

OCT 10 1996

Mr. Andrew Harris
Aministrator
Mercy Haverford Hospital
2000 Old West Chester Pike
Havertown, PA 19083

Dear Mr. Harris:

In accordance with 10 CFR 35.14, your letter dated July 6, 1996 is accepted as notification that you have permitted the individual named in your letter referenced above to work as an authorized user pursuant to 10 CFR 35.13(b)(1). Frederick Kramer, M.D. has been approved to use materials specified in 10 CFR 35.100 and 35.200 only. Robert Graziano, M.D. will be removed from your license as an authorized user at the time of the next amendment. No further correspondence on this matter is required.

Your cooperation is appreciated.

Sincerely,

ORIGINAL SIGNED BY:
JO ANN V. STAMBAUGH

JoAnn V. Stambaugh
Division of Nuclear Materials Safety

License No. 37-13464-02
Docket No. 030-13669
Control No. 123609

Enclosure:
10 CFR Part 35

DOCUMENT NAME: R:\WPS\MLTR\L3713464.02

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	Stambaugh/jvs						
DATE	10/10/96	10/	/96	10/	/96	10/	/96

ML 10

OFFICIAL RECORD COPY

9610280196 961010
PDR ADOCK 03013669
C PDR

September 10, 1996

Licensing Assistance Section
Nuclear Medicine Safety Branch
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

RE: Notification Letter
License Number: 37-13464-02

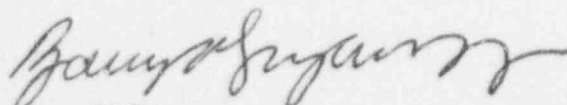
Dear License Reviewer:

In compliance with regulations addressed in 10 CFR 35.14(b)(1), please allow this correspondence to notify the Nuclear Regulatory Commission (NRC) that Robert Graziano, M.D. has permanently discontinued his performance of activities related to the byproduct material license.

This notification letter will remain on file to confirm the deletion of this authorized user.

If you have additional questions, please contact Michael W. Lairmore or myself. Mr. Lairmore may be reached at (201) 447-3303.

Sincerely,



Barry Smoger, M.D.
Radiation Safety Officer

123609
OCT - 1 1996

TELEPHONE CONVERSATION RECORD		Date:	Time:
CONTROL NO. 123609		8/28/96	1:00 AM
Person Called:	Organization:	Telephone (201) Number:	
Mike Laconore (Consultant)	Murray Haverford Hox	447-3303	
Person Calling: J. Stambaugh			
Subject: Lic Amend.			
Summary:			
<p>Licensee sent in possible notification to add user. Dr Kramus needs to submit receptor for I 131 → or withdraw request. Also 35.972 recentness of training - proof</p>			
Licence No. 37-13464-02		Docket No. 030-13669	
Action Required/Taken: Letter			
Signature: J. Stambaugh		Date: 8/28/96	

1996 OCT 15 PM 3:33

2000 Old West Chester Pike
Havertown, PA 19083
(215) 645-3600
FAX (215) 449-0415

September 28, 1996

Ms. Brenda Brown
License Fee Analyst
License Fee & Debt Collection Branch
Office of the Controller
U.S. Nuclear Regulatory Commission
Washington D.C. 20555-0001

RE: Response to NRC Form 577
License Number: 37-13464-02
Control Number: 123609

Dear Ms. Brown:

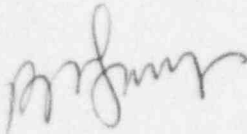
On July 6, 1996, a "Notification Letter" was forwarded to NRC Region I offices for review. Specifically, this document was prepared to notify the NRC that the radiation safety committee had named Frederick Kramer as an authorized user on the byproduct material license.

Subsequently, representatives from NRC Region I offices contacted this licensee and indicated that an amendment application would be needed to name Dr. Kramer as an authorized user. Additionally, it was determined that Dr. Kramer would require additional training prior to amendment preparation.

Therefore, we will not proceed with an amendment request at this time.

If you require additional information, please contact Michael W. Lairmore or myself. Mr. Lairmore may be reached at (201) 447-3303.

