

MATERIALS LICENSE

Amendment No. 12

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.

301974

Licensee

1. Amersham Life Science, Inc.

2. 26111 Miles Road
Cleveland, OH 44122

In accordance with the letter dated
October 21, 1996
3. License Number 34-23417-01 is amended in
its entirety to read as follows:

4. Expiration Date March 31, 2005

5. Docket or
Reference No. 030-210476. Byproduct, Source, and/or
Special Nuclear Material7. Chemical and/or Physical
Form8. Maximum Amount that Licensee
May Possess at Any One Time
Under This License

A. Hydrogen-3

A. Any

A. 50 millicuries

B. Carbon-14

B. Any

B. 25 millicuries

C. Phosphorus-32

C. Any

C. 30 millicuries

D. Sulfur-35

D. Any

D. 50 millicuries

E. Phosphorus-33

E. Any

E. 50 millicuries

9. Authorized Use:

A. through E. To be used for in vitro tracer studies to measure enzyme activity.CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 26101 Miles Road, Cleveland, Ohio.

11. A. Licensed material shall be used by, or under the supervision of, Parke K. Flick, Ph.D., Carl W. Fuller, Ph.D., John W. Chase, Ph.D., R. Bruce Moffett, Ph.D., Shauna Brummett, Ph.D. or Charles McBride.

B. Radiation Safety Officer: Joseph Anthony Mamone, M.S.

C. Alternate Radiation Safety Officer: Parke K. Flick, Ph.D.

12. Licensed material shall not be used in or on human beings, or in products distributed to the public.

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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

34-23417-01

Docket or Reference Number

030-21047

Amendment No. 12

13. The licensee is authorized to hold radioactive material with a physical half-life of less than 90 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 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.
14. 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 July 27, 1994; and
 - B. Letters dated November 8, 1990, January 18, 1991, July 1, 1991, July 15, 1991, February 13, 1992, November 16, 1993, March 6, 1995, March 14, 1995 and October 21, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 10/31/96

By

Michael F. Weber

Nuclear Materials Licensing Branch, Region III

COPY

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02410
Status Code: 0
Fee Category: 3M
Exp. Date: 20050331
Fee Comments:
Decom Fin Assur Req'd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: AMERSHAM LIFE SCIENCE INCORPORATED
Received Date: 961022
Docket No: 3021047
Control No.: 301974
License No.: 34-23417-01
Action Type: Amendment

2. FEE ATTACHED

Amount: 610
Check No.: 174248

3. COMMENTS

Signed
Date

D. Hersey
10-24-96

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / ☒ /)

1. Fee Category and Amount: 3M \$610

2. Correct Fee Paid. Application may be processed for:

Amendment ☒
Renewal ☐
License ☐

3. OTHER

Signed
Date

SC
10/28/96

OCT 31 1996

Log	OCT 12 711
Remitter	
Check No.	174248
Amount	\$610
Fee Category	3M
Type of Fee	Amend
Date Check Rec'd	10/28/96
Date Completed	10/28/96
By	SC

1996 OCT 28 AM 11:33

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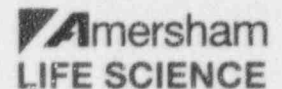
October 21, 1996

United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle, IL 60532-4351

Amersham Life Science Inc.
26111 Miles Road
Cleveland, OH 44128

tel (216) 765-5000
tel (800) 321-9322
fax (216) 464-5075

RE: Amendment to NRC License #34-23417-01

Amersham
LIFE SCIENCE

Dear Sir or Ms.:

We would like to amend the above license to change the person designated as the Radiation Safety Officer (RSO) and to incorporate changes in the text, as recommended by Mr. Wayne Slawinski (Sr. Radiation Specialist, NRC Region I), during our last inspection.

I. Change in RSO.

Mr. Charles McBride is currently the RSO. Due to changes in responsibilities, Mr. McBride will no longer be able to fulfill the RSO's duties. Mr. Joseph Anthony Mamone has been selected as Mr. McBride's replacement.

Mr. Mamone's experience and qualifications are summarized on the following pages.

