NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 33

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.

OFFICIAL RECORD COPY

Licensee	
1. Pfizer, Inc. Central Research 2. Eastern Point Road Groton, Connecticut 06340-5196	In accordance with the letter dated February 11, 1997, 3. License Number 06-05869-01 is amended in its entirety to read as follows: 4. Expiration Date September 30, 2004 5. Docket or Reference No. 030-03790

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 with half-lives less than 120 days	A. Any	A. Not to exceed 300 millicuries per radionuclide and 20 curies total
B. Hydrogen 3	B. Any	B. 500 curies
C. Carbon 14	C. Any	C. 50 curies
D. Phosphorus 32	D. Any	D. 5 curies
E. Phosphorus 33	E. Any	E. 5 curies
F. Sulfur 35	F. Any	F. 5 curies
G. Calcium 45	G. Any	G. 1 curie
H. Chromium 51	H. Any	H. 1 curie
I. Rubidium 86	I. Any	I. 1 curie
J. Yttrium 90	J. Any	J. 2 curies
K. Iodine 125	K. Any	K. 5 curies
L. Iodine 131	L. Any	L. 1 curie
M. Nickel 63	M. Plated sources or foils	M. Not to exceed 15 millicuries per source and 1 curie total
N. Californium 252	N. Sealed sources (Isotope Products Laboratories Model FF252/SK362)	N. Not to exceed 20 microcuries per source and 40 microcuries total

9. Authorized use

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

M. In electron capture detector cells which are distributed under a specific license issued by the U.S. Nuclear Regulatory Commission or Agreement State.

N. For use in a Biolon Model 20 Mass Spectrometer

ML 10

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 06-05869-01

Docket or Reference Number: 030-03790

Amendment No. 33

CONDITIONS

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

11. A. Licensed material shall be used by, or under the supervision of, individuals designated in writing by the Radiation Safety Committee, John Stam, Ph.D., Chairperson.

    B. The Radiation Safety Officer for this license is Joseph M. Merenda.

12. Licensed material shall not be used in or on human beings.

13. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.

    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 three months.

    C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

    D. 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.

    E. Sealed sources and detector cells 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

        (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 transfer 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 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 and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken.

G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

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

15. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.

16. 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.

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

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

19. 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:

A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

B. 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.

C. A record of each such 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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 06-05869-01

Docket or Reference Number: 030-03790

Amendment No. 33

20. Radioactive waste generated shall be stored in accordance with the statements, representations, and procedures included with the waste storage plan described in the licensee's letters dated July 30, 1992, March 26, 1993 and January 6, 1995.

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

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 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 July 30, 1992
B. Letter dated March 26, 1993
C. Application dated August 2, 1993
D. Letter dated July 15, 1994
E. Letter dated August 9, 1994
F. Letter dated September 12, 1994
G. Letter dated September 14, 1994
H. Letter dated January 6, 1995
I. Letter dated April 25, 1995
J. Letter dated February 11, 1997
K. Letter dated March 12, 1997

For the U.S. Nuclear Regulatory Commission

Date APR - 4 1997

By ORIGINAL SIGNED BY: JOHN D. KINNEMAN
Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

APR - 4 1997

Mr. Daniel P. Brannegan
Director, Environmental Health
and Safety
Central Research
Pfizer, Inc.
Eastern Point Road
Groton, CT 06340-5196

Dear Mr. Brannegan:

This refers to your license amendment request. Enclosed with this letter is the amended license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

ORIGINAL SIGNED BY:
JOHN D. KINNEMAN

John D. Kinneman, Chief
Nuclear Material Safety Branch 2
Division of Nuclear Materials Safety

License No. 06-05869-01
Docket No. 030-03790
Control No. 124270

Enclosure:
Amendment No. 33
DOCUMENT NAME: R:\WPS\MLTR\L0605886.01

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI	✓				
NAME	JBondick/jmb		JKinneman					
DATE	04/02/97		04/ /97		04/ /97		04/ /97	

