03003043

VOID SHEET

TO: License Fee Management Branch

FROM: RI

SUBJECT: VOIDED APPLICATION

Apr 2 I
7C
117879

Control Number: 117879

Applicant: Cooper Hospital/Center City

Date Voided: 11-29-93

Reason for Void: Amendment not necessary because Franklin Square Hospital filed for bankruptcy. No need to change name. After action has been processed - will change name back to Franklin Square. After review. 37-04871-01

Rebecca J. Brown 11/29/93
Signature Date

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

Final Review of VOID Completed:

Refund Authorized and processed

✓ No Refund Due

Fee Exempt or Fee Not Required

Comments: After Review

Log completed

Processed by: Linda Mitchell
5/10/94

110059

OFFICIAL RECORD COPY ML 10

TELEPHONE CONVERSATON RECORD	Date: 11/23/93	Time: 11:20
Mail Control No.:	**License No.:** [redacted]37-04871-01	**Docket No.:** 030-03043
Person Calling: Arthur Leibersohn, Trustee for Cooper Hospital/Center City duing business as Franklin Square Hospital	**Organization:** Franklin Square Hospital	**Telephone Number:** 215-922-7990
Person Called: David G. Mann		
Subject: License termination		
Summary: Mr. Leibersohn called at my request via the Cooper Hospital/University Medical Center. I asked if he would be submitting a NRC license termination request. He questioned the benefit of requesting termination instead of transferring the license to a new owner should he sell the institution soon. I explained that either is possible; however, the new management would be held to the committments made by the old owner. I explained that the new owner could easily apply for a NRC license and make committments for themselves. In addition, no fees would be assessed for the interim time period. Mr. Liebersohn wants to discuss these options with legal counsel. He agreed to call me with a verbal indication of their decision.		
Action Required/Taken: ~~None~~ D MANN WILL FOLLOW-UP WITH LICENSEE IN PERSON.		
Signature: Dennis Costello	**Date:** 11/23/93	

TELEPHONE CONVERSATON RECORD	**Date:** 03 Aug 93	**Time:** 0900
Mail Control No.: 117879	**License No.:** 37-04871-01	**Docket No.:** 030-03043
Person Called: Dr. Polutan	**Organization:** Cooper/CC.	**Telephone Number:** 215-238-2000
Person Calling: David G. Mann		
Subject: Response letter dated 21 July 1993		
Summary: Please provide your procedure for the bioassay of personnel who prepare and administer 30 mCi or greater of ^{131}I for therapy.		
Action Required/Taken: Response letter within 30 days.		
Signature: DGM	**Date:** 4 Aug 93	

OFFICIAL RECORD COPY ML 10

117879

Cooper Hospital/Center City
201 North Eighth Street • Philadelphia, Pennsylvania 19106
(215) 238-2000

M516
J-7

July 21, 1993

U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19408

ATTN: David Mann
Nuclear Materials Safety Branch

Re: License No. 37-04871-01
Mail Control No. 117879

Dear Mr. Mann:

This correspondence is in response to your letter dated 6/21/93 wherein you requested additional information concerning our I-131 therapy program. The following information is supplied for your review and approval. The information is based on a conversation you had with our consultant physicist, Diana Stockdale on July 12, 1993.

1. Attached is a bioassay worksheet which indicates the methodology we will use for performing bioassays of personnel who prepare and/or administer greater than 30 mCi of I-131. Bioassay measurements will be performed on a Picker uptake probe and Elscint scaler. Action levels are indicated on the worksheet.

2. We will designate a patient room for each I-131 therapy procedure based on room availability at the time of the procedure. We will ensure that the room utilized complies with all regulations contained in 10 CFR Parts 20 and 35. All patients will be assigned a private room with private toilet facilities. Surveys will be conducted of all contiguous areas to ensure compliance with regulatory exposure limits.

Please feel free to contact me if you have any additional questions.

