

MATERIALS LICENSE

Amendment No. 01

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. Symphony Pharmaceuticals, Inc.

2. 600 Swedesford Road
Frazer, Pennsylvania 19355In accordance with the letter dated
October 18, 1996,3. License Number 37-30091-02 is amended in its
entirety to read as follows:

4. Expiration Date July 31, 2001

5. Docket or
Reference No. 030-341846. Byproduct, Source, and/or
Special Nuclear Material7. Chemical and/or Physical
Form8. Maximum Amount that Licensee
May Possess at Any One Time
Under This LicenseA. Phosphorus 32
B. Sulfur 35
C. Technetium 99mA. Any
B. Any
C. AnyA. 20 millicuries
B. 90 millicuries
C. 30 millicuries

9. Authorized use

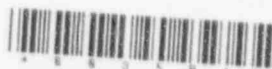
A. through C. Research and development as defined in 10 CFR 30.4.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at
600 Swedesford Road, Frazer, Pennsylvania.11. A. Licensed material shall be used by, or under the supervision of Anthony
Giordano, Ph.D., Kishena Wadhwani, Ph.D., or Debbie Beach, Ph.D.B. Licensed material listed in item 6.C. shall be used by, or under the supervision
of Koon Yan Pak, Ph.D.

C. The Radiation Safety Officer for this license is Anthony Giordano, Ph.D.

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

13. The licensee shall not use licensed material in field applications where activity is
released except as provided otherwise by specific condition of this license.14. 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.9706160023 961112
PDR ADOCK 03034184
C PDR

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

37-30091-02

Docket or Reference Number

030-34184

Amendment No. 01

- 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.
15. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
16. 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. Application dated June 21, 1996
- B. Letter dated July 8, 1996
- C. Letter dated October 18, 1996

NOV 12 1996

Date _____

For the U.S. Nuclear Regulatory Commission

Original Signed By:

Pamela J. Henderson

By _____

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

NOV 12 1996

Anthony Giordano, Ph.D.
Director, Molecular Biology Laboratory
Symphony Pharmaceuticals, Inc.
600 Swedesford Road
Frazer, Pennsylvania 19355

Dear Dr. Giordano:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that based on the documentation of his training, Dr. Koon Yan Pak is not authorized to use or supervise the use of sulfur 35 and phosphorus 32. However, he may use these isotopes under the supervision of an authorized user. Additionally, Part B of Condition 10 of your license is deleted because it is no longer applicable to your license. Condition 14 authorizes you to hold radioactive waste containing sulfur 35 for decay-in-storage.

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:
Pamela J. Henderson

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

License No. 37-30091-02
Docket No. 030-34184
Control No. 123813

Enclosure:
Amendment No. 01

DOCUMENT NAME: R:\WPS\MLTR\13730091.02

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	SLodhi		JKinneman			
DATE	10/30/96		10/7/96	10/ /96		10/ /96

OFFICIAL RECORD COPY

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October 18, 1996

Licensing Assistant Section
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Rd.
King of Prussia, PA 19406-1415

Gentlemen:

This is to request modification of our NRC license # 37-30091-02 as follows:

- a) Add the use of Sulfur 35 in any chemical form for use in research and development as defined in 10 CFR 30.4. The maximum amount of Sulfur 35 that will be possessed at any one time will be 90 millicuries. The primary focus of our initial work will utilize Sulfur 35 labeled methionine for labeling cellular proteins in performing immunoprecipitation experiments.
- b) Add new laboratory space where licensed material will be used and stored. This space is on the ground floor of our existing facility and has durable easily cleaned floor and work surfaces. In addition to the equipment listed in our initial application, this lab has a laminar flow hood that is essential for the tissue culture work. An annotated drawing of this lab is given in Appendix A.
- c) Add Sulfur 35 to the list of radionuclides that we will dispose of by storage for decay following the procedures as established in our initial application. A copy of the revised instructions to employees is given in Appendix B.

A check in the amount of \$610.00 is enclosed for the license amendment fee.

If you require additional information in support of this request please contact me at (610) 725-9948.

Sincerely,

Anthony Giordano, Ph.D.

Enclosures: Check
Appendix A and B

Symphony Pharmaceuticals, Inc.

Appendix B

Instructions for employees concerning the segregation of radioactive wastes:

