

MATERIALS LICENSE

Amendment No. 41

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. Allegheny University Hospitals, East Falls
Radiation Safety Office2. 3300 Henry Avenue
Philadelphia, Pennsylvania 19129In accordance with the letter dated
July 16, 1996,3. License Number 37-02562-01 is amended in
its entirety to read as follows:

4. Expiration Date April 30, 2005

5. Docket or
Reference No. 030-030226. 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. Any byproduct material
identified in 10 CFR
35.100B. Any byproduct material
identified in 10 CFR
35.200C. Any byproduct material
identified in 10 CFR
35.300D. Any byproduct material
identified in 10 CFR
35.400E. Any byproduct material
identified in 10 CFR
31.11

F. Gadolinium 153

G. Depleted Uranium

A. Any radiopharmaceutical
identified in 10 CFR
35.100B. Any radiopharmaceutical
identified in 10 CFR
35.200C. Any radiopharmaceutical
identified in 10 CFR
35.300D. Any brachytherapy source
identified in 10 CFR
35.400

E. Prepackaged Kits

F. Sealed Sources
(North American Scientific
Model MED 3601)

G. Metal

A. As needed

B. As needed

C. 1000 millicuries

D. 1100 millicuries

E. 3.0 millicuries

F. Not to exceed 250
millicuries per source
and 1000 millicuries
total

G. 160 kilograms

9. Authorized use

A. Any uptake, dilution and excretion procedure approved in 10 CFR 35.100.

B. Any imaging and localization procedure approved in 10 CFR 35.200.

C. Any radiopharmaceutical therapy procedure approved in 10 CFR 35.300.

D. Any brachytherapy procedure approved in 10 CFR 35.400.

E. In vitro studies.

F. Two sources to be used in an ADAC Laboratories Model Vantage device for patient attenuation correction during S.P.E.C.T. imaging, and two sources in their shipping container for source replacement.

G. Shielding in a linear accelerator.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

37-02562-01

Docket or Reference Number

030-03022

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CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at East Falls Campus, 3300 Henry Avenue, Philadelphia, Pennsylvania.
11. The Radiation Safety Officer for this license is Theodore Villafana, Ph.D.
12. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:
- A. In accordance with 10 CFR 35.13(b)(1)(3) and (4), physicians, dentists, or podiatrists working as authorized users as defined in 10 CFR 35.2.

| <u>Authorized Users</u> | <u>Material and Use</u> |
|----------------------------|---|
| Mark R. Krakovitz, M.D. | 35.100; 35.200; 35.300 |
| Pradeep Jacob, M.D. | 35.100; 35.200; 35.300 |
| Joan M. Mack, M.D. | 35.100; 35.200; 35.300 <u>In vitro</u> studies |
| Steven J. Brown, M.D. | 35.100; 35.200; 35.300 <u>In vitro</u> |
| Harry J. Lessig, M.D. | 35.100; 35.200; 35.300 <u>In vitro</u> studies |
| Sumathi N. Murthy, M.D. | 35.100; 35.200; 35.300 <u>In vitro</u> studies |
| John Matthews, M.D. | 35.100; 35.200; 35.300 <u>In vitro</u> |
| William A. VanDecker, M.D. | 35.200 for cardiovascular clinical procedures Gadolinium 153 |
| Santosh Gupta-Bala, M.D. | 35.200 for cardiovascular clinical procedures Gadolinium 153 |
| Howard Rosner, D.O. | 35.200 for cardiovascular clinical procedures Gadolinium 153 |
| Ami Iskandrian, M.D. | 35.200 for cardiovascular clinical procedures Gadolinium 153 |
| Jaekyeong Heo, M.D. | 35.200 for cardiovascular clinical procedures Gadolinium 153 |
| Curtis T. Miyamoto, M.D. | 35.400 Depleted Uranium for shielding |

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| | |
|-------------------------|--|
| Enrique Hernandez, M.D. | 35.400 Depleted Uranium for shielding |
| Luther Brady, M.D. | 35.400 Depleted Uranium for shielding |
| William Serber, M.D. | 35.400 Depleted Uranium for shielding |
| Bizhan Micaily, M.D. | 35.400 Depleted Uranium for shielding |
| John Young, M.D. | 35.400 Depleted Uranium for shielding |
| Jeffrey Damsker, M.D. | 35.400 Depleted Uranium for shielding |
| Fariba Asrari, M.D. | 35.400 Depleted Uranium for shielding |

- C. In accordance with 10 CFR 32.72(L)(2)(i) or (4), pharmacists working as authorized nuclear pharmacists.
13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d), 40.36(b), and 70.21(d) for establishing financial assurance for decommissioning.
14. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material at a single location to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material.
15. Notwithstanding the requirements of 10 CFR 35.400(d) and (g), the licensee may use iridium-192 as seeds encased in nylon ribbon and palladium-103 as a sealed source in seeds for topical, interstitial, and intracavitary treatment of cancer. The licensee may deviate from the manufacturer's radiation safety and handling instructions to the extent that the instructions are not applicable to the type of use proposed by the licensee.
16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

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17. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- E. Sealed sources and detector cells need not be leak tested if:
 - (i) they contain only hydrogen-3; or
 - (ii) they contain only a radioactive gas; or
 - (iii) the half-life of the isotope is 30 days or less; or
 - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
 - (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken.

