

U.S. NUCLEAR REGULATORY COMMISSION

**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.

*OC 02511*

*575736*

Licensee

**In accordance with letters dated July 21, 2011, and application dated July 26, 2011,**

1. **Mallinckrodt, LLC**

3. License number 24-04206-05MD is amended in its entirety to read as follows:

2. 2703 Wagner Place

4. Expiration date **May 31, 2011**

Maryland Heights, MO 63043

5. Docket No. 030-10801  
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. Chromium-51

A. Sodium Chromate (NDA 16-708)

A. Not Applicable

B. Xenon-133

B. Gas (NDA 18-327)

B. Not Applicable

C. Iodine-125

C. Radioiodinated Human Serum Albumin (NDA 17-844)

C. Not Applicable

D. Iodine-131

D. Sodium Iodohippurate (NDA 16-666)

D. Not Applicable

E. Iodine-131

E. Sodium Iodide Capsules (NDA 16-517)

E. Not Applicable

F. Iodine-131

F. Sodium Iodide Solution (NDA 16-515)

F. Not Applicable

G. Phosphorus-32

G. Chromic Phosphate (NDA 17-084)

G. Not Applicable

H. Phosphorus-32

H. Sodium Phosphate (NDA 11-777)

H. Not Applicable

I. Molybdenum-99

I. Molybdenum-99/Technetium-99m generators (Mallinckrodt, Inc. Ultra-Technekow FM Dry Top Eluting Generators NDA No. 17-243)

I. No single generator to exceed 19.5 curies at the time of shipment

J. Molybdenum-99

J. Molybdenum-99/Technetium-99m generators (Bristol-Myers Squibb TechneLite Generators NDC No. 11994-090)

J. No single generator to exceed 19.5 curies at the time of shipment

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
24-04206-05MDDocket or Reference Number  
030-10801

Amendment No. 39

K. Indium-111	K. Indium Chloride sterile solution (NDA 20-314 and 19-841)	K. Not Applicable
L. Thallium-201	L. Thallous Chloride sterile solution (NDA 18-150)	L. Not Applicable
M. Gallium-67	M. Gallium-67 Citrate sterile solution (NDA 18-058)	M. Not Applicable
N. Iodine-123	N. Sodium Iodide solution absorbed into sucrose within a gelatin capsule (NDA 17-910)	N. Not Applicable

**9. Authorized Use:**

Pursuant to Section 32.72 and 32.74 of 10 CFR Part 32, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 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, for the Sections indicated below:

- A. Section 35.100.
- B. Section 35.200.
- C. Section 35.100.
- D. Section 35.100.
- E. Sections 35.100 or 35.300.
- F. Section 35.300.
- G. Section 35.300.
- H. Section 35.300.
- I. Section 35.200 or for distribution to Mallinckrodt Inc. nuclear pharmacy licenses or other commercial nuclear pharmacies.
- J. Section 35.200 or for re-distribution to Mallinckrodt Inc. nuclear pharmacy licenses or other commercial nuclear pharmacies.

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K. through M. Section 35.200

N. Sections 35.100 or 35.200

CONDITIONS

10. This license does not authorize possession or use of licensed material.
11. The Radiation Safety Officer for this license is Daniel Hoffman.
12. The licensee shall notify the U.S. Nuclear Regulatory Commission within thirty (30) days of the termination of a "Notice of Claimed Investigational Exemption for a New Drug (IND) for licensed material described in Items 6 and 7.
13. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
14. Any proposed change to shielding that will increase the radiation levels of the packaging shall be submitted to the NRC for review. Any proposed change to labeling that will cause a change to radioactive markings or labeled activity, other than position and increasing the size of symbols and wording, shall be submitted to NRC for review.
15. Except as specifically provided otherwise by this license, the licensee shall manufacture, package, label and distribute licensed material described in Items 6. and 7. of this license in accordance with the statements, representations, and procedures contained in:
  - A. Applications dated November 17, 2000, April 25, 2003 (with attached letter dated April 24, 2003), and April 27, 2005 (with attached letter dated April 27, 2005 and attachments); and
  - B. Letters dated November 28, 2000, May 16, 2001, March 14, 2003, August 11, 2005, December 13, 2005, February 7, 2006, March 31, 2009, July 21, 2011 and **July 21, 2011**;
  - C. Facsimiles dated August 1, 2005, and December 12, 2005 (received December 14, 2005)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date OCT 12 2011By   
William P. Reichhold  
Materials Licensing Branch  
Region III