Amendment No. 23

U.S. NUCLEAR REGULATORY COMMISSION

# 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 | |
|---|---|
| 1. Boehringer Ingelheim Pharmaceuticals, Inc. | In accordance with the letter dated July 18, 2011, 3. License No. 06-19183-01 is amended in its entirety to read as follows: |
| 2. 900 Ridgebury Road<br>P. O. Box 368<br>Ridgefield, Connecticut 06877-0368 | 4. Expiration Date: January 31, 2015<br>5. Docket No. 030-17101 |

| 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 50 millicuries per radionuclide and 1 curie total |
| B. Hydrogen 3 | B. Any | B. 50 curies |
| C. Carbon 14 | C. Any | C. 20 curies |
| D. Phosphorus 32 | D. Any | D. 100 millicuries |
| E. Phosphorus 33 | E. Any | E. 5 curies |
| F. Sulfur 35 | F. Any | F. 5 curies |
| G. Iodine 125 | G. Any | G. 1 curie |

9. Authorized use:

A. through G. Research and development as defined in 10 CFR 30.4; animal studies.

## CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at the Research and Development Center, Briar Ridge Road, Ridgefield, Connecticut, and the Production Plant, Briar Ridge Road, Danbury, Connecticut.

11. The Radiation Safety Officer (RSO) for this license is William L. Galdenzi.

12. Licensed material shall be used by, or under the supervision of, individuals designated by the licensee's Radiation Safety Committee

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13. The licensee shall not use licensed material in or on human beings.

14. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.

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

16. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months or at 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.

    B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.

    C. 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.

    D. 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.

    E. Sealed sources need not be 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 not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.

    F. 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.

    G. 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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H. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U. S. Nuclear Regulatory Commission or an Agreement State to perform such services.

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

17. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

18. 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 sources and/or devices received and possessed under the license. Records of inventories shall be maintained for five 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.

19. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

C. Maintains records of the disposal of licensed materials for three years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.

20. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

21. Notwithstanding the requirements of License Condition 22, the licensee is authorized to make program changes and changes to procedures specifically identified in the condition, which were previously approved by the U. S. Nuclear Regulatory 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.

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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.

22. 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 August 24, 2004 [ML042400524]
B. Letter dated December 23, 2004 [ML050110099]
C. Letter dated January 11, 2005 [ML050330011]
D. Letter dated July 20, 2007 [ML072070213]

For the U. S. Nuclear Regulatory Commission

Date August 3, 2011

By ***Original signed by Dennis R. Lawyer***

Dennis R. Lawyer
Commercial and R&D Branch
Division of Nuclear Materials Safety
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King of Prussia, Pennsylvania 19406