OFFICIAL RECORD COPY ML 10

TELEPHONE CONVERSATON RECORD	Date:4/2/97	Time:2:45
Mail Control No.:124270	**License No.:** 06-05869-01	**Docket No.:** 030-03790
Person Called: Daniel P. Brannegan, Director, Envir. Health & Safety	**Organization:** Pfizer, Inc.	**Telephone Number:** 860-441-3654
Person Calling: J. Bondick	**Organization:** NRC	**Telephone Number:** 6951
Subject: Answer to the deficiency letter dated March 6, 1997.		
Summary: Spoke to Mr. Brannegan, and told him we received their response dated March 12, 1997 to our deficiency letter, however, they did not answer Item 3.a. completely. Mr. Brannegan stated that they did not know how to answer question 3.a. since they have plans for expansion into a new building within 2 1/2 years, but they did not intend to use the Yt 90 in the new building. He confirmed this fact with the RSO, Mr. Joseph M. Merenda during the phone conversation.		
Action Required/Taken: Note to file; prepare license amendment and cover letter.		
Signature: JBondick	**Date:** 4/2/97	

Central Research Division
Pfizer Inc
Eastern Point Road
Groton, CT 06340
Tel 860 441 4100

Pfizer

Central Research

MS16
Q-6

March 12, 1997

U. S. Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

RE: Amendment to Radioactive Materials License No. 06-05869-01
Docket No. 030-03790
Control No. 124270

Pfizer Central Research
Eastern Point Road
Groton, CT 06340-5196

Contact regarding this amendment request:
Mr. Joseph M. Merenda, RSO
(860) 441-4744

Dear Mr. Kinneman:

Thank you very much for your response to our request for an amendment to our Nuclear Regulatory Commission License. The following are our responses to the questions you have raised:

1. I have enclosed a copy of the original amendment request which is signed by our management representative, Mr. Daniel P. Brannegan, Director,

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MAR 15 1997

Environmental Health and Safety. Mr. Brannegan has also signed this document.

2 (a). Yttrium-90 will be used in accordance with the definition of "research and development" as defined in 10 CFR 30.4. Its use will include the internal or external administration of this byproduct material (or the radiation thereof) in animal studies.

2 (b). Since yttrium is a high-energy beta emitter, both whole body as well as extremity dosimeters will be worn by those handling mCi quantities. In addition, tools to indirectly handle this isotope will be employed whenever possible and appropriate shielding will be used as well. As always, this isotope will be used in accordance with all Nuclear Regulatory Commission rules and regulations, the Pfizer Central Research Materials License, and sound radiochemical handling precautions and practices. It is anticipated that the yttrium-90 will be used during various "campaigns" and not on a regular basis.

3 (a). Research activities which involve the use and handling of radiochemicals will be conducted at our facility which is located on Eastern Point Road, Groton, Connecticut.

3 (b). Our research activities are defined in 10 CFR 30.4 and do <u>not</u> include field studies.

Thank you once again for your review of our amendment request and I hope that the above responses will permit your approval of this application.

Respectfully submitted,

D P Brannegan

Joseph M. Merenda

Daniel P. Brannegan
Director, Environmental Health & Safety
(860) 441-3654

Joseph M. Merenda
Radiation Safety Officer
(860) 441-4744

Central Research Division
Pfizer Inc
Eastern Point Road
Groton, CT 06340
Tel 860 441 4100

Central Research

February 11, 1997

U. S. Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

RE: Amendment to Radioactive Materials License No. 06-05869-01
Pfizer Central Research
Eastern Point Road
Groton, CT 06340-5196

Contact regarding this amendment request:
Mr. Joseph M. Merenda, RSO
(860) 441-4744

Dear Sir / Madam:

With this letter, Pfizer Inc Groton Central Research hereby requests an amendment of its Materials License, No. 06-05869-01, for the possession of 2 curies of Yttrium-90 and an increase of the limit for Carbon-14 from 20 curies to 50 curies, both in any chemical and/or physical form.

As our research activities continue to expand and diversify, it has become necessary to submit this amendment request. In February of 1995, our Letter of Credit (# PG632955, Standby Trust Agreement with Chase Manhattan Bank) was increased by $377,738 which brought the total to $1,737,138. This was done to cover the acquisition of the SmithKline Beecham Animal Health Facility located in West Chester, Pennsylvania. Shortly after the acquisition, this facility was decommissioned and removed from our Materials License. Our Radiation Safety Committee has reviewed the decommissioning funding plan, and is in agreement that this recent increase (which is now no longer necessary to cover the Animal Health Facility) would cover any potential decommissioning costs associated with this amendment. We will continue to review the funding plan on an annual basis.

