

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, 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); and to import such byproduct and source material. 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 April 27, 1983	
1. Mallinckrodt, Inc.		3. License number 24-04206-01 is amended in its entirety to read as follows:	
2. 2703 Wagner Place Maryland Heights, Missouri 63043		4. Expiration date December 31, 1985	
5. Docket or 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 Nos. 1 through 83, except as listed below	A. Any	A. Not to exceed 100 curies of each radionuclide	
B. Strontium 90	B. Any	B. 25 curies	
C. Molybdenum 99	C. Any	C. 10,000 curies	
D. Technetium 99m	D. Any	D. 10,000 curies	
E. Iodine 131	E. Any	E. 500 curies	
F. Selenium 75	F. Any	F. 200 curies	
G. Xenon 133	G. Any	G. 200 curies	
9. Authorized use			
A. through G. For use in the development and production of radiopharmaceuticals, radiochemicals and sources; and for distribution to persons authorized to possess the licensed material pursuant to the terms and conditions of a specific license issued by the Nuclear Regulatory Commission or an Agreement State.			

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10. Licensed material shall be used only at 2703 Wagner Place, Maryland Heights, Missouri.
11. The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 19, "Notices, Instructions and Reports to Workers; Inspections" and Part 20, "Standards for Protection Against Radiation."
12. Licensed material shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee, Don Soldan, Chairman.

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13. A. (1) Each sealed source acquired from another person and containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for contamination and/or leakage prior to use. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.
- (2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.
- (3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.
- B. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source. If the inspection or test reveals any construction defects or 0.005 microcurie or greater of contamination, the source shall not be used or transferred as a sealed source until it has been repaired, decontaminated and retested.
- C. Each sealed source containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six months except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed three months.
- D. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

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- E. If the test required by Subsection A. or C. of this condition reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the test with the U. S. Nuclear Regulatory Commission, Region III, Office of Inspection and Enforcement, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, describing the equipment involved, the test results, and the corrective action taken.
14. A. Individuals involved in operations which utilize, at any one time, more than 100 millicuries of Hydrogen 3 in a non-contained form, other than metallic foil, shall have bioassays performed within one week following a single operation and at weekly intervals for continuing operations.
- B. (1) Tritium shall not be used in such a manner as to cause any individual to receive a radiation exposure such that urinary excretion rates exceed 28 microcuries of tritium per liter when averaged over a calendar quarter.
- (2) Urinalysis shall be performed at weekly intervals on all individuals who work in the restricted areas of facilities in which tritium is used. If the average concentration of tritium in urine for any single individual during a calendar quarter is less than 10 microcuries per liter, urinalysis may be performed on that individual at monthly intervals for the following calendar quarter and may continue at monthly intervals so long as the average concentration in the calendar quarter remains below 10 microcuries per liter. The urine specimen shall be collected on the same day of the week insofar as possible.
- (3) A report of an average concentration in excess of the limit specified in B(1) above for any individual shall be filed, in writing, within thirty (30) days of the end of the calendar quarter with the Office of Inspection and Enforcement, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, with a copy to the Regional Office of Inspection and Enforcement. The report shall contain the results of all urinalyses for the individual during the calendar quarter, the cause of the excessive concentrations, and the corrective steps taken or planned to assure against a recurrence.
- (4) Any single urinalysis which discloses a concentration of greater than 50 microcuries per liter shall be reported, in writing, within seven (7) days of the licensee's receipt of the results, to the Office of Inspection and Enforcement, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, with a copy to the U. S. Nuclear Regulatory Commission, Region III, Office of Inspection and Enforcement, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

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15. Pursuant to Section 32.71, 10 CFR Part 32, the licensee is authorized to distribute iodine 125 or iodine 131 for in vitro clinical laboratory studies or laboratory testing under the general license of Section 31.11, 10 CFR Part 31. Vials containing iodine 125 or iodine 131, distributed pursuant to Section 32.71 of 10 CFR Part 32 shall be labeled in accordance with Section 32.71(c), except that the caution symbols on vial labels is exempt from the color requirements of 20.203(a)(i).
16. The licensee may transport licensed material or deliver licensed material to a carrier for transport in accordance with the provisions of Title 10, Code of Federal Regulations, Part 71, "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions."
17. The licensee shall maintain, and execute the response measures of his Radiological Contingency Plan submitted to the Commission on December 2, 1981 and revised on March 2, 1982, June 24, 1982, and April 27, 1983. The licensee shall also maintain implementing procedures for his Radiological Contingency Plan as necessary to implement the Plan. The licensee shall make no change in his Radiological Contingency Plan that would decrease the response effectiveness of the Plan without prior Commission approval as evidenced by license amendment. The licensee may make changes to his Radiological Contingency Plan without prior Commission approval if the changes do not decrease the response effectiveness of the Plan. The licensee shall maintain records of changes that are made to the Plan without prior approval for a period of two years from the date of change and shall furnish the Chief, Material Licensing Branch, Division of Fuel Cycle and Material Safety, NMSS, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, and the appropriate NRC Regional Office specified in Appendix D of 10 CFR Part 20, a report containing a description of each change within six months after the change is made.
18. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated September 29, 1977; letter with attachments dated October 11, 1978; letters dated May 16, 1978, January 18, 1979, October 8, 1980, December 2, 1981, March 2, 1982, June 24, 1982, October 28, 1982, March 14, 1983, and April 27, 1983. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

FOR THE U. S. NUCLEAR REGULATORY COMMISSION

Date

OCT 31 1983

By

Material Licensing Branch
Division of Fuel Cycle and Material
Safety
Washington, D. C. 20555