



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

KTH

FEB 09 2004

Timothy L. Popp, RSO
Pfizer, Inc.
7000 Portage Road
Kalamazoo, MI 49001

Dear Mr. Popp:

Enclosed is Amendment No. 60 amending your NRC Material License No. 21-00182-03 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Kevin G. Null
Materials Licensing Branch

License No. 21-00182-03
Docket No. 030-04781

Enclosure: Amendment No. 60

Information in this record was deleted
in accordance with the Freedom of Information
Act, exemptions 2
FOIA- 2005-0293

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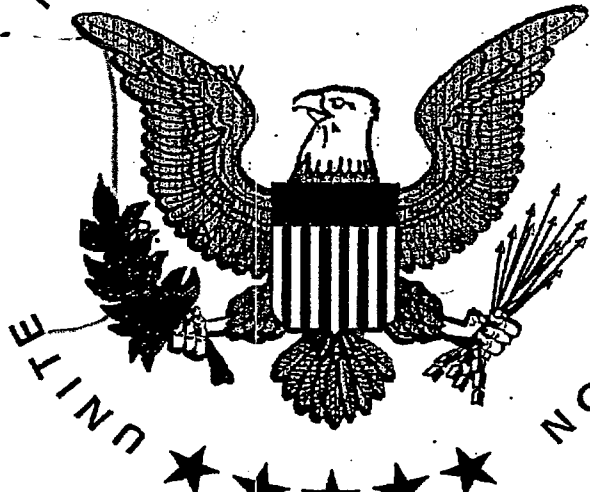
MATERIALS LICENSE

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.

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<p>Licensee</p> <p>1. Pharmacia & Upjohn Company</p> <p>2. 7000 Portage Road Kalamazoo, MI 49001</p>	<p>In accordance with letter dated December 23, 2003,</p> <p>3. License number 21-00182-03 is amended in its entirety to read as follows:</p> <p>4. Expiration date January 31, 2005</p> <p>5. Order No. 030-04781 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A.</p> <p>B.</p> <p>Ex2</p> <p>C. Americium-241</p> <p>D. Nickel-63</p>	<p>7. Chemical and/or physical form</p>  <p>C. Sealed sources (An evaluated source which has been registered with the NRC or an agreement State in accordance with 10 CFR 32.210)</p> <p>D. Plated or foil sources (Any source which has been evaluated by the NRC or an Agreement State in accordance with 10 CFR 32.210)</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. Not to exceed [] per radionuclide. Total possession not to exceed []</p> <p>B. Not to exceed [] per radionuclide. Total possession not to exceed [] except as listed below: Hydrogen-3 150 curies Carbon-14 20 curies; Iodine-125 3 curies</p> <p>C. Not to exceed 150 millicuries per source. Not to exceed [] curie total.</p> <p>D. No single source to exceed 25 millicuries. Not to exceed 5 curies total</p>
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6. Byproduct, source, and/or special nuclear material

E. Cesium-137

G. Iodine-125

H. Carbon-14

7. Chemical and/or physical form

E. Sealed sources (Any source which has been evaluated by the NRC or an Agreement State in accordance with 10 CFR 32.210)

G. In-vitro test kits

8. Maximum amount that licensee may possess at any one time under this license

E. No single source to exceed 100 millicuries. Not to exceed 2 curies total

G. 200 millicuries total (No single test kit to exceed 10 microcuries)

H. 2 millicuries

9. Authorized Use:

- UNITED STATES NUCLEAR REGULATORY COMMISSION
- labeled erythromycin in mouth test
- To be used in research involving human subjects in accordance with the provisions of Section 35.6 of 10 CFR Part 35.
 - For pharmaceutical research and development as defined in Section 30.4, 10 CFR Part 30, including animal studies.
 - To be used as sources for calibration and standardization of radiation detection instrumentation, and in NRC approved source holders for measurements of flow, level and/or density of materials.
 - To be used in gas chromatographs for sample analysis.
 - To be used in NRC approved source holders for measurements of flow, level and/or density of materials.
 - For research and development as defined in 30.4 of 10 CFR Part 30, excluding irradiation of flammables and/or explosives.
 - To be used for distribution to persons generally licensed pursuant with Section 31.11, 10 CFR Part 31, or equivalent in accordance with the requirements of Section 32.71, 10 CFR Part 32.

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- H. To be used for pharmaceutical research in humans limited to the carbon-14 labeled erythromycin breath test (ERMBT).

