UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

January 8, 2004

Timothy L. Popp
Radiation Safety Officer
Pharmacia & Upjohn Company
7000 Portage Road
Kalamazoo, MI 49001

SUBJECT: ACKNOWLEDGMENT OF CORRESPONDENCE
(Letter Dated 12/23/03)

Dear Timothy L. Popp:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

_____ New License ___✓___ Amendment _____ Termination

No Administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

It appears that your request is routine (see 1-2 below, as applicable).

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.

2. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number(s). Please direct any questions concerning your request to the Materials Licensing Branch at (630) 829-9887.

Materials Licensing Branch

Mail Control Nos. 312874
License No. 21-00182-03

NRC FORM 374

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	In accordance with the **application** dated **October 17, 2003**
1. U.S. Department of Health and Human Services National Institute of Environmental Health Sciences	3. License No. 32-12358-01 is **renewed** in its entirety to read as follows:
2. P.O. Box 12233 Research Triangle Park, North Carolina 27709	4. Expiration Date: **April 30, 2014**
	5. Docket No. 030-05596

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. 18.5 gigabecquerels (GBq) [500 millicuries (mCi)] per radionuclide and 1.85 terabecquerels (TBq) [50 curies (Ci)] total
B. Hydrogen 3	B. Any	B. 740 GBq (20 Ci)
C. Carbon 14	C. Any	C. 74 GBq (2 Ci)
D. Sulfur 35	D. Any	D. 74 GBq (2 Ci)
E. Phosphorus 32	E. Any	E. 74 GBq (2 Ci)
F. Phosphorus 33	F. Any	F. 74 GBq (2 Ci)
G.		
H. Cesium 137	H. Sealed source (New England Nuclear Corp. Model NER-570)	H. 3.7 GBq (100 mCi)
I. Cesium 137	I. Sealed source (Amersham Model 77302)	I. 5.92 GBq (160 mCi)
J. Americium 241	J. Sealed source (Amersham variable energy source Z1989)	J. 0.37 GBq (10 mCi)

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9. Authorized Use:

A. - F. For use in research and development as defined by 10 CFR 30.4.

G. For use in a [redacted] for irradiation of biological samples except those of explosive or hazardous nature.

H. For use in a ThermoRetec Model 64-764 calibrator for instrument calibration.

I. For use in an Amersham Model 773 calibrator for instrument calibration.

J. For storage only incident to disposal.

CONDITIONS

10. Licensed material shall be used only at the [redacted]

11. A. Licensed material shall only be used by, or under the supervision of, individuals designated by the Radiation Safety Committee, Dr. Anton M. Jeffcoat, Chairperson.

B. The Radiation Safety Officer (RSO) for this license is William R. Fitzgerald, Jr., CHP.

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

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

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. This license does not authorize commercial distribution of licensed material.

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

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.

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16. 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 need not be leak tested if:

1) they contain only hydrogen-3; or
2) they contain only a radioactive gas; or
3) the half-life of the isotope is 30 days or less; or
4) they contain not more than 3.7 megabecquerels (MBq) [100 microcuries (uCi)] of beta and/or gamma emitting material or not more than 370 kilobecquerels (kBq) (10 uCi) of alpha emitting material; or
5) 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 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 or detector cell 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 185 becquerels (Bq) (0.005 uCi) of radioactive material on the test sample. If the test reveals the presence of 185 Bq (0.005 uCi) 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. The report shall be filed within five days of the date the leak test result is known with the appropriate U. S. Nuclear Regulatory Commission, Regional Office referenced in Appendix D of 10 CFR Part 20. The report shall specify the source involved, the test results, and corrective action taken.

G. The license 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.

17. Sealed sources or detector cells containing licensed material shall not be opened, nor the sources removed from the detector cell by the licensee.

18. The licensee shall not acquire licensed material in a sealed source or device that contains a sealed source unless the source or device has been registered with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.

19. The licensee shall conduct a physical inventory every six months to account for all sources and/or devices received and possessed under the license.

20. 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 temperature from exceeding that specified by the manufacturer and approved by the Commission.

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

21. 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 Commission or an Agreement State to perform such services.

22. 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. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

    B. 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.

    C. A record of each disposal permitted under this 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. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

24. The procedures contained in the [redacted] instruction manual for the [redacted] ([redacted]) shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of the device.

25. The licensee shall not repair, remove, replace, or alter any of the following: electrical and mechanical systems that control source or shielding movement, the irradiator's shielding or sealed source, safety interlocks, or any component that may affect safe operation of the irradiator. These activities shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.

26. For each [redacted] installed and used, the licensee shall:

    A. Permit the use of the irradiator only when a calibrated and operable radiation survey meter or room monitor is available; and

    B. Permit the irradiator door to be opened only after the operator has checked visual indicators to verify that the source has returned to its safe storage position; and

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26. C. Have room monitors installed that will:

    1) Operate at all times when the irradiator is in use; and
    2) Activate a visible and audible alarm when radiation exceeds 2 millirems per hour; and
    3) Detect any radiation leaking from the irradiator door; and
    4) Be visible to the irradiator user when the user is next to the irradiator; or

    D. If a room monitor is not installed, have available a calibrated and operable survey meter which will be used to:
    1) Determine the radiation level at the irradiator door when the door is closed; and
    2) Check for any increase in radiation levels each time the irradiator door is opened.

    E. If abnormal radiation levels or any malfunctions of the irradiator are detected at any time, stop using the irradiator, restrict access to the area housing the irradiator, immediately notify the Radiation Safety Officer, and submit all reports required under 10 CFR Parts 20, 21 or 30.

    F. Not repair or authorize repairs of the irradiator except by the manufacturer or other persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

27. The irradiation of foods and the distribution of foods for human consumption shall be in accordance with the rules and regulations of the U.S. Department of Health and Human Services, U.S. Food and Drug Administration.

28. Pursuant to 10 CFR 20.2002, and 20.2004, 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 2, Column 1, 10 CFR Part 20. Ash residues may be disposed of as ordinary waste provided appropriate surveys pursuant to 10 CFR 20.2002 are made to determine that concentrations of licensed materials appearing in the ash residues do not exceed the concentrations (in terms of microcuries per gram) specified for water in Appendix B, Table 2, Column 2, 10 CFR Part 20.

29. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of unsealed licensed material or readily dispersible source material to quantities less than 10^5 times the applicable limits in Appendix B of 10 CFR Part 30 as specified in 10 CFR 30.35(d), or 3.7 GBq (100 mCi) as specified in 10 CFR 40.36(b).

30. Notwithstanding the requirements of Condition 31, the licensee is authorized to make program changes and changes to procedures specifically identified in the application dated October 17, 2003, which was previously approved by the 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;

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30. 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.

31. 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 October 17, 2003 [renewal]

FOR THE U. S. NUCLEAR REGULATORY COMMISSION

DATE April 12, 2004

BY */RA/*

Bryan A. Parker, Health Physicist
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