Sincerely,

Leroy J. Rosenberg
Executive Vice President and
Chief Executive Officer

117879

OFFICIAL RECORD COPY ML 10

JUL 26 1993

COOPER HOSPITAL/CENTER CITY

NUCLEAR MEDICINE DEPARTMENT
BIOASSAY WORKSHEET

Date of Bioassay: _____
Date of I-131 Administration: _____
Patient Name: _____
Administered Dose: _____

Name of Person Performing Bioassay: _____

I. SENSITIVITY CALCULATIONS (S):

1. A = I-131 STANDARD CAPSULE ACTIVITY = _____ uCi
2. B = background = _____ cts/5 mins _____ cpm
3. C = I-131 CAPSULE = _____ cts/5 mins _____ cpm
4. S = A / (C - B) uCi/cpm = _____ E_____ uCi/cpm

II. MINIMUM DETECTABLE ACTIVITY (MDA):

1. MDA = (S) (4.66) ($B^{1/2}$ / 5) = _____ cpm
2. Action Level = (0.04 uCi) / S = _____ cpm

III. BIOASSAY MEASUREMENTS:

Individuals who helped administer and/or prepare I-131 dosages:

1. _____ _____ cpm x S = _____ uCi
2. _____ _____ cpm x S = _____ uCi
3. _____ _____ cpm x S = _____ uCi
4. _____ _____ cpm x S = _____ uCi

Results: Are All Measurements Less than 0.04 uCi? _____ Yes _____ No

If No, explain:

JUN 21 1993

License No. 37-04871-01
Docket No. 030-03043
Control No. 117879

Cooper Hospital/Center City
ATTN: Leroy J. Rosenberg, FACHE
Chief Executive Officer
201 North Eighth Street
Philadelphia, Pennsylvania 19106

Dear Mr. Rosenberg:

This is in reference to your request in a letter dated June 9, 1993, to amend License No. 37-04871-01. In order to continue our review, we need the following additional information:

1. Item 5 of your letter dated June 9, 1993 did not provide; your procedure for the bioassay of personnel who prepare and administer 30 millicuries or greater of ^{131}I for therapy or the instrumentation that will used, as requested. Please provide your procedure and identify the instrumentation in your response to this letter. In addition, please provide your action levels for investigation of positive personnel uptakes.

2. Item 7 of your letter dated June 9, 1993 did not provide; a facility diagram depicting the room(s) to be used for radiopharmaceutical therapy and all adjacent areas, as requested. Please provide a specific facility diagram depicting the room(s) to be used for radiopharmaceutical therapy and all adjacent areas.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I office and refer to Mail Control No. 117879. If you have any technical questions regarding this deficiency letter please call me at (215) 337-5237.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

Original Signed By:
David G. Mann

David G. Mann
Nuclear Materials Safety Branch
Division of Radiation Safety
and Safeguards

OFFICIAL RECORD COPY - G:\WPS\DLTR\D93-222 - 06/21/93

ML 10

DRSS:RI
Mann/David:smh

6/ 21 /93

Cooper Hospital/Center City
201 North Eighth Street • Philadelphia, Pennsylvania 19106
(215) 238-2000

MS16
J-7

June 9, 1993

David G. Mann
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

Re: License Number: 37-04871-01
Mail Control Number: 117879

Dear Mr. Mann:

This letter is in response to your correspondence dated May 11, 1993 wherein you request additional information concerning our amendment request. The following information is provided for your review and approval:

1.

a. The company was reorganized.

b. The only changes are related to Administrative Management. All facilities, equipment and technical personnel have remained the same.

c. The company was not sold. Franklin Square Hospital was dissolved.

d. N/A

e. The management of Cooper Hospital/Center City agrees to abide by all commitments and representations previously made to the NRC by Franklin Square Hospital.

f. N/A

2. All wipes are counted on a Picker Well. The instrument is capable of detecting down to less than 200 dpm. Our trigger levels for I-131 will be 200 dpm.

3. We confirm that we will not release patient until either the exposure rate is less than 5 mR/hr at 1 meter or the retained radioactivity is less than 30 mCi.

4. We confirm that we will comply with safety precautions described in 10 CFR Part 35.315.

117879

5. We are in the process of setting up a thyroid probe uptake system. We will ensure that testing is performed to ensure that the device is capable of detecting down to 20 nCi of I-131 in the thyroid. Base on the sensitivity of the unit a procedure for the counting time and other parameters will be developed at that time. No I-131 therapy procedures will be performed until the thyroid probe system is available and bioassay procedures in place.

6. We confirm that we will comply with 10 CFR Parts 35.75 and 35.210.

7. Facility diagrams are attached for the Hot Lab Area where the I-131 will be received and stored. Individual patient rooms will be selected based on availability and suitability at the time of the procedure.

