

St. Francis Hospital
Seventh and Clayton Streets
Wilmington, Delaware 19805

Office of President

March 27, 1985

RECEIVED BY LFMB	
Date	4/3/85
Leg.	MAR 19 I
By	Brown
Orig. To	
Action Compl.	4/5/85

Nuclear Regulatory Commission
Region I, Material Licensing Section
631 Park Avenue
King of Prussia, Pennsylvania 19406

RE: LICENSE #07-16862-01
AMENDMENT #05

Gentlemen:

Please amend the above-named license to reflect the following changes in procedures and/or representations.

1. The Mo-99-Tc-99m generators will be dismantled and the radioactive column held for decay as currently provided in the license or will be returned to the manufacturer for disposal. Manufacturer's instructions will be followed.
2. A Xenogard Xenon Room Air and Trap Monitor has been purchased. Therefore, the operation of the Xenon-133 Trap System will be checked as follows: Every two weeks the Xe-133 Room Air/Trap Monitor will be attached to the exhaust port of "Nonex" Trap System. The system will be operated and the effluent air from the Xenon Trap monitored. Whenever concentrations are present which can result in a Xenon Room Air concentration approaching 1 MPC, the cartridge will be stored with other radioactive waste in the "hot lab" until decay permits disposal through normal channels.
3. As pertains to the receipt of radioactive materials during off-duty hours, acceptance will be in accordance with the attached procedure (Attachment 1).
4. Please add Carlos Pena, M.D., and Muhammad Haq, M.D., to the license as users for Groups I-III, and Ronald D. Petrocelli, M.D., (Groups I-V) Xenon-133, and in vitro studies. Their supplements are attached (Attachment 2).
5. The amendment fee of \$120.00 has been remitted via St. Francis Hospital Check #24078.

Sincerely,

Richard A. Long
Richard A. Long
President

RECEIVED-REGION I
MAR 28 11 30 AM '85

"OFFICIAL RECORD COPY"

ML10

03593

MAR 28 1985

Applicant	24078
Check No.	24078
Amount	\$120.00
Type of Fee	Amendment
Date Check	4/3/85
Received By	Brown
RAL/mte	
Attachments	

8506130272 850522
REQ1 LIC30
07-16862-01 PDR

ST. FRANCIS HOSPITAL, INC.
Wilmington, Delaware

Section: NUCLEAR MEDICINE

POLICY AND PROCEDURE MANUALSubject: DELIVERY OF NUCLEAR MEDICINE
RADIOPHARMACEUTICALSPOLICY:

In order to ensure the safety of personnel, and to comply with the U.S. Nuclear Regulatory Commission's regulations regarding the receipt of radioactive materials, the appropriate personnel of this hospital shall take the following action:

PROCEDURE:A. During the hours from 0800 hours to 1630 hours - Monday through Friday

1. Radioactive materials should be delivered directly to Nuclear Medicine by the hospital's Materials Management receiving area personnel.
2. Upon receipt at the loading dock area, the shipment is to be inspected by receiving personnel for damage. If there is any indication of damage, take action as described in Paragraph C.
3. When the shipment is delivered to Nuclear Medicine, the technologist on duty will inspect the shipment for damage and take action described in Paragraph C as necessary.

B. After the above mentioned hours and on Saturday, Sunday, and Holidays

1. The shipment of radioactive material will be delivered to the Emergency Room Office.
2. Upon receipt, Emergency Room personnel will note any obvious damage to the shipment. If there is indication of damage, the Receptionist should take action described in Paragraph C.
3. If no damage is apparent, a Radiologic Technologist on duty in Radiology shall be notified of the arrival of the shipment by the Emergency Room Receptionist and will sign for receipt of the shipment.
4. The Radiologic Technologist on duty, after inspection for damage, shall deliver the shipment to Nuclear Medicine via the Radiology Department. The key to Nuclear Medicine and the Hot Lab is retained in the Radiology Department Key Box.
5. The shipment shall be placed in the room marked "Hot Lab" (Room #325C), on top of the yellow bin on the left hand wall. The Hot Lab is the small locked room in the far corner of Nuclear Medicine. The Hot Lab is to be locked after delivery of the shipment.