Mr. McBride has worked with Mr. Mamone to help train Mr. Mamone on the RSO's responsibilities, procedures and the corresponding necessary documentation. Mr. McBride will continue to act as the RSO and be available to help Mr. Mamone with any questions during the transition period until the NRC officially recognizes a new RSO.

II. Change in text.

During Mr. Slawinski's inspection, he noted language in the license which he believed was overly restrictive for our operations. This text appears on page 20 of the license, in paragraph K, Personnel Monitoring. The entire paragraph is reproduced below.

Personnel working with radioactive materials are provided whole body film badges and ring TLD dosimeters. Dosimeters are currently purchased from and analyzed by Landauer, Inc. of Glenwood, Illinois. These are issued on a monthly basis. Records are maintained by the RSO and are available to all employees upon request.

(underlined emphasis added)

continued...

Pm: 10-21-96

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REGION III

OCT 22 1996

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Page 2/continued...

Mr. Slawinski felt that the word "and" (underlined in the above text) made our procedure for issuing dosimeters unnecessarily restrictive, based on the activity levels and the type of radioactive materials we handle. Our historical data for exposures, including extremities, has also been extremely low.

To address Mr. Slawinski's recommendation, we propose to amend paragraph K to read:

Personnel working with radioactive materials are provided whole body film badges. Personnel working with ^{32}P labeled materials are also provided ring TLD dosimeters. Dosimeters are currently purchased from and analyzed by Landauer, Inc. of Glenwood, Illinois. These are issued on a monthly basis. Records are maintained by the RSO and are available to all employees upon request.

Our check, in the amount of \$610, for the NRC's fee to process the amendments, is enclosed.

Please do not hesitate to contact me if you need additional information.

Sincerely,



Denise S. Richardson
Director, Regulatory Affairs

cc: C. McBride, T. Mamone, J. Chase, A. Carr, M. Doruff

Item 7. TRAINING IN RADIATION SAFETY - RADIATION SAFETY OFFICER

Joseph Anthony Mamone

Educational Background: BS Chemistry, 1988 - Ohio State University
 MS Biochemistry, 1990 - Ohio State University

Radiation Safety - training and experience

Course Content	Where Trained	Duration of Training	On Job	Formal Course/ Seminar
Basic principles of radiation safety, measurement of radioactivity	Ohio State University	1 day	No	Yes
Radiation Safety and use of ^{33}P	United States Biochemical Corp. 1992	~2 hours	No	Yes
Standards for protection against radiation (New Part 20)	1993	~2 hours	No	Yes
Basic principals of radiation safety, biological effects of radiation	Amersham Life Science 1995	~2½ hours	No	Yes
	1994	~2½ hours	No	Yes

Experience with Radiation

Radionuclide	Maximum Amount	Where Experience was Gained	Duration of Experience	Type or Experience
^3H	10 mCi	United States Biochemical	6 years	Enzyme Assay
^{14}C	1mCi	United States Biochemical	6 years	Enzyme Assay
^{32}P	10mCi	Ohio State University	4 years	Enzyme Assay
		United State Biochemical	6 years	Enzyme Assay
^{33}P	1mCi	United States Biochemical	6 years	Enzyme Assay
^{35}S	1mCi	Ohio State University	4 years	Enzyme Assay
		United States Biochemical	6 years	Enzyme Assay

NOV 01 1996

Denise S. Richardson
Director, Regulatory Affairs
Amersham Life Science, Inc.
26111 Miles Road
Cleveland, OH 44128

Dear Ms. Richardson:

Enclosed is Amendment No. 12 to your NRC Material License No. 34-23417-01 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we 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 licensee's mailing address 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 when you decide to terminate all activities involving materials authorized under the license.
4. Request and obtain a license amendment before you:
 - a. Change Radiation Safety Officers;

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- b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
 - d. Change ownership of your organization.
5. Submit a complete renewal application with proper fee 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 Policy and Procedures 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,

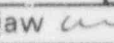
Original Signed By
Michael F. Weber
Nuclear Materials Licensing Branch

License No.: 34-23417-01
Docket No.: 030-21047

Enclosure: Amendment No. 12

DOCUMENT NAME: M:\03021047.CL6

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII	<input checked="" type="checkbox"/>							
NAME	MWEBER:jaw 								
DATE	10/31/96								

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