MATERIALS LICENSE

Amendment No. 16

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	In accordance with the letter dated July 19, 1996,
1. SmithKline Beecham Clinical Laboratories	3. License Number 20-12707-01 is amended in its entirety to read as follows:
2. 343 Winter Street Waltham, Massachusetts 02254	4. Expiration Date July 31, 2004
	5. Docket or Reference No. 030-04721

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. Iodine 125	A. Prepackaged Kits	A. 15 millicuries

9. Authorized use

A. In vitro laboratory studies.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 343 Winter Street, Waltham, Massachusetts.

11. A. Licensed material shall be used by, or under the supervision of Stephen Dungan, Edward Freedman, or Kathleen Sellon.

B. The Radiation Safety Officer for this license is Edward Freedman.

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 65 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.

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.

0/1

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 20-12707-01

Docket or Reference Number: 030-04721

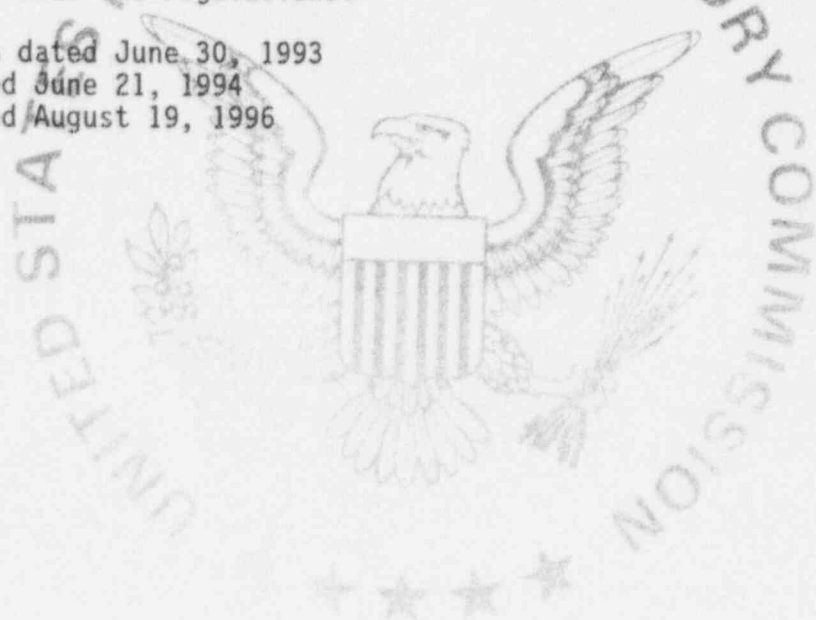
Amendment No. 16

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 30, 1993
B. Letter dated June 21, 1994
C Letter dated August 19, 1996



For the U.S. Nuclear Regulatory Commission

Date SEP 20 1996

By Original Signed By:
John D. Kinneman

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

SEP 20 1996

Stephen M. Dungan, Ph.D.
Technical Director
SmithKline Beecham Clinical Laboratories
343 Winter Street
Waltham, MA 02254

Dear Dr. Dungan:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that as part of this amendment, in accordance with 10 CFR 30.36, effective February 15, 1996, the expiration date of your license has been extended by a period of five years. The new expiration date is stated in Item 4 of the license.

We noted that a wrong license number was entered on page 2 of your NRC license (amendment No. 15). This error has been corrected. 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:

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

License No. 20-12707-01
Docket No. 030-04721
Control No. 123463

Enclosure:
Amendment No. 16

DOCUMENT NAME: R:\WPS\MLTR\L2012707.01
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	N				
NAME	SLodhi		JKinneman					
DATE	08/26/96		08/26/96		08/ /96		08/ /96	

OFFICIAL RECORD COPY ML 10

SmithKline Beecham
Clinical Laboratories

MS 16
Q-2

August 19, 1996

20-12707-01

Sattar Lodhi, Ph.D.
U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406

RE: Mail Control # 123463

Dear Dr. Lodhi:

I am responding to your request for training and experience background on two employees whom we would like to add to our NRC license:

Edward Freedman

Ted has 26 years of experience with isotopes (I-131, I-125, and Cobalt-57).

Kathleen Sellon

Kathy has nearly 5 years of experience working with I-125 and Cobalt-57.

Both employees are familiar with our radiation safety program, and they were trained by the former Radiation Safety Officer before she left the company (Jo Ann Savoy).

As I mentioned during our recent telephone conversation, we are currently using only one regulated isotope and that is Iodine-125. The assay is Vitamin B12/Folate, and each kit contains a maximum of 16 microcuries. We use approximately 12 kits per month.

I also want to acknowledge receipt of NRC Form 483; thank you for sending it along and thank you also for your assistance in updating our license.

Sincerely,

Stephen M. Dungan, Ph.D.
Technical Director

cc: Edward Freedman, Radiation Safety Officer
Kathleen Sellon, Serology/Immunoassay Department Facilitator
Maureen Smith, Quality Assurance Coordinator

radlicen.doc

OFFICIAL RECORD COPY

ML 10

123463

AUG 22 1996

343 Winter Street, Waltham, MA 02254, (617) 890-6161

MNSB TELEPHONE CONVERSATION RECORD

Person Called: Steve Dungan, Director **Phone No.:** (617) 890 6161

Person Calling: Sattar Lodhi **Date:** 8/12/96

Facility Name: Smithkline Beecham Clinical Labs, Waltham, MA **Time:** 3:30 p.m.

