

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, 37, 39, 40, 70 and 71, 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 1. Mallinckrodt, LLC Research and Development 2. 675 McDonnell Boulevard Hazelwood, MO 63042		In accordance with application dated October 26, 2017, 3. License No.: 24-17450-01 is amended in its entirety to read as follows:	4. Expiration Date: December 31, 2025
			5. Docket No.: 030-12559 Reference No.:
6. Byproduct, source, and/or special nuclear material A. Any byproduct material with Atomic Nos. 1 through 83 B. Technetium-99m	7. Chemical and/or physical form A. Any B. Any	8. Maximum amount that licensee may possess at any one time under this license A. Not to exceed 100 millicuries per radionuclide. Total possession limit not to exceed 500 millicuries, except as listed below. B. 500 millicuries total	9. Authorized use A. To be used for research and development as defined in 10 CFR Part 30, instrument calibration, and animal studies. B. Same as Item 9.A.

CONDITIONS

10. Licensed material shall be used or stored only at the licensee's facilities located at 675 McDonnell Boulevard, Hazelwood, Missouri, 63042.
11. The Radiation Safety Officer (RSO) for this license is Scott J. Surovi.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

24-17450-01

Docket or Reference Number

030-12559

Amendment No. 36

12. Licensed material shall only be used by, or under the supervision of, individuals designated, in writing, by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for three years after the individual's last use of licensed material.
13. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as specified by the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of 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 the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement state, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
- C. Sealed sources need not be leak tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain no more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material.
- D. 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.
- E. The leak 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 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.
- F. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
24-17450-01Docket or Reference Number
030-12559

Amendment No. 36

G. Records of leak test results shall be kept in units of microcuries and shall be maintained for three years.

14. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sealed sources and/or devices received and possessed under the license. Records of inventories shall be maintained for three years from the date of each inventory, and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.
15. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.
16. Licensed material shall not be used 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 material shall not be used for human consumption.
18. 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 in ordinary trash provided:
- A. 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.
- B. A record of each 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 material 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.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

24-17450-01

Docket or Reference Number

030-12559

Amendment No. 36

19. Notwithstanding the requirements of License Condition No. 21, the licensee is authorized to make program changes and changes to procedures specifically identified in the applications dated July 1, 2015, and October 26, 2017, which were previously approved by the Commission and incorporated into the license without prior Commission approval, as long as:
- A. the proposed revision is documented, reviewed, and approved by the licensee's Radiation Safety Committee, in accordance with established procedures prior to implementation;
 - B. the revised program is in accordance with regulatory requirements, will not change the license conditions, and will not decrease the effectiveness of the Radiation Safety Program;
 - C. the licensee's staff is trained in the revised procedures prior to implementation;
 - D. the licensee's audit program evaluates the effectiveness of the change and its implementation.
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.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
24-17450-01Docket or Reference Number
030-12559

Amendment No. 36

21. 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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. 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 July 1, 2015 (excluding App. B re: Decommissioning Funding Plan) (ML15183A457)
- B. Letter dated January 20, 2017 (ML17023A219)
- C. Application dated October 26, 2017 (ML17300B391)
- D. Letter dated January 22, 2018 (ML18023A103)



FOR THE U. S. NUCLEAR REGULATORY COMMISSION

Date: JAN 24 2018By: Bryan A. Parker
Region III