

OFFICIAL RECORD COPY**MATERIALS LICENSE****Amendment No. 2**

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.

Licensee

In accordance with the letter dated January 11, 1997

3. License Number 52-25232-01

is amended in its entirety to read as follows:

4. Expiration Date **January 31, 2003 (Extended)**5. Docket or
Reference No. 030-330266. 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 35.100A. Any radiopharmaceutical
identified in 10 CFR 35.100

A. As needed

B. Any byproduct material
identified in 10 CFR 35.200B. Any radiopharmaceutical
identified in 10 CFR 35.200

B. As needed

C. Iodine 131

C. Any unsealed form for
preparation and
administration as specified in
10 CFR 35.300

C. 55.5 gigabecquerels (1.5 curies)

D. Any byproduct material with
a half-life less than 120 days
except iodine 131D. Any form for uses described
in 10 CFR 35.300 initially
distributed in accordance
with a specific license issued
to 10 CFR 32.72 or a specific
license issued to the
manufacturer by an
Agreement State pursuant to
equivalent State regulations.D. As needed, not to exceed
3.7 gigabecquerels (100 millicuries)
per container070020
9705070168 970411
PDR ADOCK 03033026
C PDR

ML 20

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number 52-25232-01

Docket or Reference Number
030-33026

Amendment No. 2

9. Authorized Use:
- A. Medical use described in 10 CFR 35.100.
 - B. Medical use described in 10 CFR 35.200.
 - C. and D. Any radiopharmaceutical therapy approved in §35.300

CONDITIONS

10. Location for use: Hospital San Cristóbal
Puerto Rico Highway 506
Coto Laurel, Ponce, Puerto Rico
11. Radiation Safety Officer: Miguel A. Serpa, M.D.
12. Authorized user(s):
- A. Miguel A. Serpa, M.D. medical uses in 10 CFR 35.100, §35.200 and §35.300
 - B. Ricardo E. Santiago-Montalvo, M.D. medical uses in 10 CFR 35.100 and §35.200 and §35.300
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 for establishing decommissioning financial assurance.
14. The licensee shall maintain records of information important to safe and effective decommissioning at the licensee's facilities listed in Condition 10 pursuant to the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number 52-25232-01

Docket or Reference Number 030-33026

Amendment No. 2

15. Except as specifically provided otherwise in the license and as provided in 10 CFR 35.51, the licensee shall conduct its program in accordance with 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. Application dated November 20, 1992

B. Letters dated:

- (1) February 11, 1993
- (2) December 27, 1995 [add auth user, submit relocation and new floor plan, commit to close-out survey for space being vacated]
- (3) March 1, 1996 Letter from NRC extending expiration date per 10 CFR 30.36
- (4) March 30, 1996 [Information on storage, hot lab floor plan, Dr. Ruiz-Rodriguez exper. and tng]
- (4) January 11, 1997 [add authorized users and change RSO, delete authorized users]

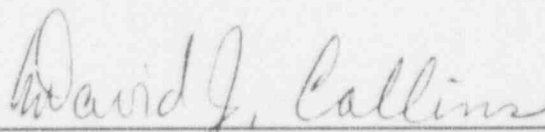
FOR THE U.S. NUCLEAR REGULATORY COMMISSION

DAVID J. COLLINS

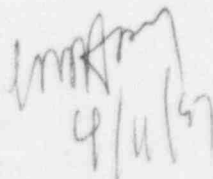
DATE APR 11 1997

N:\MLICENSE\52-25232.A02

BY



Region II, Division of Nuclear Materials Safety
61 Forsyth Street SW, Suite 23T85
Atlanta, Georgia 30303



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: Hospital San Cristobal

ADDRESS: Attn: Rene Rivera, MHA Administrator

ADDRESS: P.O. Box 501, Coto Laurel

CITY: Ponce STATE: PR ZIP: 00780

TRANS CODE: PX

TRANS TYPE: FE FUND: X5280 JOB CODE: _____ AMOUNT: \$20.00

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

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

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

TOTAL REFUND AMOUNT: \$20.00

COMMENTS: Opent And fee Lic 52-25232-01

CK 28805

(Limit comments to 40 characters, including spaces)

PREPARED BY: Lita Messier DATE: 1/22/97

AUTHORIZED BY: Alvin Jackson DATE: 1/23/97

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

REFUND ENTERED INTO COLLECT BY: _____

REFUND DETERMINED BY: _____ DATE: _____

PLEASE ATTACH APPROPRIATE SUPPORTING DOCUMENTATION

7C
AA905 AMD
Jan 2 II

CK # 28805
dated 1/15/97
for \$460
257339

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: 20030131
: Fee Comments: _____
: Decom Fin Assur Req'd: N
: ::::::::::::::::::::::::::::::