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- G. The licensee is authorized to collect leak test samples for on-site analysis. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.
18. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
19. 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, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. 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 September 29, 1994
 - B. Letter dated December 9, 1994
 - C. Letter dated January 5, 1995
 - D. Letter dated January 18, 1995
 - E. Letter dated March 13, 1995
 - F. Letter dated January 4, 1996, with attachment

For the U.S. Nuclear Regulatory Commission

Original Signed By:
Pamela J. Henderson

By

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

Date SEP 24 1996

SEP 24 1996

Christine Nezu, Ph.D.
Vice Provost for Research
Allegheny University Hospitals
East Falls
3300 Henry Avenue
Philadelphia, PA 19129

Dear Dr. Nezu:

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. Your new expiration date is stated in Item 4 of the license.

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
Division of Nuclear Materials Safety

License No. 37-02562-01
Docket No. 030-03022
Control No. 123471

Enclosure:
Amendment No. 41

cc:
Theodore Villafana, Ph.D.
Radiation Safety Officer
Allegheny University Hospitals
East Falls
Radiation Physics and Safety Office
3300 Henry Avenue
Philadelphia, PA 19129

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C. Nezu, Ph.D.
Allegheny University Hospitals
East Falls

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DOCUMENT NAME: R:\WPS\MLTR\L3702562

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 <i>CH</i> | N | DNMS/RI | | | | |
| NAME | PHenderson | | | | | | |
| DATE | 07/29/96 | | 07/ /96 | | 07/ /96 | | 07/ /96 |

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Christine Nezu, Ph.D.
Associate Provost for Research



ALLEGHENY
UNIVERSITY
OF THE HEALTH SCIENCES

Broad & Vine
Philadelphia, PA 19102-1100
215-762-7000

2900 Queen Lane
Philadelphia, PA 19129
215-991-8100

August 2, 1996

Ms. Pamela Henderson
Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406

MS-16
received
8/5/96

Dear Ms. Henderson:

The following is a supplement to our letter of July 16, 1996 sent by our Radiation Safety Officer (Dr. Theodore Villafana) informing the NRC of the name change of our institution from the Medical College of Pennsylvania and Hahnemann University to Allegheny University of the Health Sciences.

Amendments

- New management person over all licenses to be Christine Nezu, Ph.D., Associate Provost for Research. Dr. Nezu replaces Dr. Vincent Cristofalo.
- Dr. Nezu concurs with name changes on all licenses as specified in letter of July 16, 1996.
- Theodore Villafana, Ph.D. to be listed as Radiation Safety Officer on all licenses.
- Mailing address for correspondence to be:

Allegheny University Hospitals, East Falls
Radiation Safety Office
3300 Henry Avenue
Philadelphia, PA 19129

Please feel free to contact Dr. Villafana at 215-842-6066 for any further information you may need concerning these amendment requests. In the future, Dr. Villafana will follow-up on any subsequent correspondence concerning our licensing.

Sincerely,

Christine Nezu, Ph.D.
Associate Provost for Research

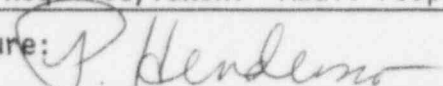
dd

cc: Theodore Villafana, Ph.D.
Radiation Safety Officer

Allegheny Health, Education and Research Foundation

Allegheny General Hospital • Allegheny Emergency Respite Group • Allegheny University of the Health Sciences • Allegheny University Hospital • St. Christopher's Hospital for Children

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| | | | |
|--|--|--|---|
| TELEPHONE CONVERSATION RECORD | | Conversation Date: July 29, 1996 | |
| Mail Control No.: 123470, 123471, 123472, 123473, 123474 | | License No.: 37-07438-15 37-02562-01 SNM-1996 37-00467-35 SNM-1369 | Docket No.: 030-12998 030-03022 070-03077 030-20830 070-01362 |
| Person Called: Ted Villafana, Ph.D. Radiation Safety Officer | | Organization: Allegheny University - Various | Telephone Number: (215) 842-6588 |
| Person Calling: Pamela J. Henderson | | | |
| Subject: License Amendments dated July 16, 1996 | | | |
| Summary: Licensee requested name changes on five licenses. However, there were inconsistencies in mailing address, RSO, and management contact. Also, Dr. Villafana signed the letter requesting the name changes. Licensee will send a letter requesting that the mailing address, RSO, and management contact be the same on all licenses. In addition, licensee will have management concur on the name change requests. | | | |
| Action Required/Taken: Await response. | | | |
| Signature:  | | Date: July 29, 1996 | |

