

**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.

<b>Licensee</b> 1. Boehringer Ingelheim Pharmaceuticals, Inc.  2. 900 Ridgebury Road P.O. Box 368 Ridgefield, CT 06877-0368		In accordance with letter dated November 26, 2019,  3. License number: 06-19183-01 is amended in its entirety to read as follows:	4. Expiration Date: March 31, 2030  5. Docket No.: 030-17101 Reference No.:
6. Byproduct, source, and/or special nuclear material  A. Any byproduct material with Atomic Numbers 1 through 83  B. Hydrogen-3  C. Carbon-14  D. Phosphorus-32  E. Phosphorus-33	7. Chemical and/or physical form  A. Any  B. Any  C. Any  D. Any  E. Any	8. Maximum amount that licensee may possess at any one time under this license  A. 50 millicuries per radionuclide and 1 curie total  B. 50 curies total  C. 20 curies total  D. 100 millicuries total  E. 5 curies total	9. Authorized use  A. For research and development as defined in 10 CFR 30.4, including animal studies.  B. For research and development as defined in 10 CFR 30.4, including animal studies.  C. For research and development as defined in 10 CFR 30.4, including animal studies.  D. For research and development as defined in 10 CFR 30.4, including animal studies.  E. For research and development as defined in 10 CFR 30.4, including animal studies.

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|---|----------------------------------|--|--|
| 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 | 9. Authorized use  |
| F. Sulfur-35  | F. Any                           | F. 5 curies total  | F. For research and development as defined in 10 CFR 30.4, including animal studies. |
| G. Iodine-125   | G. Any                           | G. 1 curie total   | G. For research and development as defined in 10 CFR 30.4, including animal studies. |
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- CONDITIONS**
10. Licensed material may be used or stored only at the licensee's facilities located at 900 Ridgebury Road, Ridgefield, Connecticut, 06877, and Briar Ridge Road, Danbury, Connecticut, 06877.
11. Licensed material shall only be used by, or under the supervision of, individuals designated in writing, by the Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for 3 years after the individual's last use of licensed material.
12. The Radiation Safety Officer (RSO) for this license is Drané O'Brien.
13. The licensee shall not use the licensed material in or on humans.
14. The licensee shall not use licensed material in field applications where activity 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 material shall not be used for human consumption.

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16. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State. In the absence of a registration certificate, sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 6 months, or at such other intervals as specified.
- 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 3 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 by 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 185 becquerels (0.005 microcuries) of radioactive material on the test sample. If the test reveals the presence of 185 becquerels (0.005 microcuries) 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 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 becquerels (microcuries) and shall be maintained for 3 years.
17. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders, or foil sources removed from detector cells by the licensee, except as specifically authorized.
18. The licensee shall conduct a physical inventory every 6 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 3 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. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
20. A. Detector cells containing a titanium tritide foil or scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperature from exceeding that specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations from an Agreement State.
- B. When in use, detector cells containing a titanium tritide foil or scandium tritide foil shall be vented to the outside.
21. 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:

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- A. Before disposal as ordinary trash, the waste 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, 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.
- B. A record of each such disposal permitted under this license condition shall be retained for 3 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.
22. Notwithstanding the requirements of License Condition 23, the licensee is authorized to make program changes and changes to procedures specifically identified in the [application/letter] dated [insert date], 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;
- C. The licensee's staff is trained in the revised procedures prior to implementation; and
- D. The licensee's audit program evaluates the effectiveness of the change and its implementation.

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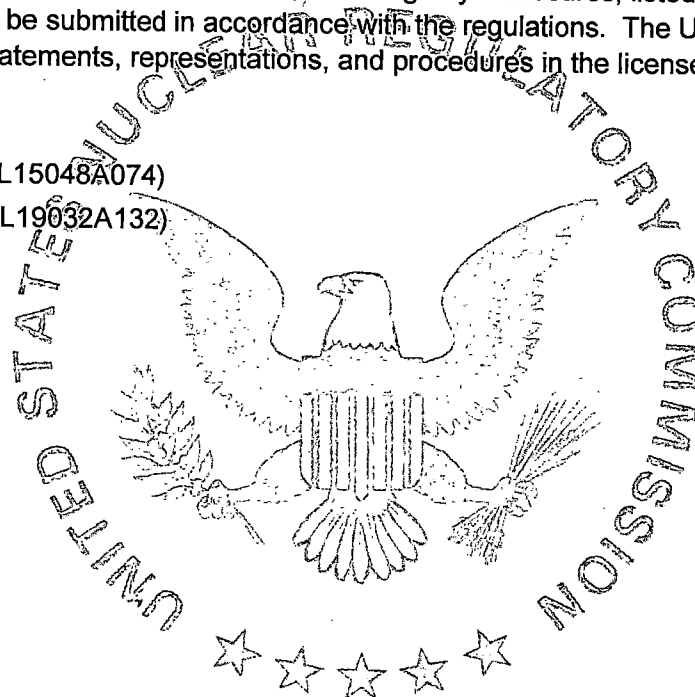
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23. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license 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. Letter dated February 5, 2015 (ML15048A074)

B. Letter dated January 16, 2019 (ML19032A132)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

By: 

Michael Reichard  
Region 1

Date: December 30, 2019