



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

December 29, 2004

Docket No. 030-32954  
Control No. 136087

License No. 24-04206-13MD

Kay M. Yoder  
Director, Radiation, Environment, Safety & Health  
Mallinckrodt Inc.  
675 McDonnell Boulevard  
P.O. Box 5840  
St. Louis, MO 63134

SUBJECT: MALLINCKRODT INC., ISSUANCE OF LICENSE AMENDMENT, CONTROL  
NO. 136087

Dear Ms. Yoder:

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.

In accordance with NRC Regulatory Issue Summary (RIS) 2004-17: Revised Decay-In-Storage Provisions for the Storage of Radioactive Waste Containing Byproduct Material (<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2004/ri200417.pdf>), your license has been modified. Your license now contains a revised decay-in-storage (DIS) condition (see Condition 19). This revised condition permits greater flexibility for DIS of waste by eliminating a specific holding period prior to disposal. Please review the RIS 2004-17, and the revised condition carefully to ensure that you understand its requirements.

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

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the NRC Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or [pdr@nrc.gov](mailto:pdr@nrc.gov).

K. Yoder  
Mallinckrodt Inc.

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Thank you for your cooperation.

Sincerely,

***Original signed by Bryan A. Parker***

Bryan A. Parker  
Health Physicist  
Commercial and R&D Branch  
Division of Nuclear Materials Safety

Enclosure:  
Amendment No. 16

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OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI			
NAME	BParker /BAP/							
DATE	12/29/04							

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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.

<p style="text-align: center;">Licensee</p> <p>1. Mallinckrodt Inc.</p> <p>2. 675 McDonnell Boulevard P.O. Box 5840 St. Louis, Missouri 63134</p>	<p>In accordance with the letter dated December 9, 2004,</p> <p>3. License No. 24-04206-13MD is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration Date: August 31, 2005</p> <hr/> <p>5. Docket No. 030-32954</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material with atomic number 3 through 83 with a half-life less than or equal to 120 days</p> <p>B. Molybdenum 99</p> <p>C. Technetium 99m</p> <p>D. Iodine 131</p> <p>E. Xenon 133</p> <p>F. Any byproduct material listed in 10 CFR 31.11(a)</p> <p>G. Any byproduct material authorized under 10 CFR 35.57(a)</p> <p>H. Depleted Uranium</p> <p>I. Cesium 137</p> <p>J. Iodine 125</p> <p>K. Any licensed material</p>	<p>7. Chemical and/or physical form</p> <p>A. Any, except sealed sources</p> <p>B. Any, except sealed sources</p> <p>C. Any, except sealed sources</p> <p>D. Any, except sealed sources</p> <p>E. Any, except sealed sources</p> <p>F. Prepackaged units for <u>in vitro</u> diagnostic tests</p> <p>G. Sealed sources</p> <p>H. Metal</p> <p>I. Sealed source (Tech Ops Model 773 or equivalent)</p> <p>J. Any brachytherapy source identified in 10 CFR 35.400</p> <p>K. Analytical samples</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. Not to exceed 500 millicuries per radionuclide and 1 curie total</p> <p>B. 200 curies</p> <p>C. 200 curies</p> <p>D. 0.999 curie</p> <p>E. 6 curies</p> <p>F. 20 millicuries</p> <p>G. 300 millicuries</p> <p>H. 600 kilograms</p> <p>I. Not to exceed 165 millicuries per source and 333 millicuries total</p> <p>J. 4 curies</p> <p>K. As needed</p>
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|---|----------------------------------|--|
| 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 |
| L. Yttrium 90   | L. Any                           | L. 1 curie   |