ST. FRANCIS HOSPITAL, INC.
Wilmington, Delaware

Section: NUCLEAR MEDICINE

POLICY AND PROCEDURE MANUALSubject: DELIVERY OF NUCLEAR MEDICINE
RADIOPHARMACEUTICALSC. Indication of Damage

1. Indication of possible damage to the shipment include:
 - a) Crushed or punctured container
 - b) Wet or leaking container
 - c) Unsealed container
2. If there is indication of damage, the Receptionist or receiving personnel should:
 - a) Ask the shipping agent to remain
 - b) Not handle the package
 - c) Block off area to minimize contact within 6' of package
 - d) Call in following order:

Senior Nuclear Medicine Tech: Robert G. Stineman, CNMT
Home Telephone: 322-0422

Radiation Safety Officer: Richard L. Ward, M.D.
Home Telephone: 428-0725

Alternate Radiologist: Radiologist on Call
Telephone Security: 4131

(8-78)

TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER

*Carlos Pena, M.D.*2. STATE OR TERRITORY IN
WHICH LICENSED TO
PRACTICE MEDICINE*MICHIGAN, NEW YORK, DELAWARE*

3. CERTIFICATION

SPECIALTY BOARD

A

CATEGORY

B

MONTH AND YEAR CERTIFIED

C

*DIAGNOSTIC RADIOLOGY**JUNE 1971*

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION			
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

PRECEPTOR STATEMENT

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.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

CARLOS PENA

STREET ADDRESS ST. FRANCIS HOSPITAL
7th & CLAYTON STREETS

CITY

WILMINGTON

STATE

DE

ZIP CODE

19805

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

- 1-Supervised examination of patients to determine the suitability for radioisotope 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 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
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION		I have trained in Nuclear Medicine from 1968-71 at HURLEY HOSPITAL, FLINT Michigan as a resident in Radiology - Then I worked with Dr. Gelman for 1 year at Community Hosp. Syracuse N.Y. in N. Medicine. Since 1976 I've worked in N. Med. at St Francis Hospital Wilmington, Delaware, under supervision of Dr. Richard Ward.
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING		
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER			
Tc-99m	BRAIN IMAGING	> 100	
	CARDIAC IMAGING	> 100	
	THYROID IMAGING	> 100	
	SALIVARY GLAND IMAGING	ABOUT 10	
	BLOOD POOL IMAGING	" 10	
	PLACENTA LOCALIZATION	" 25	
	LIVER AND SPLEEN IMAGING	> 100	
	LUNG IMAGING	> 100	
	BONE IMAGING	> 100	
OTHER			

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	5	
P-32 (Colloidal)	INTRACAVITARY TREATMENT	0	
I-131	TREATMENT OF THYROID CARCINOMA	2	
	TREATMENT OF HYPERTHYROIDISM	5	
Au-198	INTRACAVITARY TREATMENT	0	
Co-60 or Cs-137	INTERSTITIAL TREATMENT	0	
	INTRACAVITARY TREATMENT	0	
I-125 or Ir-192	INTERSTITIAL TREATMENT	0	
Co-60 or Cs-137	TELETHERAPY TREATMENT	0	
Sr-90	TREATMENT OF EYE DISEASE	0	
	RADIOPHARMACEUTICAL PREPARATION	0	
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

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

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

a. NAME OF SUPERVISOR

Richard L. Ward, M.D.

b. NAME OF INSTITUTION

St. Francis Hospital, Inc.

c. MAILING ADDRESS

7th & Clayton Streets

d. CITY

Wilmington, DE 19805

5. MATERIALS LICENSE NUMBER(S)

#07-16862-01

6. PRECEPTOR'S SIGNATURE

Richard L. Ward MD

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

Richard L. Ward, M.D.

8. DATE

Nov. 2, 1984

HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA

3400 Spruce Street / G1 Philadelphia, PA 19104 (215) 662-3000

DEPARTMENT OF RADIOLOGY

Mohammad Ikramul Haq, M.D.

has successfully completed Nuclear Medicine Course 210, a course under my direction covering the basic science and principles of Nuclear Medicine. This course extended from 8 January 1979 to 26 January 1979 at the Hospital of the University of Pennsylvania, and included 67.5 hours of lecture. Subjects included the basic principles of radiation physics, instrumentation, radiation biology, radiopharmaceuticals, in vivo studies, in vitro studies and therapeutic uses of radionuclides.

Abass Alavi, M.D.

Abass Alavi, M.D.