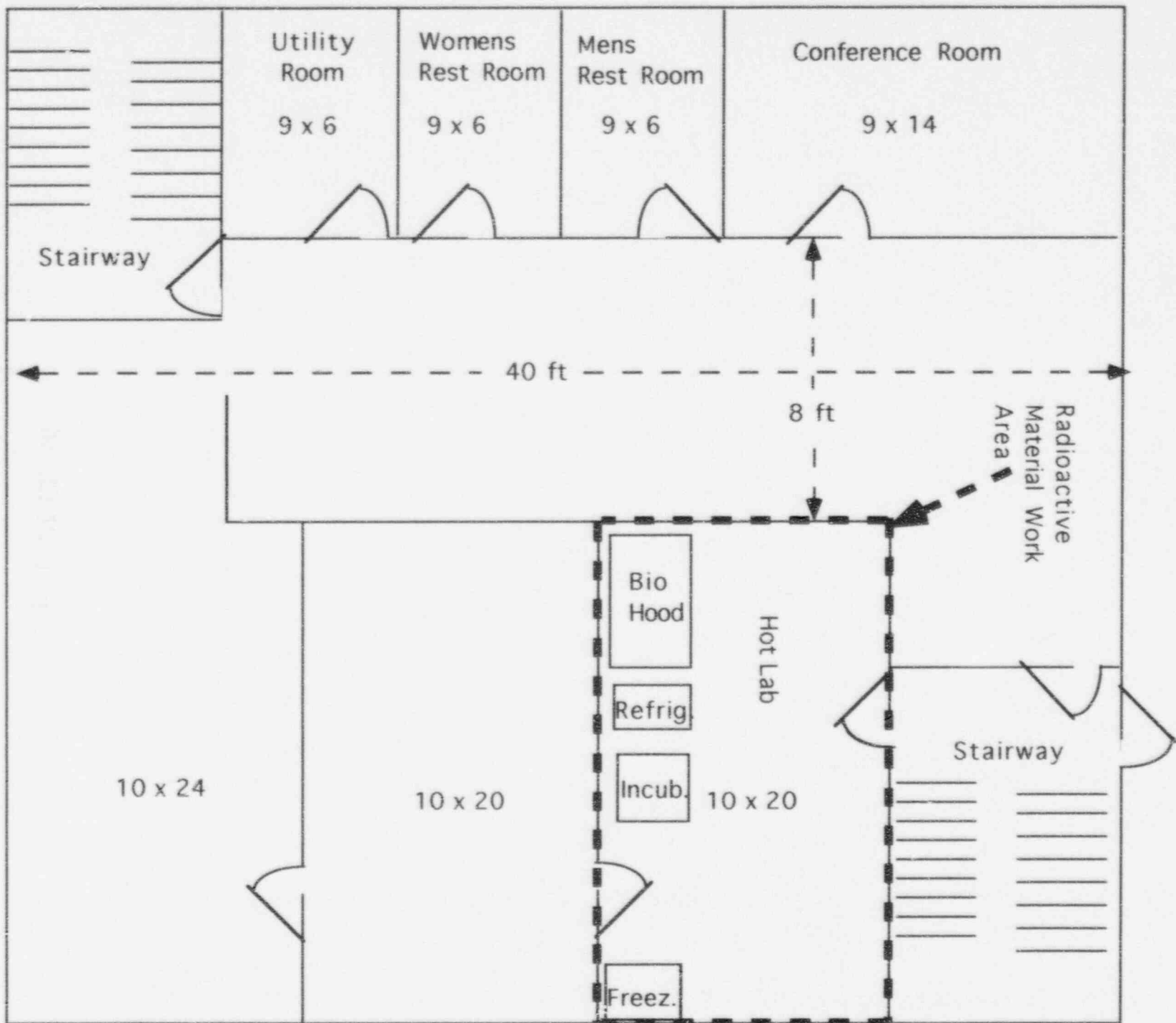
WASTE DISPOSAL

The disposal of radioactive wastes involves one process, storage for decay. It is extremely important to segregate wastes as they are generated into properly labeled containers and to follow the disposal procedures listed below. Failure to follow these procedures will result in restrictions on your use of radioactivity. If you have any questions concerning waste disposal contact Dr. Anthony Giordano.

STORAGE FOR DISPOSAL BY DECAY

All P-32, S-35 or Tc-99m materials may be disposed by decay-in-storage. The following rules apply when using this method of disposal:

- a) Keep all wastes segregated by radio nuclide as they are generated and do not mix wastes.
- b) Clearly label each waste container by radionuclide.
- c) When waste container is full, seal and identify the container. Generate a record that identifies the waste container, the radio nuclide, the date sealed and the authorized user.
- d) The container must be stored in the waste storage area for 10 half lives.
- e) Prior to disposal monitor all sides of the container with an appropriate survey meter in an area free of radiation levels above background. The container can be discarded if the meter measures no radiation levels above background. An appropriate meter is a Ludlum model 3 equipped with a 44-9 probe (Pancake GM). The MDA for this survey method is less than 0.01 microcuries.
- f) All radiation labels in or on the container must be obliterated prior to disposal.
- g) A record containing the following must be generated: Container ID number, date sealed, date disposed, survey meter identity, survey results, person surveying.



APPENDIX A

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03620

STATUS CODE: 0

FEE CATEGORY: 3M

EXP. DATE: 20010731

FEE COMMENTS: -----

DECOM FIN ASSUR REQD: N
.....

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: SYMPHONY PHARMACEUTICALS, INC.

RECEIVED DATE: 961022

DOCKET NO: 3034184

CONTROL NO.: 123813

LICENSE NO.: 37-30091-02

ACTION TYPE: AMENDMENT

2. FEE ATTACHED

AMOUNT: \$610.00

CHECK NO.: 366668

3. COMMENTS

SIGNED
DATE

Rebecca J. Brown
10/25/96

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

1. FEE CATEGORY AND AMOUNT: 3M 8610

2. CORRECT FEE PAID* APPLICATION MAY BE PROCESSED FOR:

AMENDMENT

RENEWAL

LICENSE

3. OTHER

SIGNED
DATE

Log

Remitter CITADEL

Check No. 366668

Amount 8610

Fee Category 3M

Type of Fee AMD

Date Check Rec'd 10/31/96

Date Completed

By: BA

1996 OCT 31 AM 8:32