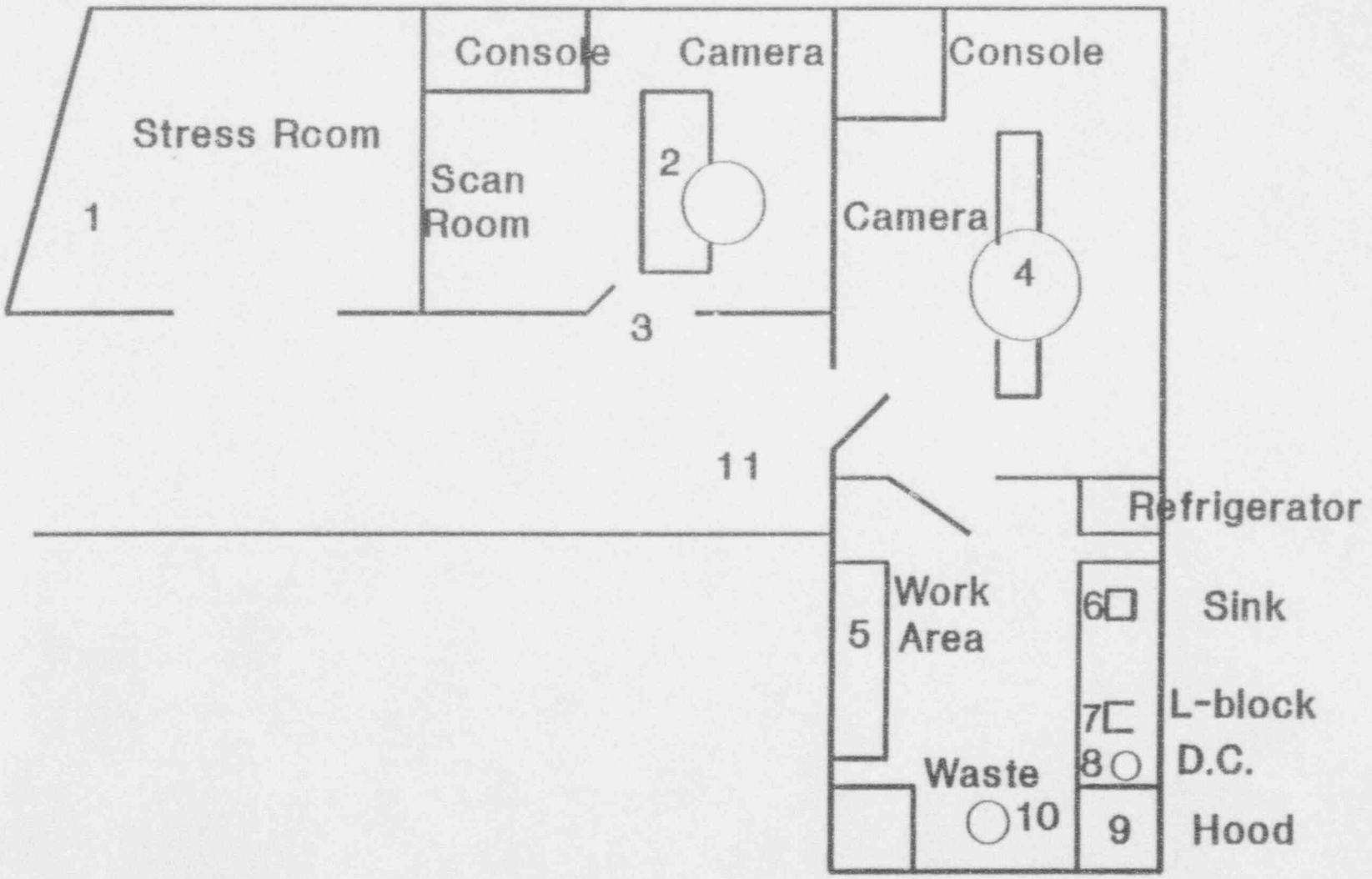
Please feel free to contact us if you have any additional questions.

