

MATERIALS LICENSE

Amendment No. 60

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 April 30, 1997, | |
| 1. St. Francis Medical Center | 3. License Number 37-01072-01 is amended in its entirety to read as follows: | |
| 2. 400 - 45th Street Pittsburgh, Pennsylvania 15201 | 4. Expiration Date August 31, 2005 | |
| | 5. Docket or Reference No. 030-02976 | |
| 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 identified in 10 CFR 35.100 | A. Any radiopharmaceutical identified in 10 CFR 35.100 | A. As needed |
| B. Any byproduct material identified in 10 CFR 35.200 | B. Any radiopharmaceutical identified in 10 CFR 35.200 except generators | B. As needed |
| C. Any byproduct material identified in 10 CFR 35.300 | C. Any radiopharmaceutical identified in 10 CFR 35.300 | C. 500 millicuries |
| D. Any byproduct material identified in 10 CFR 35.400 | D. Any brachytherapy source identified in 10 CFR 35.400 | D. 2 curies |
| E. Any byproduct material identified in 10 CFR 31.11 | E. Prepackaged Kits | E. 2 millicuries |
| F. Strontium 90 | F. Sealed Source | F. 10 millicuries |
| 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. <u>In vitro</u> studies. | | |
| F. Constancy checks of ionization chamber | | |



240023

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 400 - 45th Street, Pittsburgh, Pennsylvania and licensed material in Item 6.B. at Room 218, Suite 100, 4221 Penn Avenue, Pittsburgh, Pennsylvania and One St. Francis Way, Cranberry Township, Pennsylvania.
11. The Radiation Safety Officer for this license is Krishnadas Banerjee, Ph.D.
12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

ML 10

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number

37-01072-01

Docket or Reference number

030-02976

Amendment No. 60

Authorized Users

Material and Use

| | |
|----------------------------|---|
| Lawrence Bucklew, M.D. | 35.200 for cardiovascular clinical procedures |
| P.P. Chengappa, M.D. | 35.200 for cardiovascular clinical procedures |
| John George, M.D. | 35.200 for cardiovascular clinical procedures |
| Revati Ghatnekar, M.D. | 35.200 for cardiovascular clinical procedures |
| Michael F. Hagerty, M.D. | 35.200 for cardiovascular clinical procedures |
| Chandra R. Polam, M.D. | 35.200 for cardiovascular clinical procedures |
| Makum Ramesh, M.D. | 35.200 for cardiovascular clinical procedures |
| Mark Schmidhofer, M.D. | 35.200 for cardiovascular clinical procedures |
| Vinod H. Shah, M.D. | 35.100; 35.200; 35.300; 35.400 |
| David P. Shreiner, M.D. | 35.100; 35.200; 35.300; <u>in vitro</u> studies |
| Andres Ticzon, M.D. | 35.200 for cardiovascular clinical studies |
| Joseph A. Wapenski, M.D. | 35.100; 35.200; 35.300; <u>in vitro</u> studies |
| Yaser Kalash, M.D. | 35.200 for cardiovascular clinical procedures |
| Ragoor K. Reddy, M.D. | 35.200 for cardiovascular clinical procedures |
| Ram L. Dhawan, M.D. | 35.200 for cardiovascular clinical procedures |
| Santosh M. Pandit, M.D. | 35.200 for cardiovascular clinical procedures |
| Parminder K. Sharma, M.D. | 35.200 for cardiovascular clinical procedures |
| Ralph Fitz, M.D. | 35.200 for cardiovascular clinical procedures |
| Krishnadas Banerjee, Ph.D. | Strontium 90 sealed source for constancy checks of ionization chamber |
| Asha Raman, M.D. | 35.200 for cardiovascular clinical procedures |

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 70.25(d) for establishing financial assurance for decommissioning.
14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number

37-01072-01

Docket or Reference number

030-02976

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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, 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 May 26, 1995
- B. Letter dated August 3, 1995
- C. Letter dated December 21, 1995
- D. Letter dated January 4, 1996
- E. Letter dated September 20, 1996
- F. Letter dated October 22, 1996
- G. Letter dated April 30, 1997

Date JUN 10 1997

For the U.S. Nuclear Regulatory Commission

ORIGINAL SIGNED BY:

By **TARA L. WEIDNER**

Nuclear Materials Safety Branch

Region 1

King of Prussia, Pennsylvania 19406

JUN 10 1997

Krishnadas Banerjee, Ph.D.
Radiation Safety Officer
St. Francis Medical Center
400 - 45th Street
Pittsburgh, PA 15201

Dear Dr. Banerjee:

This refers to your license amendment request. Enclosed with this letter is the amended 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:
TARA L. WEIDNER**

Tara L. Weidner
Division of Nuclear Materials Safety

License No. 37-01072-01
Docket No. 030-02976
Control No. 124602

Enclosure:
Amendment No. 60

DOCUMENT NAME: R:\WPS\MLTR\L3701072.01

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 | <input checked="checked" type="checkbox"/> N | DNMS/RI | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| NAME | Weidner | | | | | | |
| DATE | 06/03/97 | 06/ /97 | 06/ /97 | 06/ /97 | | | |

OFFICIAL RECORD COPY



030-02976

ST. FRANCIS MEDICAL CENTER

April 30, 1997

400 - 45th Street
Pittsburgh, PA 15201-1198
412-622-4343

U. S. Nuclear Regulatory Commission
Licensing Assistant Section
Nuclear Materials Safety Branch
475 Allendale Road
King of Prussia, PA 19406-1415

RE: License #37-01072-01

Gentlemen:

We would like to amend our NRC license #37-01072-01 to include the following:

1. Make Doctor Asha Raman an authorized user for radiopharmaceuticals in 10 CFR 35.200. Enclosed you will find preceptor forms signed by one of the authorized users and also a certificate showing the 200 hours required as a qualification to become an authorized user.
2. We are remodeling the existing nuclear medicine department to accommodate a PET scanner. The changes to be made are shown on the enclosed diagram.

Enclosed you will find a check for \$460.00 to cover the amendment fee. If you have any questions, please do not hesitate to contact me.

Very truly yours,

Krishnadas Banerjee
Krishnadas Banerjee, Ph.D.
Radiation Safety Officer

KB:cf

Enclosures

124602

MAY 27 1997

**EXHIBIT 3
SUPPLEMENT B**

| SUPPLEMENT | | U. S. NUCLEAR REGULATORY COMMISSION | |
|--|---|--|---|
| PRECEPTOR STATEMENT | | | |
| <i>Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.</i> | | | |
| 1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS <hr/> FULL NAME <p align="center"><i>Asha Raman, MD</i></p> <hr/> STREET ADDRESS <p align="center"><i>St. Francis Med Center</i></p> <hr/> CITY STATE ZIP CODE <p align="center"><i>Pittsburgh</i> <i>PA</i> <i>15201</i> </p> | | KEY TO COLUMN C PERSONAL PARTICIPATION SHOULD CONSIST OF: 1-Supervised examination of patients to determine the suitability for radiolotope diagnosis and/or treatment and recommendation for prescribed dosage. 2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data. 3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment. | |
| 2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN | | | |
| ISOTOPE <small>A</small> | CONDITIONS DIAGNOSED OR TREATED <small>B</small> | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION <small>C</small> | COMMENTS <small>(Additional information or comments may be submitted in duplicate on separate sheets.) <small>D</small></small> |
| | Thyroid scan | | <p align="center" style="font-size: 1.2em;">Our records showed that Dr. Asha Raman has interpreted and supervised the following tests as recorded during her tenure as a Cardiology Fellow at SFMC from July 1, 1988 to Dec 1991 spending more than 800 hours in these activities.</p> <p align="right" style="font-family: cursive;">[Signature]</p> |
| | Thyroid uptake | | |
| | Lung perfusion scan | | |
| | Xenon ventilation study | | |
| | Aerosol ventilation scan | | |
| | Renal Flow scan | | |
| | Brain scan | | |
| | Liver/spleen scan | | |
| | Bone scan | | |
| | Gastroesophageal study | | |
| | LeVeen shunt study | | |
| | Cystogram | | |
| | Dacryocystogram | | |
| | Cardiac perfusion scan. | 555 | |
| | Cardiac stress ventriculogram | 27 | |
| Cardiac rest ventriculogram | 534 | | |
| Gallium scan | | | |
| | | | |
| | | | |
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| | | | |
| | | | |

EXHIBIT 3 (Continued)

PROPOSED PHYSICIAN USER

PRECEPTOR STATEMENT (Continued)