We furthermore agree to abide by all Nuclear Regulatory Commission Rules and Regulations and all Materials License requirements for the possession and use of these proposed additions, as well as, all licensed material.

Hopefully, I have provided the information necessary to allow for the expedient approval of this amendment. However, please do not hesitate to contact me directly should you need additional information.

A check in the amount of $660.00 is enclosed to cover the fee for the requested amendment.

Respectfully submitted,

D P Brannegan

Joseph M. Merenda

Daniel P. Brannegan
Director, Environmental Health & Safety
(860) 441-3654

Joseph M. Merenda
Radiation Safety Officer
(860) 441-4744

MAR - 6 1997

License No. 06-05869-01
Docket No. 030-03790
Control No. 124270

Mr. D. P. Brannegan
Director, Environmental Health
and Safety
Central Research
Pfizer, Inc.
Eastern Point Road
Groton, CT 06340-5196

Dear Mr. Brannegan:

This is in reference to your letter dated February 11, 1997 requesting an amendment to Nuclear Regulatory Commission License No. 06-05869-01. In order to continue our review, we need the following additional information:

1. Your application should have been signed by a management representative rather than the Radiation Safety Officer (RSO). Please submit a letter signed by a management representative indicating that management has reviewed the application and concurs in the statements and representations contained therein. Note also that a management representative should sign all future correspondence that requests a change in your license.

2. Your letter requests the addition of 2 curies in any form of yttrium-90.

   a. Please specify whether the intended use for yttrium-90 is research and development as defined in 10 CFR 30.4, and specify whether yttrium-90 will be used in animal studies.

   b. Please describe any special handling procedures that will be used for the yttrium-90.

3. Your rationale for the yttrium-90 and carbon-14 requests was: "As our research activities continue to expand and diversify."

   a. Please confirm that the expansion and diversification of your research activities does not include expansion into additional/new facilities.

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b. Please confirm that the expansion and diversification of your research activities are encompassed by research and development as defined in 10 CFR 30.4, and do not include field studies.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I Office and refer to Mail Control No. 124270. If you have any technical questions regarding this deficiency letter, please call James M. Bondick at (610) 337-6951.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

Original Signed By:
Pamela J. Henderson

John D. Kinneman, Chief
Nuclear Material Safety Branch 2
Division of Nuclear Materials Safety

License No. 06-05869-01
Docket No. 030-03790
Control No. 124270

Enclosures:
10 CFR Parts 20 and 30

DOCUMENT NAME: R:\WPS\DLT\D0605869.01
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI	N				
NAME	JBondick/jmb		JKinneman					
DATE	03/06/97		03/ /97		03/ /97		03/ /97	

OFFICIAL RECORD COPY

Central Research Division
Pfizer Inc
Eastern Point Road
Groton, CT 06340
Tel 860 441 4100

Pfizer

Central Research

030-03790

February 11, 1997

U. S. Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

RE: Amendment to Radioactive Materials License No. 06-05869-01
Pfizer Central Research
Eastern Point Road
Groton, CT 06340-5196

Contact regarding this amendment request:
Mr. Joseph M. Merenda, RSO
(860) 441-4744

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124270

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Hopefully, I have provided the information necessary to allow for the expedient approval of this amendment. However, please do not hesitate to contact me directly should you need additional information.

A check in the amount of $660.00 is enclosed to cover the fee for the requested amendment.

Respectfully submitted,

Joe Merenda

Joseph M. Merenda
Radiation Safety Officer
(860) 441-4744

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03610
STATUS CODE: 0
FEE CATEGORY: 3L
EXP. DATE: 20040930
FEE COMMENTS: TYPE B BROAD
DECOM FIN ASSUR REQD: Y

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: PFIZER, INC.
RECEIVED DATE: 970214
DOCKET NO: 3003790
CONTROL NO.: 124270
LICENSE NO.: 06-05869-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: $660.00
CHECK NO.: NY0100126 4203

3. COMMENTS

SIGNED M. A. Berlin
DATE 2/18/97

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED / 11

1. FEE CATEGORY AND AMOUNT: 3L $660

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT
RENEWAL
LICENSE

3. OTHER

SIGNED
DATE

I (97)
Fee 15
Check No. NY0100126 4203
Amount 660
Fee Category 3L
Type of Fee Amd
Date Check Rec'd 2/28/97
Date Completed
By BB

1997 FEB 25 AM 8:32