Sincerely,

Leroy S. Rosenberg
Executive Vice President and CEO

cc: R. Polutan, RSO
T. Mazzone, Administrator
D. Watson, Manager

NUCLEAR MEDICINE



MAY 11 1993

License No. 37-04871-01
Docket No. 030-03043
Control No. 117879

Cooper Hospital\Center City
ATTN: Leroy J. Rosenberg, FACHE
Chief Executive Officer
201 North Eighth Street
Philadelphia, Pennsylvania 19106

Dear Dr. Rosenberg:

This is in reference to your request in a letter dated April 8, 1993, to amend License No. 37-04871-01. In order to continue our review, we need the following additional information:

1. In your letter, you request an amendment to change your name from Franklin Square Hospital to Cooper Hospital/Center City. Since a change of name can be occasioned by a variety of changes in a licensed entity, each of which may have a different effect on the conduct of the licensed program, the NRC needs to understand exactly what kind of change is contemplated before your request can be processed. For example, the NRC is particularly sensitive to reorganizations that place a licensee's assets in one entity, and its liabilities, such as a contaminated facility with large clean-up costs, in another entity. Please answer the following questions with this in mind:

   a. Describe the process by which the name change occurred. For example, was the company sold, reorganized, just changed its name, or some other process?

   b. List all changes in organization, facilities, equipment or personnel.

   c. If the company was sold, will Franklin Square Hospital remain in business?

   d. Is the transfer accomplished by purchase of assets or by purchase of stock?

   e. Affirm that Cooper Hospital/Center City agrees to abide by all commitments and representations previously made to the NRC by Franklin Square Hospital.

   f. Affirm that buyer and seller agree to the transfer.

OFFICIAL RECORD COPY - G:\WPS\DLTR\D178 - 05/11/93

ML 10

As a general rule, if a licensed company is purchased and the seller will not continue in business as a separate entity, the present license can be amended to simply change the name. However, if a licensed operation is purchased from a seller who continues in business as a separate entity with or without using licensed material, the buyer must submit a complete new license application and obtain a new license, even if the licensed facilities and personnel do not change. If the name of the organization is simply changed, then the present license will be amended to reflect the new name.

2. 10 CFR 35.70 requires that a licensee be able to detect contamination, on each wipe sample, of 2000 dpm for ^{99m}Tc and 35.315(a)(7) requires a contamination trigger level of 200 dpm for ^{131}I. Please submit revised procedures to change your removable contamination trigger levels to the regulatory requirements and also describe the instrument you will use for these determinations.

3. 10 CFR 35.75 requires that licensees not release any patient until either the exposure rate from the patient is less than 5 mR/hr at 1 meter of the retained radioactivity is less than 30 mCi. Please confirm.

4. With regard to your procedures and precautions for radiopharmaceutical therapy, 10 CFR 35.315 requires that for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 35.75 that:

   a. a measurement of the thyroid burden of each individual who helped prepare or administer a dosage of ^{131}I be performed within three (3) days after administering the dosage and that a record by maintained;

   b. the patient room not be reassigned until removable contamination is determined to be less than 200 dpm/100 cm^2;

   c. before release, the patient be provided with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable;

   d. promptly after administration of the dosage, a measurement of the dose rates be made in contiguous restricted and unrestricted areas;

   Please confirm that the use of radiopharmaceuticals for therapy will be in accordance with the safety precautions described in 10 CFR 35.315.

5. Please provide your procedure for the bioassay of personnel who prepare and administer 30 millicuries or greater of ^{131}I for therapy, the instrument you will use,

and the instrument's sensitivity. Please provide your action levels for investigation of positive personnel uptakes.

6. Please confirm that all personnel caring for patients receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75 will be instructed in accordance with 35.310.

7. Please provide facility diagrams depicting the rooms to be used for radiopharmaceutical therapy and all adjacent areas.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I office and refer to Mail Control No. 117879. If you have any technical questions regarding this deficiency letter please call me at (215) 337-5237.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

Original Signed By:
David G. Mann

David G. Mann
Nuclear Materials Safety Branch
Division of Radiation Safety
and Safeguards

Enclosures:
1. 10 CFR Parts 19, 20, and 35
2. Regulatory Guide 10.8

DRSS:RI
Mann\David;amw

5/11/93

Cooper Hospital/Center City
201 North Eighth Street • Philadelphia, Pennsylvania 19106
(215) 238-2000

030-03043

April 8, 1993

Mr. Keith Brown
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

Re: License Number 37-04871-01

Dear Mr. Brown:

Please amend our byproduct material license (37-04871-01) as follows:

1. Change the name of our facility from Franklin Square Hospital to Cooper Hospital/Center City. A letter of Agreement from the new management of our facility is attached for your review.

