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

RIII

DEC 18 2002

Stanley Hampton, M.S.
Radiation Safety Officer
Eli Lilly and Company
Lilly Corporate Center
Radiation Safety
Indianapolis, IN 46285

Dear Mr. Hampton:

Enclosed is Amendment No. 56 which renews your NRC Material License No. 13-01133-02 in accordance with your request. Please note that some of the changes made to your license are printed in bold font. Please review the enclosed document carefully and be sure that you understand all conditions.

Your June 26, 2002 letter stated that the renewal application contained minimal changes to your current license and operating procedures; however, you did not identify those documents currently identified in License Condition 27. (tie-down) that you wished to retain and those you wished to delete. Consequently, we have retained all of those documents in your renewal. If you wish to delete any of those references, you need to be sure that you have included alternate procedures to replace those that you may wish to delete or modify. Please refer to NUREG-1556 Volume 11 (copy enclosed) when preparing your response. Also, note in particular that certain activities (e.g., animal use, incineration, disposal of ash, releases to the environment) need to be accurately defined and described in your application. Please note in particular, the following items:

1. We have not increased/added 200 curies of tritium gas to your license at this time. In order to authorize this request, it will be necessary for you provide a complete description of the intended use for this material, maximum quantities, estimates of leakage from the process, surveys, etc. Your application indicated that it would be used in a trisorber which you stated also contains uranium; however, you did not request the addition of uranium to your license, please clarify. Also include in your justification modifications to your radiation safety program specific to the increase requested (e.g., adjusted quantities of H-3 used per study and revised radiation safety procedures that will reflect larger quantities of materials in use). Provide calculations for effluent releases of hydrogen-3 and provide the assumptions used in your calculations.

2. You renewal application did not address your Decommissioning Funding Plan (DFP) and possible modifications to your financial assurance for decommissioning that would be required as a result of the significant increase in possession limits for hydrogen-3. In order to authorize such an increase, it will be necessary for you to revise your decommissioning funding plan to incorporate the changes in quantities of materials used, as well as changes to the facilities and waste that will be generated as a result of the increased utilization of hydrogen-3 at your facility. In addition, you will also need to modify your DFP and submit financial assurance to reflect current cost estimates. Please refer to NUREG-1727 "NMSS Decommissioning Standard Review Plan" when preparing your response to this item.

3. Regarding your request to incinerate materials at the Tippecanoe Laboratories, be

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advised that you will need to submit a complete description of the incinerator and proposed incineration program for that facility. Please refer to Appendix V. of NUREG-1556 Volume 11 for a complete description of what you will need to provide.

4. In your renewal application, your requested to dispose byproduct material with a half-life of 163 days (calcium-45) by decay-in-storage and to dispose of incinerator ash containing 66 dpm/g of carbon-14 as "non-radioactive" in state permitted municipal solid waste landfills. Be advised that if you wish to pursue these requests, they each will require an environmental review pursuant to 10 CFR Part 51 and Part 61. Please refer to the enclosed copy of NUREG-1748 " Environmental Review Guidance for Licensing Actions Associated with NMSS Programs" and prepare your environmental review accordingly.

5. Item 7. of your application indicated that you wanted to designate both Steve Farmer and Trenton Mays as Assistant Radiation Safety Officers. Be advised that you may designate an Assistant Radiation Safety Officer once you have defined the position and identified in what capacity the Assistant may act on behalf of the Radiation Safety Officer. We will not authorize multiple assistants on the license.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify me at the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9868 so that I can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC, in writing, within 30 days:

   a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the mailing address listed on the license changes. (No fee is required if the location of byproduct material remains the same.)

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:

   a. When you decide to terminate all activities involving materials authorized under the license; or

   b. If you decide not to complete the facility, acquire equipment, or possess and use authorized material.

4. Request and obtain a license amendment before you:

   a. Order byproduct material in excess of the amount, or radionuclide, or form different

b. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

c. Change ownership of your organization.

5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Patricia J. Pelke
Health Physicist
Materials Licensing Branch

License No. 13-01133-02
Docket No. 030-04330

Enclosures: Amendment No. 56
NUREG-1556 Volume 11 "Program Specific Guidance About Licenses of Broad Scope"
NUREG-1748 "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs"

NRC FORM 374 U.S. NUCLEAR REGULATORY COMMISSION

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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. PC03611 310835

Licensee	In accordance with letter dated June 26, 2002,
1. Eli Lilly and Company Lilly Corporate Center	3. License number 13-01133-02 is renewed in its entirety to read as follows:
2. Radiation Safety, MC 190 Indianapolis, IN 46285	4. Expiration date **January 31, 2013**
	5. Docket No. 030-04330 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.		
B. Carbon-14	B. Any	B. 100 curies
C. Hydrogen-3	C. Any	C. 100 curies
D.		
E. Krypton-85	E. Any	E. 5 curies
F. Phosphorus-32	F. Any	F. 2 curies
G. Phosphorus-33	G. Any	G. 2 curies
H. Sulfur-35	H. Any	H. 2 curies
I.		
J.		