Sincerely,



Barry Smoger, M.D.
Radiation Safety Officer
Mercy Haverford Hospital

2000 Old West Chester Pike
Havertown, PA 19083
(215) 645-3600
FAX (215) 449-0415

July 6, 1996

030-13669

Licensing Assistance Section
Nuclear Medicine Safety Branch
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

RE: Notification Letter
License Number: 37-13464-02

Dear License Reviewer:

Pursuant to regulations addressed in 10 CFR 35.14, please allow this correspondence to notify representatives within the Nuclear Regulatory Commission (NRC) that the Radiation Safety Officer and Radiation Safety Committee have granted authorized user status for Frederick Kramer, M.D. Specifically, this physician has been approved for all procedures identified within 35.100, 35.200 and 35.300.

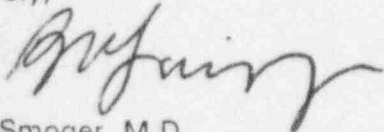
Until recently, Dr. Kramer has been identified as an authorized user on license number: 37-06572-02. A copy of this document has been enclosed within Attachment A for your examination.

Following your review, we request a letter be sent confirming the NRC's approval.

If you have additional questions, please contact Michael W. Lairmore or myself. Mr. Lairmore may be reached at (201) 447-3303.

We thank you in advance for your assistance with this licensing action.

Sincerely,



Barry Smoger, M.D.
Radiation Safety Officer

OFFICIAL RECORD COPY

ML 10

123609

AUG 26 1996

2000 Old West Chester Pike
Havertown, PA 19083
(215) 645-3600
FAX (215) 449-0415

Attachment A

NRC Form 374
(1-84)

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 OF 4 PAGES

MATERIALS LICENSE

Amendment No. 35

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, 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. The Lower Bucks Hospital
2. Bath Road and Orchard Avenue
Bristol, Pennsylvania 19007

In accordance with letter dated
October 26, 1989,
3. License number 37-06572-02 is amended in
its entirety to read as follows:

4. Expiration date December 31, 1989

5. Docket or
Reference No. 030-03073

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. Any byproduct material
listed in Groups I and
II of Schedule A, Section
35.100 of 10 CFR 35
- B. Any byproduct material
listed in Group III of
Schedule A, Section
35.100 of 10 CFR 35
- C. Any byproduct material
listed in Group IV of
Schedule A, Section
35.100 of 10 CFR 35
- D. Any byproduct material
listed in Section 31.11(a)
of 10 CFR 31

- A. Any radiopharmaceutical
listed in Groups I and
II of Schedule A, Section
35.100 of 10 CFR 35
- B. Any form listed in Group
III of Schedule A, Section
35.100 of 10 CFR 35
- C. Any radiopharmaceutical
listed in Group IV of
Schedule A, Section
35.100 of 10 CFR 35
- D. Prepackaged kits

- A. As necessary for uses
authorized in
Subitem 9.A.
- B. 2 curies of each
byproduct material
authorized in
Subitem 6.B.
- C. As necessary for uses
authorized in
Subitem 9.C.
- D. 3 millicuries of each
byproduct material
authorized in
Subitem 6.D.
- E. 200 millicuries

E. Xenon 133

- E. Gas or gas in solution
that is the subject of
an active (i.e., not
withdrawn or terminated)
"New Drug Application"
(NDA) approved by FDA
or an active (i.e., not
withdrawn, terminated or
on "clinical hold")
"Notice of Claimed In-
vestigational Exemption
for a New Drug" (IND)
that has been accepted
by FDA

NRC Form 374A

U.S. NUCLEAR REGULATORY COMMISSION

(3.11)

PAGE 2 OF 4 PAGES

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number:

37-06572-02

Docket or Reference number:

030-03073

Amendment No. 35

9. Authorized use

- A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100, Title 10, Code of Federal Regulations.
- B. Preparation and use of radiopharmaceuticals for any diagnostic procedure listed in Group III of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
- C. Any therapeutic procedure listed in Group IV of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
- D. In vitro studies.
- E. Blood flow and pulmonary function studies.

CONDITIONS

10. Licensed material shall be used only at Lower Bucks County Hospital, Bath Road & Orchard Street, Bristol, Pennsylvania.

11. A. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

James O. Gregersen, M.D.

Groups I, II and III

In vitro studies

Xenon 133

Phosphorus 32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions.

Iodine 131 for treatment of hyperthyroidism and cardiac dysfunction

Edwin LePar, M.D.

Groups I, II, III and IV

In vitro studies

Xenon 133

Philip Brackin, M.D.

Groups I, II and III

In vitro studies

Xenon 133

Richard D. Fleisher, D.O.