2. Please add Dr. Amando Tiu, M.D. as an authorized user. Dr. Tiu was previously an authorized user at Saratoga Hospital in Saratoga Springs, N.Y. (A copy of the license is enclosed for your review). It is requested that Dr. Tiu be listed as an authorized user for all uses.

3. Please add authorization for radioactive materials specified in 35.300. We will establish and implement the model procedure for radiation safety during radiopharmaceutical therapy that was published in Appendix P to Regulatory Guide 10.8, Revision 2. Dr. Tiu will be the authorized user for radiopharmaceutical therapy.

We have enclosed our Quality Management Program for your review and approval.

The required amendment fee of $540.00 is enclosed. If you have any questions concerning this amendment request, please contact Ms. Trudy Mazzone at 215-238-2067.

Sincerely,

Leroy J. Rosenberg
CEO

Enclosures

License Fee Information
on ltr dtd 3/12/93

117879

APR 09 1993

OFFICIAL RECORD COPY ML 10

Cooper Hospital/Center City
201 North Eighth Street • Philadelphia, Pennsylvania 19106
(215) 238-2000

March 30, 1993

U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA

Gentlemen:

Cooper Hospital/Center City is committed to radiation protection and enforcing the rules and regulations of the Nuclear Regulatory Commission.

The Hospital was formerly Franklin Square Hospital. On or about March 5, 1993 it became Cooper Hospital/Center City and the terms of the NRC license were assumed.

Please contact Trudy Mazzone at 215-238-2067, if you have any additional questions.

Sincerely,

LeRoy J. Rosenberg
CEO

cc: T. Mazzone

License Fee Information
on ltr. dtd 3/12/93

Cooper Hospital/Center City
201 North Eighth Street • Philadelphia, Pennsylvania 19106
(215) 238-2000

37-04871-01
030-03043

March 12, 1993

Keith Brown, Ph.D.
Health Physicist
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

Name Change

Dear Dr. Brown:

As you may know, Cooper HealthCare of Pennsylvania has assumed responsibility for the operation of Franklin Square Hospital. Accordingly, this letter is to inform you that as of Friday, March 5, 1993, Franklin Square Hospital has changed its name to **Cooper Hospital/Center City**.

All operations will continue as they currently exist; however, please direct all correspondence, invoices, checks, etc. to Cooper Hospital/Center City and also please change your records where appropriate to indicate our new name. Thank you for your cooperation.

Very truly yours,

Leroy J. Rosenberg, FACHE
Executive Vice President/
Chief Executive Officer

LJR:rsr

SC ✓

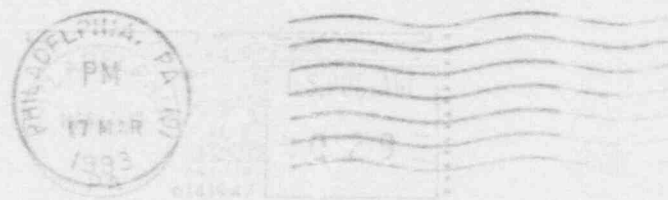
Log
Remitter
Check No. 020756
Amount $350 + $40 = $390 total
Fee Category 2C
Type of Fee Amd
Date Check Rec'd
Date Completed
By:

117879

OFFICIAL RECORD COPY ML 10

MAR 18 1993

COOPER HOSPITAL/CENTER CITY
201 NORTH EIGHTH ST.
PHILADELPHIA, PA 19106



Keith Brown, Ph.D.
Health Physicist
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE

Pursuant to the Public Health Law and Part 16 of the New York State Sanitary ode, and in reliance on statements and representations heretofore made by the icensee designated below, a license is hereby issued authorizing radioactive aterial(s) for the purpose(s), and at the place(s) designated below. The license is ubject to all applicable rules, regulations, and orders now or hereafter in effect f all appropriate regulatory agencies and to any conditions specified below.