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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
K. Nickel-63	K. Sealed sources in election capture detectors (registered pursuant to Section 32.210 of 10 CFR Part 32 or equivalent Agreement State regulations).	K. 10 curies total
L. [illegible]		
M. [illegible]		
N. Phosphorus-32	N. Any form of waste	N. 5 curies
O. Phosphorus-33	O. Any form of waste	O. 5 curies
P. [illegible]		
Q. [illegible]		
R. Nickel-63	R. Sealed or foil sources	R. 20 curies
S. [illegible]		
T. Sulfur-35	T. Any form of waste	T. 5 curies

9. Authorized Use:

A. through H. Research and development as defined in Section 30.4 of 10 CFR Part 30 (including animal studies), analytical instrumentation/standardization, and instrument calibration. The licensee may transfer (on a non-commercial basis) compounds containing hydrogen-3, carbon-14, or sulfur-35 (for medical use in human research subjects) to persons authorized to receive the material pursuant to the terms and conditions of a specific license issued by the Nuclear Regulatory Commission or an Agreement State.

I. through L. To be used in gauging devices, analytical instruments (e.g. gas chomatographs), and static elimination devices registered pursuant to Section 32.210 of 10 CFR Part 32 or equivalent Agreement State regulations and instrument calibration of the licensee's survey meters.

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M. through T. For storage only pending disposal.

CONDITIONS

10. **Licensed material shall be used at the Eli Lilly and Company facilities specified in application dated June 26, 2002. Licensed material may also be received at the**

11. **The Radiation Safety Officer for this license is Stanley Hampton, M.S.**

12. Licensed material shall be used by, or under the supervision of, individuals designated by the Radiation Safety Officer, Stanley Hampton, M.S. The licensee shall maintain records of individuals designated as users.

13. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 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 3 months.

    C. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

    D. Sealed sources 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 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.

    E. The leak 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

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contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(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 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, ATTN: Chief, Nuclear Materials Safety Branch, 801 Warrenville Road, Lisle, Illinois 60532-4351. The report shall specify the source involved, the test results, and corrective action taken.

F. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

14. The licensee shall conduct a physical inventory every 6 months 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 quantities and kinds of byproduct material, manufacturer's name and model numbers, location of the sources and/or devices, and the date of the inventory.

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

16. 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 U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.

17. Prior to initial use and after installation, relocation, dismantling, alignment, or any other activity involving the source or removal of the shielding, the licensee shall assure that a radiological survey is performed to determine radiation levels in accessible areas around, above and below the gauge with the shutter open. This survey shall be performed only by persons authorized to perform such services by the Commission or an Agreement State. A record of the results of this survey shall be maintained for the duration of the license.

18. The licensee shall operate each gauge within the manufacturer's specified temperature and/or environmental limits such that the shielding and shutter mechanism of the source holder are not compromised.

19. The licensee shall assure that the shutter mechanism is locked in the closed position during periods when a portion of an individual's body may be subject to the direct radiation beam. The licensee shall review and modify as appropriate its "lock-out" procedures whenever a new gauge is obtained to incorporate the device manufacturer's recommendations.

20. Installation, initial radiation survey, relocation, or removal from service of devices containing sealed sources shall be performed by Larell Palmer or by persons specifically licensed by the Commission or an Agreement State to perform such services. Maintenance and repair of devices and installation, replacement, and disposal of sealed sources shall be performed only by persons specifically licensed by the Commission or an Agreement State to perform such services.

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21. The licensee is authorized to hold radioactive material with a physical half-life of 120 days or less 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 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.

22. The licensee shall not store licensed material contained in waste for more than five years from the date the waste is put into storage. The licensee shall maintain records which indicate the date that licensed material contained in waste is put into storage [redacted]

23. A. Pursuant to 10 CFR 20.1302 and 10 CFR 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 II, 10 CFR Part 20.

    B. Pursuant to 10 CFR 20.2002, the licensee may dispose of incinerator ash containing radioactive materials with Atomic Nos. 1-83, other than those isotopes listed below, as ordinary waste in a landfill, provided the concentrations of the isotopes, expressed in µCi per gram of ash, at the time of disposal, do not exceed the numerical values listed in Table II, Column 2, of 10 CFR 20, Appendix B. Isotopes not included are hydrogen-3, carbon-14, aluminum-26, chlorine-36, silver-108m, niobium-94,iodine-129, technetium-99, and thallium-204, for which the concentrations must not exceed 10 percent of the values listed in Table II, Column 2, of 10 CFR 20, Appendix B.

24. 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."

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

26. The licensee is authorized to receive byproduct material, in the form of waste, from their wholly owned subsidiary, Sphinx Pharmaceuticals, incident to final processing, incineration, and/or transfer to a waste disposal vendor specifically licensed by the NRC or an Agreement State to receive such wastes.

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

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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 26, 2002 (with attachments), September 2, 1997(with attachments), November 23, 1998 and **June 26, 2002 (with attachments; except Tippecanoe Laboratories incinerator)**; and

B. Letters dated July 8, 1992 (with attachments), March 30, 1994 (except Items 3., 4., 5., 8., and 10. listed on page 1), December 14, 1994, and January 18, 1995, May 29, 1998 (with attachments), February 26, 1999 (with attached Decommissioning Report (Volumes 1 and 2) for the Orchard Area at Greenfield Laboratories), December 8, 1999 (with attachments; except Appendixes 1 and 3) and May 19, 2000 (with attachments).

UNITED STATES NUCLEAR REGULATORY COMMISSION

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date DEC 18 2002

By _____
Patricia J. Pelke
Materials Licensing Branch
Region III