic tests	F. 20 millicuries

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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

9. Authorized Use:

A. through E. and I. 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 labelling 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.

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 **Todd Kliche, R.Ph.**

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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
Debra (Debrowiak) Ross
Todd Kliche
David McLeland
Kyle Oelrichs
Joseph Blair
Chau Bosgraaf
Andrew J. Farrow
David Wright Persinger
Stephen Pugh
Jonathan Vaught
Brenda C. Ochylski
Joseph M. Huber
Fred Gattas
Jerrod Brown
Mathew Burgin

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.

E. Tests for leakage and/or contamination shall be performed by the licensee or other persons specifically licensed by the Commission or an Agreement State to perform such services. In addition, the licensee is authorized to collect leak test samples for analysis by persons specifically licensed by the Commission or an Agreement State to perform such services.

13. Sealed sources containing licensed material shall not be opened.

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

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15. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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

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

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

17. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements and representations in application dated February 15, 2007.

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

    A. Application dated February 15, 2007; and

    B. Letters dated June 21, 2007, July 19, 2007, June 17, 2008, and July 3, 2008.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date OCT 10 2008

By Kevin G. Null
Kevin G. Null
Materials Licensing Branch
Region III