UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

February 09, 2005

Docket No. 03030602 License No. 37-28218-01
Control No. 135937

Joan M. Chapdelaine, Ph.D.
Vice President, Immunology
Calvert Laboratories, Inc.
Scott Technology Park
100 Discovery Drive
Olyphant, PA 18447

SUBJECT: CALVERT LABORATORIES, INC., ISSUANCE OF LICENSE RENEWAL, CONTROL NO. 135937

Dear Dr. Chapdelaine:

This refers to your request for renewal of your NRC license. Enclosed with this letter is the renewed license. 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 I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

The NRC is required to have your Taxpayer Identification Number in order to make payments (refunds). The self-addressed, stamped NRC Form 531, “Request for Taxpayer Identification Number,” is enclosed.

The NRC expects licensees to conduct their programs with meticulous attention to detail and high standards of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your program according to NRC regulations, the conditions of your NRC license, and the representations made in your application. 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 the NRC in writing of any change in mailing address.

3. In accordance with 10 CFR 30.36(d), notify the 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 acquire or possess and use authorized material.

4. Request and obtain a license Amendment before you:

   a) change Radiation Safety Officers;

   b) order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license; or

   c) add or change the areas of use, or addresses of use identified in the license application or on the license; or

   d) change the name or 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.

In addition, please note that NRC Form 313 requires the applicant, by 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 a certifying official of the licensee rather than a consultant.

You will be periodically inspected by the 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 NUREG 1600, "General Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy).

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

In accordance with 10 CFR 2.390, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at http://www.nrc.gov/reading-rm.html.

Thank you for your cooperation.

Sincerely,

Original signed by Thomas K. Thompson

Thomas K. Thompson
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosures:
1. Amendment No. 14
2. 10 CFR Parts 19, 20, 21, 30, 71, 170, and 171
3. NRC Forms 3, 313, and 531
4. Section 206 of the Energy Reorganization Act of 1974
5. NUREG 1600, General Policy and Procedure for NRC Enforcement Actions (Enforcement Policy)

cc:
William Tuman, Radiation Safety Officer

DOCUMENT NAME: E:\Filenet\ML050410184.wpd

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OFFICE	DNMS/RI	N	DNMS/RI	N	DNMS/RI			
NAME	JNicholson/JJN		TThompson/TKT					
DATE	02/09/2005		02/09/2005					

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U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 14

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	
1. Calvert Laboratories, Inc.	In accordance with the application dated November 29, 2004, 3. License number 37-28218-01 is amended in its entirety to read as follows:
2. Scott Technology Park 100 Discovery Drive Olyphant, Pennsylvania 18447	4. Expiration date February 28, 2015 5. Docket No. 030-30602 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. Hydrogen 3	A. Any	A. 75 millicuries
B. Carbon 14	B. Any	B. 70 millicuries
C. Phosphorus 32	C. Any	C. 10 millicuries
D. Sulfur 35	D. Any	D. 10 millicuries
E. Calcium 45	E. Any	E. 2 millicuries
F. Calcium 47	F. Any	F. 50 millicuries
G. Chromium 51	G. Any	G. 10 millicuries
H. Iron 59	H. Any	H. 10 millicuries
I. Technetium 99m	I. Any	I. 50 millicuries
J. Iodine 125	J. Protein Bound	J. 10 millicuries
K. Iodine 131	K. Protein Bound	K. 10 millicuries

9. Authorized use:

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

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
37-28218-01

Docket or Reference Number
030-30602

Amendment No.14

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at Scott Technology Park, 100 Discovery Drive, Olyphant, Pennsylvania.

11. A. Licensed material shall be used by, or under the supervision of, Joan M. Chapdelaine, Ph.D., Steven Sloneker, Charles B. Spainhour, V.M.D., Ph.D., or William G. Tuman.

    B. The Radiation Safety Officer for this license is William G. Tuman

12. The licensee shall not use licensed material in or on human beings.

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

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

15. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

    A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

    B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

    C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.

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

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
37-28218-01

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Amendment No.14

17. 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 November 29, 2004 (ML043380155)
B. Letter dated January 21, 2005

For the U.S. Nuclear Regulatory Commission

Date February 9, 2005
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By *Original signed by Thomas K. Thompson*

Thomas K. Thompson
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406