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at Richland, Michigan and Upjohn Research Center - Kalamazoo, Michigan, Portage, Michigan. Licensed material listed in Subitem G. may be received, stored, and distributed from the Pharmacia & Upjohn warehouse located at Kalamazoo, Michigan. Ex 2
11. A. Licensed material shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.
- B. The Radiation Safety Officer for this license is Timothy L Popp.
- C. The use of licensed material on humans shall be by a physician, dentist, or podiatrist as defined in 10 CFR 35.2.
- D. Physicians, dentists, or podiatrists designated to use licensed material in or on humans shall meet the training criteria established by the Radiation Control Committee and shall be designated by the licensee's Radiation Control Committee.
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.
- 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

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- (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.

F. 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(b)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, ATTN: Chief, Nuclear Materials Safety Branch, 801 Warrenville Road, Lisle, Illinois 60532-4351. The report shall specify the source involved, the test results, and corrective action taken.

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. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee. In this condition, sealed sources described in change No. 4 of the licensee's letter dated May 27, 1977, may be removed from source holders by the licensee.
14. The licensee shall assure that the shutter mechanism is locked in the closed position during periods when a portion of an individual's body may be subjected to the direct radiation from the gauges. The licensee shall also modify their "lock-out" procedure whenever a new gauge is obtained for use other than purposes for which they are currently authorized to incorporate the device manufacturer's recommendations.
15. The licensee shall not use licensed material on or in human beings except as provided otherwise by specific condition of this license.
16. The licensee shall not use licensed material 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 is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
19. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material.

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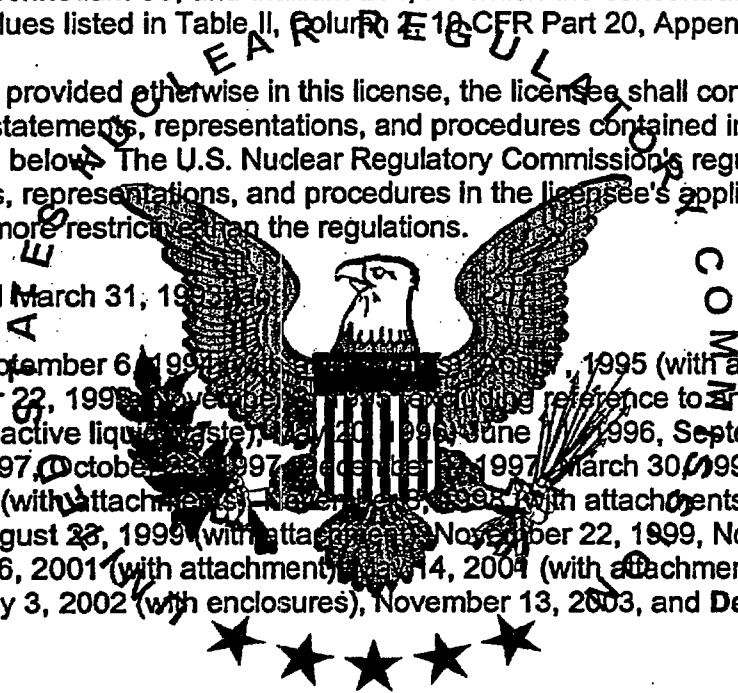
20. A. Pursuant to 10 CFR 20.1302 and 10 CFR 20.2001, the licensee is authorized to dispose of licensed material by incineration provided the gaseous effluent from incineration does not exceed the limits specified for air in Appendix B, Table II, 10 CFR Part 20.

B. Pursuant to 10 CFR 20.2002, the licensee may dispose of incinerator ash containing radioactive materials with Atomic Nos. 1-83, other than those isotopes listed below, as ordinary waste in a landfill, provided the concentrations of the isotopes, expressed in μCi per gram of ash, at the time of disposal, do not exceed the numerical values listed in Table II, Column 2, 10 CFR 20, Appendix B. Isotopes not included are hydrogen-3, carbon-14, aluminum-26, chlorine-36, silver-108m, niobium-94, iodine-129, technetium-99, and thallium-204, for which the concentrations must not exceed 10 percent of the values listed in Table II, Column 2, 10 CFR Part 20, Appendix B.

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. 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 March 31, 1995

B. Letters dated September 6, 1995 (with attachments), 1995 (with attachments), August 17, 1995, September 27, 1995 (with attachments), May 20, 1996 (with attachments), June 1, 1996, September 25, 1996, May 13, 1997, June 2, 1997, October 23, 1997, December 12, 1997, March 30, 1998 (with attachments), August 20, 1998 (with attachments), November 6, 1998 (with attachments), April 1, 1999 (with attachments), August 23, 1999 (with attachments), November 22, 1999, November 27, 2000 (except item 2.), March 16, 2001 (with attachment), May 14, 2001 (with attachment), August 7, 2001 (with attachments), July 3, 2002 (with enclosures), November 13, 2003, and December 23, 2003.



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date FEB 09 2004

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