

## MATERIALS LICENSE

Amendment No. 04

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.

ORIGINAL SIGNED BY:

Licensee	In accordance with the letter dated July 16, 1996,	
1. Allegheny University Hospitals, East Falls Radiation Safety Office	3. License Number SNM-1996 is amended in its entirety to read as follows:	
2. 3300 Henry Avenue Philadelphia, Pennsylvania 19129	4. Expiration Date September 30, 2002	
	5. Docket or Reference No. 070-03077	
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. Plutonium (principal radionuclide Pu-238)	A. Sealed source	A. Not to exceed 250 milligrams per source and 0.25 grams total

## 9. Authorized use

- A. As a component of Coratomic Model C-101 nuclear-powered cardiac pacemakers for clinical evaluation in accordance with manufacturer's protocol dated November 1, 1975, this authorization includes: follow-up, explantation, recovery disposal, but not implantation.

## CONDITIONS

10. Licensed material may be used only at the licensee's facilities at 3300 Henry Avenue, Philadelphia, Pennsylvania.
11. A. The physician responsible for follow-up, explantation, and return to the manufacturer for proper disposal is John Fontaine, M.D.  
B. The Radiation Safety Officer for this license is Theodore Villafana, Ph.D.
12. The specified possession limit includes all licensed material possessed by the licensee under this license whether in storage, implanted in patients, or otherwise in use.
13. The licensee shall continue patient follow-up and replacement procedures for the nuclear pacemaker during the life of the patient. Procedures for recovery and authorized disposal of the nuclear pacemaker by return to the manufacturer shall be followed upon the death of the patient.
14. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders or detector cells by the licensee.

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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

SNM-1996

Docket or Reference Number

070-03077

Amendment No. 04

15. The licensee may 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. Letter dated March 31, 1976
  - B. Application dated April 10, 1992
  - C. Two letters dated April 16, 1992
  - D. Letter dated July 10, 1992
  - E. Application dated February 5, 1993
  - F. Letter dated January 5, 1995



For the U.S. Nuclear Regulatory Commission

Original Signed By:

By

Pamela J. Henderson

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.

Conditions 13, 14 and 18 which appear in Amendment No. 03 of your license were deleted with the issuance of this Amendment (No. 04). It is no longer the policy of the NRC to use these conditions.

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. SNM-1996  
Docket No. 070-03077  
Control No. 123472

Enclosure:  
Amendment No. 04

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

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

DOCUMENT NAME: R:\WPS\MLTR\LSNM1996

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	<input checked="" type="checkbox"/> N	DNMS/RI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NAME	PHenderson						
DATE	08/01/96	08/ /96	08/ /96	08/ /96	08/ /96	08/ /96	08/ /96

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Christine Nezu, Ph.D.  
Associate Provost for Research



ALLEGHENY  
UNIVERSITY  
OF THE HEALTH SCIENCES

Broad & Vine  
Ph: 412-261-1100  
215-762-7000

2000 Chestnut 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 Integrated Health Group • Allegheny University of the Health Sciences • Allegheny Children's Hospital • St. Christopher's Hospital for Children

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<b>TELEPHONE CONVERSATION RECORD</b>		<b>Conversation Date:</b> July 29, 1996	
<b>Mail Control No.:</b> 123470, 123471, 123472, 123473, 123474	<b>License No.:</b>	<b>Docket No.:</b>	
	37-07438-15 37-02562-01 SNM-1996 37-00467-35 SNM-1369	030-12998 030-03022 070-03077 030-20830 070-01362	
<b>Person Called:</b> Ted Villafana, Ph.D. Radiation Safety Officer	<b>Organization:</b> Allegheny University - Various	<b>Telephone Number:</b> (215) 842-6588	
<b>Person Calling:</b> Pamela J. Henderson			
<b>Subject:</b> License Amendments dated July 16, 1996			
<b>Summary:</b>  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.			
<b>Action Required/Taken:</b> Await response.			
<b>Signature:</b> <i>P. Henderson</i>		<b>Date:</b> July 29, 1996	

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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

070-03077

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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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,



Theodore Villafana, Ph.D.  
Radiation Safety Officer

TV:dmt

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



BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM  
AND  
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)  
INFORMATION FROM LTS

PROGRAM CODE: 22160  
STATUS CODE: 0  
FEE CATEGORY: EX 7C  
EXP. DATE: 20020930  
FEE COMMENTS: PACEMAKER/37-07438-15  
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED  
APPLICANT/LICENSEE: MEDICAL COLLEGE HOSPITALS  
RECEIVED DATE: 960722  
DOCKET NO: 7003077  
CONTROL NO.: 123472  
LICENSE NO.: SNM-1996  
ACTION TYPE: AMENDMENT

2. FEE ATTACHED

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

3. COMMENTS

SIGNED M. A. Serbion  
DATE 7/23/96

8. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE Q3 IS ENTERED) ✓

1. FEE CATEGORY AND AMOUNT: EX 7C Pacemaker

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

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

3. OTHER -----

SIGNED -----  
DATE -----

RECEIVED BY LFDCB	
Date	8/6/96
By	Aug 3 <u>(initials)</u>
By	BB
Date Completed	8/6/96

(Also see 123470, 123471, 123474,  
123473 + 123476)