NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 78

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	In accordance with **letter dated October 13, 2008**,
1. Mallinckrodt Inc.	3. License number 24-04206-01 is amended in its entirety to read as follows:
2. 2703 Wagner Place Maryland Heights, MO 63043 PC 03211	4. Expiration date January 31, 2012 5. Docket No. 030-00001 Reference No. 317582

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 Nos. 1 through 83	A. Any	A. Not to exceed 100 curies per radionuclide. Total possession not to exceed 300 curies; except as listed below: Molybdenum-99, 13,000 curies; Technetium-99m, 10,000 curies; Iodine-131, 500 curies; Xenon-133, 800 curies; and Rhenium-186, 200 curies
B. Cesium-137	B. Sealed Sources	B. Not to exceed 100 curies total
C. Americium-241	C. Sealed Sources	C. Not to exceed 5 microcuries total
D. Depleted Uranium	D. Metal	**D. 67,000 kilograms**
E. Depleted Uranium	**E. Metal (in slab form)**	E. 1 millicurie

9. Authorized Use:

A. For research and development of radiopharmaceuticals as defined in 30.4(q), 10 CFR Part 30, including animal studies. For use in manufacturing, processing and packaging of radiopharmaceuticals and/or radiochemicals.

B. For use in instruction calibration and irradiation of TLD materials.

C. and E. For use in instrument calibration.

D. For use as shielding in transportation containers and molybdenum-99/technetium-99m generators.

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CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 2703 Wagner Place, and 2600 Wagner Place, Maryland Heights, Missouri.

11. A. Licensed material shall be used by, or under the supervision of, individuals approved by the licensee's Radiation Safety Committee, April C. Chance, Chairman.

    B. The Radiation Safety Officer for this license is James R. Schuh.

12. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.

    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 3 months.

    C. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 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 need not be leak tested if:

        (I) they contain only hydrogen-3; or

        (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 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 or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

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F. 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.

G. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

13. 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."

14. The specified possession limit includes all licensed material possessed by the licensee under this license whether in storage or otherwise in use.

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

16. The licensee shall not use licensed material in or on human beings or in field applications where activity is released except as provided otherwise by specific condition of this license.

17. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

18. The licensee shall maintain, and execute the response measures of Revision 3 to its Emergency Plan submitted under letter April 29, 2003. The licensee shall also maintain implementing procedures for its Emergency Plan as necessary to implement the Plan. The licensee shall make no change in the emergency plan submitted pursuant to 10 CFR 30.32(I) that would decrease the effectiveness of the plan without prior Commission approval. The licensee may make changes to its Emergency Plan without prior Commission approval if the changes do not decrease the effectiveness of the plan. The licensee shall maintain records of changes that are made to the plan without prior approval for a period of three years from the date of the changes and shall furnish the Chief, Medical, Academic, and Commercial Use Safety Branch, Division of Industrial and Medical Nuclear Safety, NMSS, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and the appropriate NRC Regional Office specified in Appendix D of 10 CFR 20, a report, within six months after the change is made, containing a description of each change.

19. In addition to the possession limits in Condition 8, the licensee shall further restrict the possession of unsealed licensed material to quantities less than 10^5 times the applicable limits in Appendix B to Part 30 as specified in 10 CFR 30.35(d).

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20. Mallinckrodt will maintain a corrective action program to identify and correct deficiencies associated with radiation safety.

    A. The licensee shall develop, implement and maintain procedures to assure that conditions adverse to radiation safety, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances that could reasonably affect exposures to workers or the public, or releases of radioactive material in effluents or to the sanitary sewer system, are promptly identified and corrected. In the case of significant conditions adverse to radiation safety, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to radiation safety, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management. The procedures shall include appropriate quantitative or qualitative acceptance criteria for determining that the procedures have been satisfactorily accomplished.

    B. The procedure(s) shall include provisions for 1) defining conditions that are adverse to radiation safety; 2) identifying conditions that are adverse to radiation safety; 3) reporting the conditions to appropriate management levels; 4) investigating adverse conditions, in sufficient detail to identify root causes; 5) developing and implementing corrective actions to address the identified root cause(s) and to prevent recurrence; and 6) establishing time tables (milestones) for each provision, commensurate with the significance of the adverse condition.

21. Notwithstanding the requirements of 10 CFR 30.32 (i) (3) (xii), the licensee is authorized to extend until July 30, 2002, the time interval for conducting their next biennial onsite exercise to test response to simulated emergencies. Subsequent exercises will be held as required on a biennial basis, with the first to be scheduled in the calendar year 2003.

22. 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.

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23. 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 28, 2001; and

    B. Letters dated November 26, 2001, April 29, 2003 (with attached Emergency Plan, Revision 3), July 30, 2003, August 16, 2004 (with attached revision to Section 8, "Training for Individuals Working in or Frequenting Restricted Areas.") , December 8, 2005 and December 16, 2005 (with attachment) and February 7, 2006.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date DEC 12 2008

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