9. Authorized use:

- A. - E. Preparation and distribution of radioactive drugs, production of technetium 99m pertechnetate, compounding of iodine 131 and distribution of unused molybdenum 99/technetium 99m generators to authorized recipients in accordance with 10 CFR 32.72 and to authorized recipients for non-medical use.
- F. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11 provided the packaging and labeling remain unchanged.
- G. Calibration and checking of the licensee's instruments. Distribution of sealed sources to authorized recipients in accordance with 10 CFR 32.74 and to authorized recipients for non-medical use.
- H. Shielding for molybdenum 99/technetium 99m generators.
- I. For storage only.
- J. Distribution of sealed sources pursuant to 10 CFR 32.74 to persons licensed pursuant to 10 CFR 35.400 or under equivalent licenses of any Agreement State.
- K. For possession incident to the performance of leak testing of customers' sealed sources.
- L. Preparation and distribution of radioactive drugs in accordance with 10 CFR 32.72.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 19 Independence Court, Folcroft, Pennsylvania.
11. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:
- A. In accordance with 10 CFR 32.72(b)(2)(i) or (4), pharmacists working as authorized nuclear pharmacists.
- B. Authorized Nuclear Pharmacists:
- |                     |              |                |
|---------------------|--------------|----------------|
| Christine Basilone  | Kelly Hall   | Craig Petzold  |
| Wendy Lou Baumering | David Hart   | Karen Pieszala |
| Quent Besing        | Michael Hess | David Poydence |

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Thomas Brady  
Padmesh Chhita  
Harold Cleveland  
Carrie Connahan  
William Crawford  
Dennis Davis  
Greg Edquist  
Joseph Fery  
Thomas Firman  
James Flynn  
Lori Follis (DeVos)  
Joseph Gatton  
Andrew Gerner  
Rudolph Gilliam  
Bonnie Gindling  
Michael Haigh

Richard Hylinski  
Homan Jarrar  
John Keenan  
Michael Klug  
Lisa Koss (Leonard)  
Timothy Layne  
David Lutes  
Brad Martin  
John Martin  
Thomas McKean  
John Minella  
Richard Nickel  
Amit Parikh  
Neal Patel  
Payal H. Patel  
Steve Petner

Debra Ross  
Barbara Scavullo  
David Schmitt  
Aly Sharaf  
Mary Sue Shrum  
Gary Spence  
Donna Lynn Stephenson  
Michael Stipanovich  
Wayne Toal  
Sally DuAnn Vanderslice  
Deborah Vanerka (Wierzba)  
Jeff Williams  
Jason Willman  
Brian Wong  
Richard Wride

12. Licensed material used for calibration of dose calibrators, or for analysis of tests for leakage and/or contamination may be used by, or under the supervision of Andrew Williams, Scott Surovi, W. Christopher Wagner, Ashok Dhar or Kay Yoder.
13. The Radiation Safety Officer (RSO) for this license is Padmesh Chhita, R.Ph.
14. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- E. Sealed sources and detector cells need not be leak tested if:
- (i) they contain only hydrogen-3; or

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- (ii) they contain only a radioactive gas; or
  - (iii) the half-life of the isotope is 30 days or less; or
  - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
  - (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer 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 or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U. S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known 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.
- G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.
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 not acquire licensed material in a sealed source or device unless the source or device has been registered with the U. S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.

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17. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license.
18. Reagent kits may be redistributed to persons licensed pursuant to 10 CFR 35.200 or under equivalent licenses of Agreement States.
19. 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.
20. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the statements, representations and procedures in the application dated December 5, 1996.
21. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
22. Except for maintaining labeling as required by 10 CFR Part 20 or 71, the licensee shall obtain authorization from the U. S. Nuclear Regulatory Commission 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 Registration Certificates issued either by the Commission pursuant to 10 CFR 32.210 or by an Agreement State.
23. This license does not authorize distribution to persons exempt from licensing.

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24. 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 June 15, 1994
  - B. Letter dated February 13, 1995
  - C. Letter dated April 6, 1995
  - D. Letter dated April 25, 1995 except Item 1
  - E. Letter dated July 19, 1995
  - F. Letter dated December 5, 1996
  - G. Letter dated February 18, 1997, except criteria for carbon filter replacement, in item 10.10, B on page 4
  - H. Letter dated November 13, 1997
  - I. Letter dated March 17, 2000
  - J. Letter dated March 7, 2002
  - K. Letter dated September 11, 2003
  - L. Letter dated October 1, 2003
  - M. Letter dated June 27, 2004

For the U. S. Nuclear Regulatory Commission

Date December 29, 2004

**Original signed by Bryan A. Parker**  
By \_\_\_\_\_  
Bryan A. Parker  
Commercial and R&D Branch  
Division of Nuclear Materials Safety  
Region I  
King of Prussia, Pennsylvania 19406