

**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.

PC 03610

316002

Licensee

In accordance with letter dated  
**January 25, 2007,**

3. License number 21-00182-03 is **amended**  
in its entirety to read as follows:

4. Expiration date July 31, 2015

5. Docket No. 030-04781  
Reference No.

1. Pharmacia & Upjohn Company LLC

2. 7000 Portage Road  
Kalamazoo, MI 49001

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 Numbers 1 through  
83

A. Any

A. **Not to exceed 150  
millicuries per  
radionuclide. Total  
possession not to exceed  
5 curies, except as listed  
below:**

**Hydrogen-3 100 curies  
Carbon-14 20 curies;**

B. Americium-241

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

B. **Not to exceed 150 millicuries  
per source. Not to exceed 1  
curie total.**

C. Nickel-63

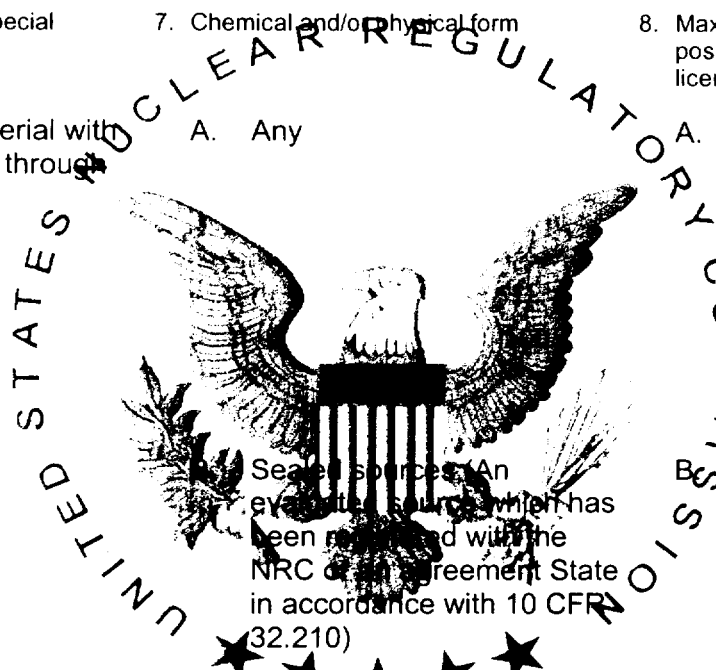
C. **Plated or foil sources (Any  
source which has been  
evaluated by the NRC or an  
Agreement State in  
accordance with 10 CFR  
32.210)**

C. **No single source to  
exceed 25 millicuries. Not  
to exceed 1 curie total**

D. Cesium-137

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

D. **No single source to  
exceed 150 millicuries.  
Not to exceed 1 curie total**



**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

21-00182-03

Docket or Reference Number

030-04781

Amendment No. 66

## 9. Authorized Use:

- A. For pharmaceutical research and development as defined in Section 30.4, 10 CFR Part 30, including animal studies.
- B. 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.
- C. To be used in gas chromatographs for sample analysis.
- D. To be used in NRC approved source holders for measurements of flow, level and/or density of materials.

**CONDITIONS**

- 10. Licensed material shall be used only at the licensee's facilities located at 333 Portage Road, Kalamazoo, Michigan, 2605 East Kilgore Road, Kalamazoo, Michigan, 5300 North Street, Richland, Michigan and 7000 Portage Road, Kalamazoo, Michigan.
- 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 [redacted].
- 12. A. Sealed sources 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. In the absence of a certificate from a transfer indicating that a leak test has been made within the interval specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested.
- C. 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.
- D. 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.

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SUPPLEMENTARY SHEET**License Number  
21-00182-03Docket or Reference Number  
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- E. Tests for leakage an/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. .
- F. Records of leak test results shall be kept in units of microcuries and shall be maintained for 3 years.
13. Sealed sources or detector cells containing licensed material shall not be opened or sources 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 subject to the direct radiation from the gauges. The licensee shall also modify their "lock-out" procedures 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 in or on 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 in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
19. In addition to the possession limits of the license, 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.
20. 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.
21. 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  $\mu\text{Ci}$  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.

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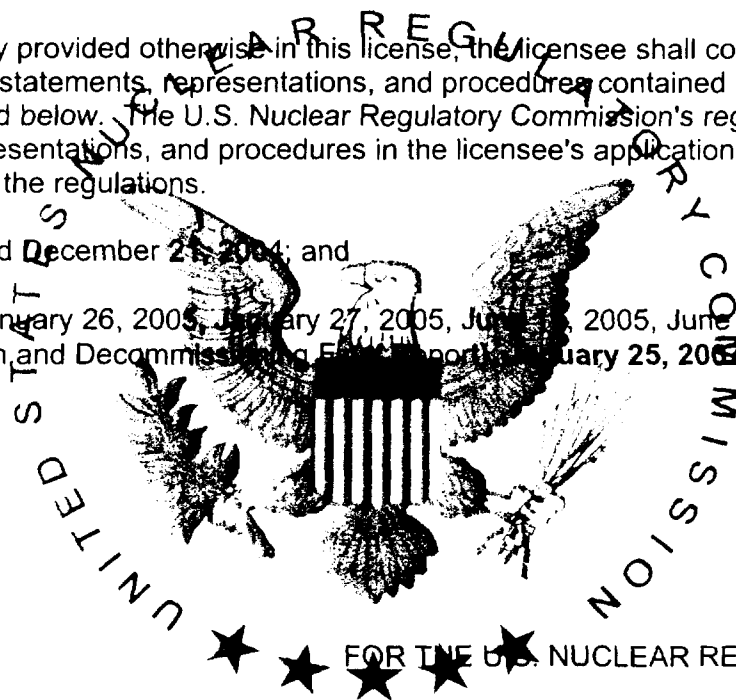
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22. The licensee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash provided:
- A. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate survey meter 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.
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 December 21, 2004; and
  - B. Letters dated January 26, 2005, January 27, 2005, June 13, 2005, June 20, 2005 (with attached Decontamination and Decommissioning Final Report), January 25, 2006, and April 17, 2007.



Date

MAY 01 2007

By

James R. Mullauer, M.H.S.  
Materials Licensing Branch  
Region III