NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 23

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. PC 02500 318499

Licensee	In accordance with letter dated **September 14, 2009,**
1. Mallinckrodt Inc.	3. License number 24-04206-12MD is amended in its entirety to read as follows:
2. 675 McDonnell Boulevard P.O. Box 5840 St. Louis, MO 63042	4. Expiration date July 31, 2012 5. Docket No. 030-32515 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 1 through 83, except molybdenum-99, technetium-99m, iodine-131, xenon-133, and yttrium-90	A. Any	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. 5 curies
E. Xenon-133	E. Any	E. 4 curies
F. Yttrium-90	F. Unsealed for preparation of radiopharmaceuticals for medical use	F. 1 curie
G. Any byproduct materials in a brachytherapy source as listed in 10 CFR 35.400	G. Sealed Sources	G. 4 curies
H. Any byproduct material listed in 10 CFR 31.11(a)	H. Prepackaged units for in vitro diagnostic tests	H. 20 millicuries
I. Any byproduct material authorized under 10 CFR 35.65(a)	I. Sealed Sources	I. 300 millicuries
J. Depleted Uranium	J. Metal	J. 600 kilograms

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
24-04206-12MD
Docket or Reference Number
030-32515
Amendment No. 23

K. Thallium-201	K. Any	K. 2 curies
L. Indium-111	L. Any	L. 1 curie
M. Fluorine18	M. Any	M. 20 curies
N. Gallium-67	N. Any	N. 500 millicuries
O. Iodine-123	O. Any	O. 500 millicuries

9. Authorized use:

A. through F., and K. through O. Preparation and distribution of radioactive drugs including compounding of iodine-131 and redistribution of unused molybdenum-99/technetium-99 generators to authorized recipients in accordance with 10 CFR 32.72. Preparation and distribution of radioactive drugs and radiochemicals including compounding of iodine-131 and redistribution of unused molybdenum-99/technetium-99m generators to authorized recipients for non-medical use.

G. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74. Redistribution of sealed sources that have been registered either with NRC under 10 32.210 or with an Agreement State and have been distributed in accordance with an NRC or Agreement State specific license authorizing distribution to persons specifically authorized by an NRC or Agreement State license to receive, possess, and use the devices.

H. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11 provided the packaging and labeling remain unchanged

I. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74. 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 State recipients.

J. Shielding for Mo99/Tc99m generators

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 712 Westport Road, Kansas City, Missouri

11. Licensed material is only authorized for use 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 (3), or

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
24-04206-12MD
Docket or Reference Number
030-32515
Amendment No. 23

B. Authorized Nuclear Pharmacists:

Chau Bosgraaf	Danielle Burroughs
Dennis Davis	Andrew Farrow
Fred Gattas	Joseph Huber
Adam Kautzner	Todd Kliche
David McLeland	Brenda C. Ochylski
David Persinger	Jennifer Mooney
Debra Ross	Barbara Scavullo
Matthew Burgin	Joseph Blair
Jerrod Brown	Kyle Oelrichs
Jonathan Vaught	

12. The Radiation Safety Officer for this license is David Persinger, R.Ph

13. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals as specified by 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 or detector cell 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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
24-04206-12MD
Docket or Reference Number
030-32515
Amendment No. 23

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 or sources removed from source holders by the licensee, except as specifically authorized.

15. The licensee shall conduct a physical inventory every six months, or at other interval approved by NRC, to account for all sources and/or devices received and possessed under the license.

16. Except for maintaining labeling as required by 10 CFR Part 20 or 71, the licensee shall obtain authorization from NRC before making any changes in the sealed source, device, or source-device combination that would alter the description or specifications as indicated in the respective Certificates of Registration issued either by the Commission pursuant to 10 CFR 32.210 or by an Agreement State.

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

A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

B. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate survey instrument 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.

C. A record of each such 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 materials 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. The licensee is authorized to retrieve, receive and dispose of radioactive waste from it's customers limited to radiopharmacy supplied syringes and vials and their contents.

19. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

20. 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.

21. This license does not authorize distribution to persons exempt from licensing.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
24-04206-12MD
Docket or Reference Number
030-32515
Amendment No. 23

22. 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 8, 2002 (excluding Radiopharmacy Audit Program, Control of Public Doses and Transportation of Radioactive Materials); and

B. Facsimile letter dated July 12, 2002 (excluding Radiopharmacy Audit Program); and

C. Letters dated September 11, 2003, May 9, 2005 (excluding Attachment A), May 13, 2005, August 13, 2008, January 9, 2009, and March 31, 2009.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date DEC 18 2009

By _____
Kevin G. Null
Materials Licensing Branch
Region III