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)

| ISOTOPE A | CONDITIONS DIAGNOSED OR TREATED B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C | COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D |
|-----------------------------|--|--|--|
| P-32 (Soluble) | TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES | | |
| P-32 (Colloid) | INTRACAVITARY TREATMENT | | |
| I-131 | TREATMENT OF THYROID CARCINOMA | | |
| | TREATMENT OF HYPERTHYROIDISM | | |
| Au-198 | INTRACAVITARY TREATMENT | | |
| Co-60 or Co-137 | INTERSTITIAL TREATMENT | | |
| | INTRACAVITARY TREATMENT | | |
| I-125 or Ir-192 | INTERSTITIAL TREATMENT | | |
| Co-60 or Co-137 | TELETHERAPY TREATMENT | | |
| Sr-90 | TREATMENT OF EYE DISEASE | | |
| | RADIOPHARMACEUTICAL PREPARATION | | |
| Mo-99m Tc-99m | GENERATOR | | |
| Sr-113/ Tc-99m | GENERATOR | | |
| Tc-99m | REAGENT KITS | | |
| Other | | | |

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

LOCATION DATES CLOCK HOURS OF EXPERIENCE
 St. Francis Med. Center 7/1/88 - 12/91 More than 1000 hours

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR

Andres R. Ticzon, M.D., FACP., FACC

b. NAME OF INSTITUTION

St. Francis Medical Center

c. MAILING ADDRESS

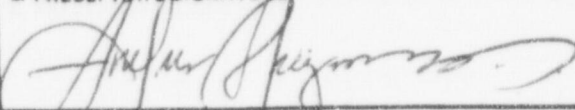
Division of Cardiology 400 45th St.

d. CITY

Pittsburgh, Pa 15201

e. MATERIALS LICENSE NUMBER(S)

f. PRECEPTOR'S SIGNATURE

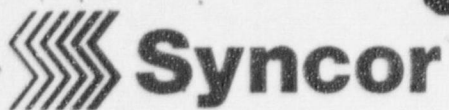


g. PRECEPTOR'S NAME (Please type or print)

Andres R. Ticzon, M.D., FACP., FACC

h. DATE

1-23-97



The Service Difference™

Syncor Pharmacy Services

February 28, 1997

To whom it may concern:

RE: Asha Raman, M.D.
3903 Shadowood Circle
Allison Park, PA 15101

This is to certify that Dr. Raman participated in radiopharmaceutical training at our facility on November 5, 1996. This training involved multiple generator elutions, Mo99 assay, alumina testing, kit preparation, chromatography and quality control, dose drawing and assay, preparation and packaging unit dose radiopharmaceuticals for DOT shipments.

Certified by:

Dan Littlefield
Pharmacy Services Manager

Howard Stoops
Radiation Safety Officer

NUCLEAR CARDIOLOGY TRAINING INSTITUTE

CERTIFICATE OF COMPLETION AND COMPETENCY

This certifies that

ASHA RAMAN, M.D.

has successfully completed all 200 hours of didactic training in:

BASICS OF RADIOISOTOPE HANDLING

and as proof of competency as evidenced through examination, is hereby awarded this

CERTIFICATE OF COMPLETION

The certificate holder demonstrated satisfactory proficiency in the following subjects:

Radiation Physics
Mathematics
Radiation Biology

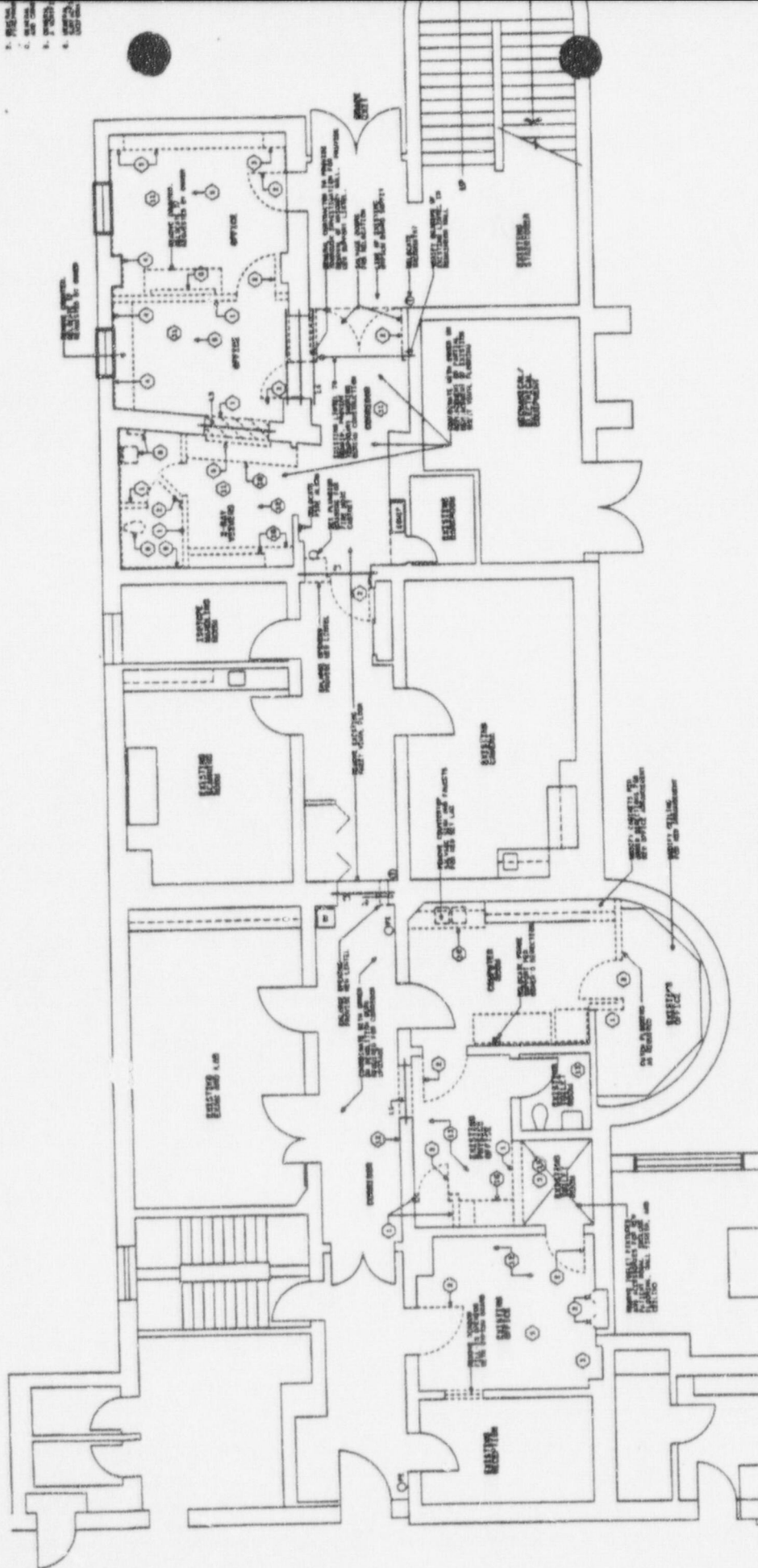
Instrumentation
Radiation Protection
Radiopharmaceutical Chemistry

Keith E. Lovato 11/11/96
Authorized Signature/Date

September 27 - October 1, 1996
October 16 - 20, 1996
November 1 - 10, 1996
Course Dates



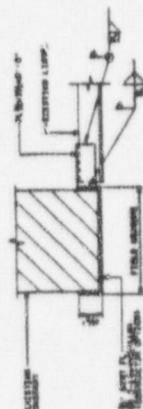
124602



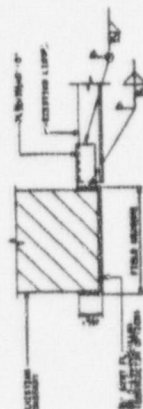
DEMOLITION PLAN SHEET NO. 1-1

- NOTATION:**
- 1 REMOVE EXISTING PARTITION
 - 2 REMOVE EXISTING WALL & PARTITION
 - 3 REMOVE WALL & PARTITION
 - 4 REMOVE WALL, WALL, CORNER
 - 5 REMOVE CORNER & PARTITION
 - 6 REMOVE WALL, WALL, CORNER
 - 7 REMOVE WALL, WALL, CORNER
 - 8 REMOVE WALL, WALL, CORNER
 - 9 REMOVE WALL, WALL, CORNER
 - 10 REMOVE WALL, WALL, CORNER
 - 11 REMOVE WALL, WALL, CORNER
 - 12 REMOVE WALL, WALL, CORNER
 - 13 REMOVE WALL, WALL, CORNER
 - 14 REMOVE WALL, WALL, CORNER
 - 15 REMOVE WALL, WALL, CORNER

