U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 42

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	In accordance with the letter dated December 4, 2012,
1. Pfizer, Inc. Groton Laboratories	3. License number 06-05869-01 is amended in its entirety to read as follows:
2. Eastern Point Road Groton, Connecticut 06340-5196	4. Expiration date September 30, 2014
	5. Docket No. 030-03790 Reference No.

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. 300 millicuries per radionuclide and 20 curies total
B. Hydrogen 3	B. Any	B. 500 curies
C. Carbon 11	C. Any	C. 10 curies
D. Nitrogen 13	D. Any	D. 5 curies
E. Carbon 14	E. Any	E. 70 curies
F. Oxygen 15	F. Any	F. 5 curies
G. Fluorine 18	G. Any	G. 10 curies
H. Phosphorus 32	H. Any	H. 5 curies
I. Phosphorus 33	I. Any	I. 5 curies
J. Sulfur 35	J. Any	J. 5 curies
K. Calcium 45	K. Any	K. 1 curie
L. Chromium 51	L. Any	L. 1 curie
M. Copper 64	M. Any	M. 100 millicuries
N. Rubidium 86	N. Any	N. 1 curie
O. Yttrium 90	O. Any	O. 2 curies
P. Iodine 124	P. Any	P. 100 millicuries
Q. Iodine 125	Q. Any	Q. 5 curies
R. Iodine 131	R. Any	R. 1 curie
S. Nickel 63	S. Plated Foils	S. 15 millicuries per source and 1

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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
		curie total

9. Authorized use:

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

B. and E. Preparation and distribution of radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.

S. To be used for sample analysis in electron capture detector cells in compatible gas chromatography devices that have been registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with a Commission or Agreement State specific license authorizing distribution to persons specifically authorized by a Commission or Agreement State license to receive, possess, and use the devices.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at Eastern Point Road, Groton, Connecticut.

11. Licensed material shall only be used by, or under the supervision of, individuals designated, in writing, by the Radiation Safety Committee.

12. The Radiation Safety Officer for this license is Mark Maiello, Ph.D.

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

14. The licensee shall not use licensed material in or on human beings 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. This license does not authorize commercial distribution of licensed material.

17. This license does not authorize distribution to persons licensed pursuant to 10 CFR 32.72 or 32.74; to persons exempt from licensing; or to general licensees.

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18. Notwithstanding 10 CFR 10 CFR 32.72(a)(2) and License Condition 17, the licensee is authorized to prepare radioactive drugs in accordance with an accepted U. S. Food and Drug Administration (FDA) Investigational New Drug (IND) application protocol; and to distribute them to medical use licensees in accordance with 10 CFR 32.72.

19. 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 3 months.

C. 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.

D. 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.

E. 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.

F. 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.

G. 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.

H. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.

20. Sealed sources or detector cells containing licensed material shall not be opened or sources removed

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from source holders by the licensee.

21. 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 5 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.

22. 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.

23. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210.

B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

24. 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 3 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.

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

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26. Notwithstanding the requirements of License Condition 30, 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.

    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.

27. 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 June 9, 2004 (ML042020557)
    B. Letter dated August 18, 2004 (ML042400163)
    C. Letter and application dated August 18, 2004 (ML042330425)
    D. Electronic mail dated September 28, 2004 (ML042740434)
    E. Letter dated June 16, 2011 (ML111751038)
    F. Letter and electronic mail dated January 2, 2013 (ML13014A529) (ML13018A240)
    G. Letter dated January 7, 2012 (ML13018A253)

For the U.S. Nuclear Regulatory Commission

Date January 23, 2013

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

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