. Name

Saratoga Hospital

. Address

211 Church Street
Saratoga Springs, New York 12866

Attention: William Newey, M.D.
Radiation Safety Officer

3. License Number

1893 Amendment No. 6 which supersedes the original license and amendments 1 through 5 in entirety

4. a. Effective Date

January 13, 1988

b. Expiration Date

March 31, 1993

5. Reference Number

DH No. 87-227

. Radioactive Materials (element & mass no.)	7. Chemical and/or Physical Form	8. Maximum quantity licensee may possess at one time
A. Any radioactive material approved for Groups I and II, as found in Appendix 16-A, Table 8, New York State Sanitary Code (10 NYCRR 16)	A. Any radiopharmaceutical approved for Groups I and II, as found in Appendix 16-A, Table 8, New York State Sanitary Code (10 NYCRR 16)	A. As necessary for uses in in subitem 9A
B. Any radioactive material approved for Group III, as found in Appendix 16-A, Table 8, New York State Sanitary Code (10 NYCRR 16)	B. Any radiopharmaceutical approved for Group III, as found in Appendix 16-A, Table 8, New York State Sanitary Code (10 NYCRR 16)	B. 2 curies of each radionuclide authorized in subitem 6B

NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE

CONDITIONS

10. A. Radioactive material listed in Item 6 shall be used by, or under the tutelage of the following individuals, with the specified limitations:

William Newey, M.D.	All items
Jack Paston, M.D.	In vitro procedures as described in Section 16.123 (c), New York State Sanitary Code (10 NYCRR 16)
Amando Tiu, M.D.	All items

B. Radioactive material listed in Item 6 shall be used by William Newey, M.D., as appropriate to fulfill the responsibilities of the Radiation Safety Officer.

11. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license, in accordance with statements, representations, and procedures contained in:

A. Amended Application for New York State Radioactive Materials License dated September 28, 1987, received November 30, 1987, and signed by Wilfred J. Addison, Chief Executive Officer.

B. Letter dated January 4, 1988, signed by Thomas Baulsir, R.T.

The New York State Health Department regulations shall govern the licensee's statements in applications or letters unless the statements are more restrictive than the regulations.

12. The use of radioactive materials in or on human beings shall be by a physician.

13. Radioactive material shall only be transferred in an unopened, labeled shipping container as received from the supplier to a person authorized to possess the material in accordance with the provisions of Part 16, New York State Sanitary Code (10 NYCRR 16).

14. Radioactive material shall be stored in a locked facility in the original shipping container, or a container providing equivalent radiation protection. Such a facility may be a cabinet, a safe, or a room, providing the facility is locked at all times when no activities are in progress relating to the use of the radioactive material. This includes periods of brief absence of personnel from a nuclear medicine department, laboratory, etc., where radioactive materials are used or stored.

APR 21 1993

DIVISION OF ACCOUNTING AND FINANCE
REQUEST FOR REFUND TO EMPLOYEE/VENDOR

THE EMPLOYEE/VENDOR IDENTIFIED BELOW HAS OVERPAID THE NUCLEAR REGULATORY COMMISSION FOR GOODS OR SERVICES PROVIDED AND IS DUE A REFUND.

EMPLOYEE/VENDOR/PAYEE CODE: * _____

NAME: Cooper Hospital / Center City

ADDRESS: ATTN: James N. Brant

ADDRESS: 201 North Eighth Street

CITY: Philadelphia STATE: PA ZIP: 19106

TRANS CODE: PX TRANS TYPE: _____ FUND: _____

JOB CODE: _____ (FOR FE TRANS TYPE) REFUND AMOUNT: _____

COMMENTS: Lic. 37-04871-01 AMD

CK 020756 OVR PYMT

(limit comments to 40 characters, including spaces)

PREPARED BY: [signature] DATE: 4/20/93

AUTHORIZED BY: [signature] TITLE: Lic. Fee Analyst

OFFICE: OC/DAF/RFDCB DATE: 4/21/93

ORIGINAL
INVOICE #: _____ DATE PAID: _____ AMOUNT: $_____

REFUND ENTERED INTO COLLECT BY: _____

REFUND DETERMINED BY: _____ DATE: _____

PLEASE ATTACH APPROPRIATE SUPPORTING DOCUMENTATION.

Apr 21
Bd 8540
117879
JC

* AN ADDRESS MUST BE PROVIDED FOR VENDORS NOT FOUND ON THE VEND TABLE.

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: 19970531
FEE COMMENTS: _____
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: COOPER HOSPITAL/CENTER CITY
RECEIVED DATE: 930318
DOCKET NO: 3003043
CONTROL NO.: 117879
LICENSE NO.: 37-04371-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: ~~---~~ Ø
CHECK NO.: ~~---~~ Ø

3. COMMENTS

SIGNED M. A. Perkins
DATE 3/29/93

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

1. FEE CATEGORY AND AMOUNT: 1C $460

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

3. OTHER _____
_____

SIGNED _____
DATE 4/29/93