| LINTEL SCHEDULE | | | | |
|-----------------|----------------|-------|------|---------|
| NO. | DESCRIPTION | QTY | UNIT | REMARKS |
| 1 | 1/2" x 4" x 8" | 2-1/2 | EA | |
| 2 | 1/2" x 4" x 8" | 2-1/2 | EA | |
| 3 | 1/2" x 4" x 8" | 2-1/2 | EA | |
| 4 | 1/2" x 4" x 8" | 2-1/2 | EA | |
| 5 | 1/2" x 4" x 8" | 2-1/2 | EA | |
| 6 | 1/2" x 4" x 8" | 2-1/2 | EA | |
| 7 | 1/2" x 4" x 8" | 2-1/2 | EA | |
| 8 | 1/2" x 4" x 8" | 2-1/2 | EA | |
| 9 | 1/2" x 4" x 8" | 2-1/2 | EA | |
| 10 | 1/2" x 4" x 8" | 2-1/2 | EA | |
| 11 | 1/2" x 4" x 8" | 2-1/2 | EA | |
| 12 | 1/2" x 4" x 8" | 2-1/2 | EA | |
| 13 | 1/2" x 4" x 8" | 2-1/2 | EA | |
| 14 | 1/2" x 4" x 8" | 2-1/2 | EA | |
| 15 | 1/2" x 4" x 8" | 2-1/2 | EA | |



LINTEL DETAIL "A"



LINTEL DETAIL "B"

OFFICIAL RECORD COPY ML 10

124602

TAX ID: # None

ic No

Docket No

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

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

EMPLOYEE/VENDOR/PAYEE CODE: _____

NAME: St. Francis Medical Center

ADDRESS: Attn: Krishnadas Banerjee, M.D.

ADDRESS: 400-45th Street

CITY: Pittsburgh STATE: PA ZIP: 15201-1198

TRANS CODE: PX

TRANS TYPE: _____ FUND: _____ JOB CODE: _____ AMOUNT: \$20⁰⁰

TRANS TYPE: IR FUND: R1435 JOB CODE: INTR AMOUNT: _____

TRANS TYPE: IR FUND: R1099 JOB CODE: ADCH AMOUNT: _____

TRANS TYPE: IR FUND: R1435 JOB CODE: FINE AMOUNT: _____

TOTAL REFUND AMOUNT: \$20⁰⁰

COMMENTS: lic 37.01072-01/ck 215938/ rfd
4/30/97 rgs

(Limit comments to 40 characters, including spaces)

PREPARED BY: Shirley Cuthbert DATE: June 4, 1997

AUTHORIZED BY: Sandra Kimberly DATE: 6/5/97

ORIGINAL INV. NO: _____ DATE PAID: _____ AMOUNT: _____

REFUND ENTERED INTO COLLECT BY: _____

REFUND DETERMINED BY: _____ DATE: _____

Jun 3 I
and 7c #440 PLEASE ATTACH APPROPRIATE SUPPORTING DOCUMENTATION
ck # 215938 #460
ADA 5/20/97
124602

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: 20050831
Fee Comments: 7C EFF 8/28/95
Decom Fin Assur Req'd: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: ST. FRANCIS MEDICAL CENTER
Received Date: 970527
Docket No: 3002976
Control No.: 124602
License No.: 37-01072-01
Action Type: Amendment

2. FEE ATTACHED

Amount: \$ 460.00
Check No.: 00215938

3. COMMENTS

Signed Mr. A. Perkins
Date 5/30/97

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered ☒)

1. Fee Category and Amount: 7C \$440

2. Correct Fee Paid ☒ Application may be processed for:

Amendment ☒
Renewal ☐
License ☐

3. OTHER

Signed SC
Date 6/3/97

EE:1 Md E-1007 L661

| | |
|------------------|----------------------------------|
| Log | <u>Open 3 I</u> |
| Remitter | |
| Check No. | <u>215938</u> |
| Amount | <u>\$460 (\$440) refund \$20</u> |
| Fee Category | <u>7C</u> |
| Type of Fee | <u>Ampl</u> |
| Date Check Rec'd | <u>6/3/97</u> |
| Date Completed | <u>6/3/97</u> |
| By | <u>SC</u> |