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ML 10



ALLEGHENY
UNIVERSITY
HOSPITALS
EAST FALLS

Radiation Physics
and Safety Office

3300 Henry Avenue
Philadelphia, PA 19129
215-842-6000
phone 215-842-6588
fax 215-843-5734

July 16, 1996

030-03022

Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406

Dear Sir/Madam:

Please be advised that our institute has recently undergone name changes. We request that our license be amended to reflect these changes.

| Former Name | NRC License # | New Name |
|---|---|--|
| Medical College of Pennsylvania and Hahnemann University East Falls Campus | 37-07438-15 (Broad License) | Allegheny University of the Health Sciences East Falls Campus |
| Medical College of Pennsylvania Hospital | 37-02562-01 (Medical License) and 1996 SNM | Allegheny University Hospitals East Falls |
| Medical College of Pennsylvania and Hahnemann University Center City Campus | 37-00467-34 (Broad License) 37-00467-35 and 1369 SNM | Allegheny University of the Health Sciences Center City Campus |
| Hahnemann University Hospital | (Medical license) Pending separation from broad license control #116791 | Allegheny University Hospitals Center City |

There will be no changes or transfers in administrative ownership, management, controls or commitment to compliance with all applicable regulatory and license conditions. It is strictly a name change.

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ML 10

123471
JUL 22 1996

Allegheny Health, Education and Research Foundation

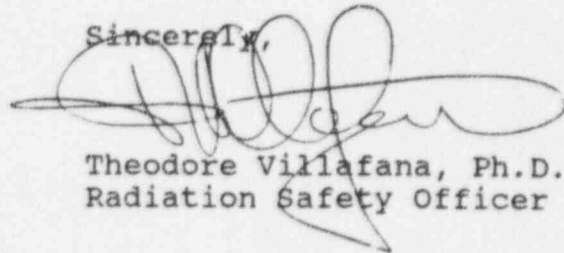
Allegheny General Hospital • Allegheny Integrated Health Group • Allegheny University of the Health Sciences • Allegheny University Hospitals • St. Christopher's Hospital for Children

Nuclear Regulatory Commission
July 16, 1996
Page Two

Additionally, there are no changes in the Radiation Safety Program, Radiation Safety Committee nor in the assignment of radiation safety responsibilities.

One additional change is that Dr. Christine Nezu has replaced Dr. Vincent Cristofalo as Vice Provost for Research. The Radiation Safety Office now reports administratively to Dr. Nezu.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Theodore Villafana', written over the word 'Sincerely,'.

Theodore Villafana, Ph.D.
Radiation Safety Officer

TV:dmt

cc: Christine Nezu, Ph.D.
Kent Lambert, M.S.

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 20555-0001MEDICAL COLLEGE OF PA & HAHNEMANN UNIVERSITY
ATTN: THEODORE VILLAFANA, PHD
RADIATION SAFETY OFFICER
3300 HENRY AVENUE
PHILADELPHIA, PA 19129

TYPE OF ACTION

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

REQUESTED DATE

7-16-96

LICENSE NUMBER

37-02562-01

CONTROL NUMBER

123471

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 |
|--------------|-------------|---------|-----------|
| 7C | \$ | \$ | \$ 440.00 |
| | \$ | \$ | \$ |
| | \$ | \$ | \$ |
| | \$ | \$ | \$ |
| | \$ | \$ | \$ |
| | \$ | \$ | \$ |
| | \$ | \$ | \$ |
| | \$ | \$ | \$ |
| | \$ | \$ | \$ |
| | \$ | \$ | \$ |

| | | |
|------------------|----|--------|
| FEE(s) DUE | \$ | 440.00 |
| PAYMENT RECEIVED | \$ | 0.00 |
| AMOUNT DUE | \$ | 440.00 |

- ☒ 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

BRENDA BROWN

LFDCB

BB
8/6/96

LFDCB

Distribution:

MAF Correspondence FY

LFDCB Chief

Invoice File w/encl

PENDING FILE

LFDCB Analyst

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: 02120
STATUS CODE: 0
FEE CATEGORY: 7C
EXP. DATE: 20050430
FEE COMMENTS: CODE 23
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: MED. COLLEGE OF PA & HAHNEMANN UNIV
RECEIVED DATE: 960722
DOCKET NO.: 3003022
CONTROL NO.: 123471
LICENSE NO.: 37-02562-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED

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

3. COMMENTS

SIGNED
DATE

M. A. Perlman
7/23/96

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

1. FEE CATEGORY AND AMOUNT: 7C \$440

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

AMENDMENT -----
RENEWAL -----
LICENSE -----

3. OTHER -----

SIGNED
DATE

Log Aug 3
Re-init 270002325?
Check No. 8440
Amount 7C
Fee Category AMD
Type of Fee 9/1/96
Date Check Rec'd 9/1/96
Date Completed BB

(Also see
123470, 123472, 123474,
123473 + 123476)

9/11/96
Per Dr. Villafra
The check for this
control is being
sent under separate
cover. Check for mail
control 123532
was received today
sent to RI
BB