26 January 1979

Attachment # 2

HUP

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER MUHAMMAD I. HAQ, M.D.		2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE NEW YORK, PENNSYLVANIA + DELAWARE
3. CERTIFICATION		
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
DIAGNOSTIC RADIOLOGY		JUNE 1982

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION			
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

PRECEPTOR STATEMENT

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.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS		KEY TO COLUMN C
FULL NAME MUHAMMAD IKRAMUL HAQ M.D.		PERSONAL PARTICIPATION SHOULD CONSIST OF: 1-Supervised examination of patients to determine the suitability for radioisotope 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.
STREET ADDRESS ST. FRANCIS HOSP. 7th & CLAYTON STS.		
CITY WILMINGTON	STATE DE	

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

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
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION		My training in nuclear medicine was at University of Pennsylvania Med CTR. Philadelphia w/ Dr. Alavi, which included lectures as well as clinical training. I have been working w/ Dr. Ward under his supervision, at St. Francis Hospital since 1982, (at Wilmington, DE).
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING		
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER			
Tc-99m	BRAIN IMAGING	> 125	
	CARDIAC IMAGING	> 125	
	THYROID IMAGING	> 100	
	SALIVARY GLAND IMAGING	5	
	BLOOD POOL IMAGING	10	
	PLACENTA LOCALIZATION	15	
	LIVER AND SPLEEN IMAGING	> 150	
	LUNG IMAGING	> 150	
	BONE IMAGING	> 150	
OTHER			

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	0	
P-32 (Colloidal)	INTRACAVITARY TREATMENT	0	
I-131	TREATMENT OF THYROID CARCINOMA	0	
	TREATMENT OF HYPERTHYROIDISM	5	
Au-198	INTRACAVITARY TREATMENT	0	
Co-60 or Cs-137	INTERSTITIAL TREATMENT	0	
	INTRACAVITARY TREATMENT	0	
I-125 or Ir-192	INTERSTITIAL TREATMENT	0	
Co-60 or Cs-137	TELETHERAPY TREATMENT	0	
Sr-90	TREATMENT OF EYE DISEASE	0	
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR	5	
Sn-113/ In-113m	GENERATOR	0	
Tc-99m	REAGENT KITS	5	
Other			

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

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:		6. PRECEPTOR'S SIGNATURE	
a. NAME OF SUPERVISOR Richard L. Ward, M.D.		Richard L. Ward M.D.	
b. NAME OF INSTITUTION St. Francis Hospital, Inc.			
c. MAILING ADDRESS 7th & Clayton Streets		7. PRECEPTOR'S NAME (Please type or print) Richard L. Ward, M.D.	
d. CITY Wilmington, DE 19805		8. DATE Nov. 2, 1984	
5. MATERIALS LICENSE NUMBER(S) #07-16862-01			

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

21-00943-03

Docket or Reference number

Amendment No. 45

St. Joseph Mercy Hospital
Dept. of Nuclear Medicine
P.O. Box 995
Ann Arbor, MI 48106

In accordance with letter dated June 13, 1984, License Number 21-00943-03 is amended as follows:

Condition 12. is amended to read:

12. 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:

Delbert E. Boblitt, M.D.

Groups I, II, III, IV, V and VI
Xenon-133
In vitro studies

LaMar J. HanKamp, M.D.

Groups I, II, III, IV, V and VI
Xenon-133
In vitro studies

Robert G. Ause, M.D.

Groups I, II, III, IV and VI
Xenon-133
In vitro studies

Lawrence R. Kuhns, M.D.

Groups I, II, and III
Iodine-131 for therapy
Xenon-133
In vitro studies

Ronald D. Petrocelli, M.D.

Groups I, II, III, IV and V
Xenon-133
In vitro studies

Douglas B. Siders, M.D.

Group I
In vitro studies

~~8411414362~~ 3pp.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

21-00943-03

Docket or Reference number

Amendment No. 45

• Jeffrey T. Colvin

Byproduct material listed in
Subitem 6.G.

Young Bae, M.D.

Group VI

William H. Straub, M.D.

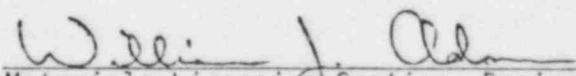
Groups I, II, III, IV and V
Xenon-133
In vitro studies

For the U.S. Nuclear Regulatory Commission

SEP 14 1984

Date _____

By


Materials Licensing Section, Region III

BETWEEN: William O. Miller, Chief
License Fee Management Branch
Office of Administration

John E. Glenn, Chief
Nuclear Materials Section B
Division of Engineering and
Technical Programs

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: St. Francis Hospital, Inc

Application Dated: 3/27/85

Control No.: 03593

License No.: 07-16862-01

2. FEE ATTACHED

Amount: \$ 120.00

Check No.: 24078

3. COMMENTS

Signed Brenda Platchek

Date 3/29/85

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 7C \$120

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

Amendment ✓

Renewal _____

License _____

Signed Frances Brown

Date 4/4/85

102 4/5/85