Groups I, II and III

In vitro studies

Xenon 133

Phosphorus 32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions

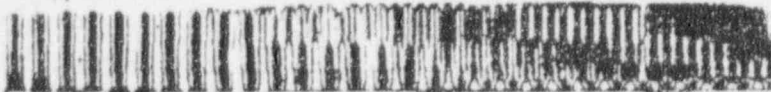
Iodine 131 for treatment of hyperthyroidism, cardiac dysfunction and thyroid carcinoma

Frederick Kramer, M.D.

Groups I, II and III

In vitro studies

Xenon 133



U.S. NUCLEAR REGULATORY COMMISSION

PAGE 3 OF 4 PAGES

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

37-06572-02

Docket or Reference number

030-03073

Amendment No. 35

(11.A. Continued)

CONDITIONS

Eugene H. Roos, D.O.

Groups I, II and III
In vitro studies
Xenon 133

Sang Song, M.D.

In vitro studies

B. Radiation Safety Officer: Edwin LePar, M.D.

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

13. 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. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.
- B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
- C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

14. For a period not to exceed 60 days in any calendar year, a visiting physician is authorized to use licensed material for human use under the terms of this license, provided the visiting physician:

- A. Has the prior written permission of the hospital's Administrator and Radiation Safety Committee, and
- B. Is specifically named as a user on a Nuclear Regulatory Commission license authorizing human use, and
- C. Performs only those procedures which the physician is specifically authorized to perform pursuant to a license issued by the Nuclear Regulatory Commission.

The licensee shall maintain for inspection by the Commission copies of the written permission specified in A, above and of the license(s) specified in B, and C, above for a period of 5 years from the date permission is granted under A, above.

Form 374A
(94)

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 4 OF 4 PAGES

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number:

37-06572-02

Docket or Reference number:

030-03073

Amendment No. 35

(Continued)

CONDITIONS

15. 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 September 28, 1984, containing ALARA Program
- B. Letter dated November 29, 1984
- C. Letter dated May 20, 1987
- D. Letter dated October 31, 1988
- E. Letter dated October 26, 1989

For the U.S. Nuclear Regulatory Commission
Original Signed By:
Lester M. Tripp

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 20555-0001MERCY HAVERFORD HOSPITAL
ATTN: BARRY SMOGER, M.D.
RADIATION SAFETY OFFICER
200 OLD WEST CHESTER PIKE
HAVERTOWN, PA 19083

TYPE OF ACTION

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

REQUESTED DATE

7-6-96

LICENSE NUMBER

37-13464-02

CONTROL NUMBER

123609

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(s) required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
7C	\$	\$	\$ 440.00
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$

FEE(S) DUE \$ 440.00
PAYMENT RECEIVED \$ 0.00
AMOUNT DUE \$ 440.00

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 licensnd program was increased. Therefore, your request is subject to the application fee(s) noted in Section I 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 I of this form.

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.

SIGNATURE -- LICENSE FEE ANALYST

BRENDA BROWN

LFDCB

LFDCB

BB *BB*
9/17/96

Distribution:

Region I Pending
BBrown LFARB RP
OC/DAF/SF (LF-3.2.7)

DATE

9-17-96

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02120
STATUS CODE: 0
FEE CATEGORY: 7C
EXP. DATE: 20040731
FEE COMMENTS: CODE 23
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION

I

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: MERCY HAVERFORD HOSPITAL
RECEIVED DATE: 960826
DOCKET NO: 3013669
CONTROL NO.: 123609
LICENSE NO.: 37-13464-02
ACTION TYPE: AMENDMENT

2. FEE ATTACHED

AMOUNT: ~~-----~~
CHECK NO.: ~~-----~~

3. COMMENTS

SIGNED
DATE

M. A. Perkins
8/22/96

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

1. FEE CATEGORY AND AMOUNT: *7C*

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

AMENDMENT ☒
RENEWAL ☐
LICENSE ☐

3. OTHER

SIGNED
DATE

~~-----~~
~~-----~~

Log	<i>Aug 17</i>
Reinitial	
Check No.	
Amount	
Fee Category	<i>X</i>
By	<i>AAO</i>
Date Check Rec'd	
Date Completed	
By	

Per Mike Perkins
charging to type 8.

BB

MS-04 deleted 10/10/96

MS-07 entered 10/10/96

BB

1996 AUG 20 PM 10:54