License No. 20-12707-01 **Docket No.** 030-04721

Subject: Additional Information for amendment request

Summary: I called Dr. Dungan to request training information of their proposed RSO and another proposed authorized user. I also gave him the information about exempt amounts of licensed materials.

He wanted to know about exempt quantities of Co-57. I informed him that the NRC does not regulate this isotope and he should contact the Commonwealth of Massachusetts regarding this. I informed him that they are authorized by the NRC to use iodine-125, and gave him the regulations stated in 10 CFR 30.18 (under 1 microcurie of iodine 125) and 31.11 (registered users of prepackaged kits with less than 10 microcuries of I-125 per kit with a max of 200 microcuries). I reminded him that any amount stored as radioactive waste would require them to have the license until the disposal of the waste. He stated that he will find out the status of waste and requested that I mail him the Form 483.

Action Required/Taken: Document/wait for response

Signature: Sattar Lodhi Mail Control No. 123463

SB

SmithKline Beecham
Clinical Laboratories

030-04721

July 19, 1996

Francis M. Costello
Chief, Medical Licensing Section
U. S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

Dear Mr. Costello:

I am writing to inform you of some changes to our Materials License (No. 20-12707-01), and ask you for some information regarding future licensing requirements.

The information in paragraph 11 of the "Conditions" section of the license should be amended as follows:

11. A. Licensed material shall be used by, or under the supervision of, Stephen Dungan, Edward Freedman, or Kathleen Sellon.

B. The Radiation Safety Officer for this license is Edward Freedman.

I also want to inform you that we currently have only one clinical assay left on-site which involves the use of radioactive isotopes. As a result, the total level of radioactivity on hand at any given time is now extremely low. I would like to know if there is a level below which a license if no longer required. Can you please advise us on this matter?

Thank you for your assistance.

Sincerely,

Stephen M. Dungan, Ph.D.
Technical Director

cc: Edward Freedman, Radiation Safety Officer
Kathleen Sellon, Serology/Immunoassay Dept. Facilitator

radioact.doc

123463

OFFICIAL RECORD COPY ML 10 JUL 22 1996

343 Winter Street, Waltham, MA 02254, (617) 890-6161

NRC FORM 577 (1-95)

U.S. NUCLEAR REGULATORY COMMISSION

LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

SMITHKLINE BEECHAM CLINICAL LABS
ATTN: STEPHEN M. DUNGAN, PH.D.
TECHNICAL DIRECTOR
343 WINTER STREET
WALTHAM, MA 02254

TYPE OF ACTION

- ☐ NEW LICENSE
- ☐ RENEWAL OF LICENSE
- ☒ AMENDMENT TO LICENSE

REQUESTED DATE: 7-19-96

LICENSE NUMBER: 20-12707-01

CONTROL NUMBER: 123463

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
3P	$	$	$ 300.00
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$

FEE(s) DUE	$ 300.00
PAYMENT RECEIVED	$ 0.00
AMOUNT DUE	$ 300.00

☒ Your request was received without the prescribed application fee.

☐ We received your Check No. _____ in the amount of $ _____. Payment of the additional fee noted above is required.

☐ Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

II. FEE NOT REQUIRED

☐ Enclosed is Check No. _____ which accompanied your request. The fee is not required because:

☐ We received your Check No. _____ in payment of the fee.

☐ The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____, Control No. _____.

☐ Your request was combined, prior to review, with your request, Control No. _____.

III. CHECK RETURNED

☐ Enclosed is Check No. _____ which was returned to us by the bank for:

- ☐ INSUFFICIENT FUNDS
- ☐ ACCOUNT CLOSED
- ☐ OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

☐ License No. _____, Amendment No. _____, issued on _____ was issued without the required fee being collected. The fee required is noted in Section I of this form.

☐ The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section 1 of this form. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section 1 of this form.

SIGNATURE – LICENSE FEE ANALYST	LFDCB	LFDCB
BRENDA BROWN	BB 8/6/96	

Distribution: PENDING F.I.
MAF Correspondence FY
LFDCB Chief LFDCB Analyst OC/DAF/SPC(LF-3-2-7)
Invoice File w/encl LFDCB R/F DAF R/F
DATE 8-6-96

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02410
STATUS CODE: 0
FEE CATEGORY: 3P
EXP. DATE: 20040731
FEE COMMENTS: 3P EFF 7/28/94
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: SMITHKLINE BEECHAM CLINICAL LABS
RECEIVED DATE: 960722
DOCKET NO: 3004721
CONTROL NO.: 123463
LICENSE NO.: 20-12707-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: ---/---
CHECK NO.: ---/---

07/26/96

3. COMMENTS

SIGNED M. A. Perkins
DATE 7/22/96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED / 7-1)

1. FEE CATEGORY AND AMOUNT: 3P $300

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT ✓
RENEWAL ---
LICENSE ---

3. OTHER ---

SIGNED AC
DATE 8/30/96

x 60

Log Aug 2
Remitter
Check No. 1320229
Amount $300
Fee Category 3P
Type of Fee Amd
Date Check Rec'd 8/30
Entry Completed
AC 96