LICENSE FEE TRANSMITTAL

A. REGION II

1. APPLICATION ATTACHED

Applicant/Licensee: HOSPITAL SAN CRISTOBAL
Received Date: 970115
Docket No: 3033026
Control No.: 257339
License No.: 52-25232-01
Action Type: Amendment

2. FEE ATTACHED

Amount: 460.00
Check No.: 28805

3. COMMENTS

Signed DIANE HEIM
Date 1/17/97

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

1. Fee Category and Amount: 7C \$4440

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

Amendment ☒
Renewal _____
License _____

3. OTHER _____

Signed Rita Nassar
Date 1/25/97

Log	<u>Jan 2 II</u>
Remitter	
Check No.	<u>28805</u>
Amount	<u>\$460.00</u> <u>Refund</u>
Fee Category	<u>7C</u>
Type of Fee	<u>Ampl</u>
Date Check Rec'd.	<u>1/21/97</u>
Date Completed	<u>1/22/97</u>
By:	<u>fern</u>

1997 JAN 21 PM 4:00



Hospital San Cristóbal

CARRETERA P.R. 506
APARTADO POSTAL 501
COTO LAUREL, PUERTO RICO 00780
TELÉFONO: 848-2100

TO : U.S. Nuclear Regulatory Commission
Region II
101 Marietta Street NY
Atlanta, GA 30623

FROM : René Rivera, MHSA
Administrator

SUBJECT : Amendment to License No. 52-25232-01
Mail Control 256882
Docket No. 030-33026

DATE : January 11, 1997

This is a notification for an amendment to license No. 52-25232-01 to:

- a. Change the entire staff of authorized users and RSO

We want to delete, Dr. Hiram Rivera-Luna as authorized user and RSO. Also, the authorized user Dr. Carmiña M. Ruiz-Rodriguez must be removed from our license.

We want to add to our staff:

1. Dr. Miguel A. Serpa as new authorized user and RSO under License # 52-25232-01
He is board certified in Nuclear Medicine (ABNM) and authorized user and RSO under License # 52-24916-01.
2. Dr. Ricardo E. Santiago-Montalvo as authorized user under License # 52-25232-01
He is board certified in Nuclear Medicine (ABNM) and authorized user under License # 52-25121-01.

We hope for a prompt evaluation and approval to continue offer our services. If you need more information, please contact us at (787) 848-2100 Ext. 4117.

A check for the amount of \$460.00 is also enclosed as the proper fee for an amendment to an NRC licence category 7C as stated in 10 CFR.

257339



THE SCHOOL OF MEDICINE
OF THE UNIVERSITY OF CONNECTICUT HEALTH CENTER

DEPARTMENT OF NUCLEAR MEDICINE MC-2804

Tel. (203) 679-3120

Fax: (203) 679-2164

52-25121-01

TO: Mr. Hector Bermudez
US Nuclear Regulatory Commission
Region II, Material Licensing Section
101 Marieta Street
Atlanta, GA 30323
FAX: 1-404-531-5559

October 20, 1995

FROM: Dr. Richard P. Spencer *RP Spencer*
Prof. & Chairman
Department of Nuclear Medicine

SUBJECT: Qualifications of Dr. Ricardo Santiago

cc: Dr. Santiago

This note is intended to clarify the training/experience at the University of Connecticut (and Consortium Hospitals) of Dr. Ricardo Santiago, during his time with us from July 1, 1993 through June 30, 1995.

1. The 2 year residency program involves a minimum of 2,000 hours per year. Hence, in the 2 years, he had 4,000 hours training (as a minimum; the true number is likely much higher).
2. The "Basic Science" Course given to the residents involves over 200 hours of lectures, demonstrations and laboratories, during the period of 2 years.
3. The supervised work experience of Dr. Santiago was much greater than 500 hours. Each of the physicians supervising Nuclear Medicine at the consortium hospitals are Board Certified in Nuclear Medicine, and hence capable of giving Dr. Santiago expert guidance during his rotations. This extended from the ordering process for radioactive materials, through receiving, surveying packages, and checking survey meters and dose calibrators. Training included calculation of radiation exposures, preparation of doses to be administered, the systems in place to prevent misadministrations, and how to handle spills and contamination. A new Mo-99 - Tc-99m radionuclide generator comes in weekly at the Health Center, and the procedures of elution, checking for the quantity of eluted Tc-99m, any breakthrough of Mo-99, and alumina contamination are gone over repeatedly.
3. During the 2 years of Dr. Santiago's training he far exceeded 500 hours of supervised clinical experience. The principles of review of requisitions for indications for the procedure (and any contraindications) were reviewed. In addition, the use of the patient and/or the referring health care worker to obtain additional data if needed, was stressed. Use of the appropriate radioactive material (and dosage form), plus route of administration was reviewed. The appropriate utilization of safety measures, such as syringe shields was stressed. The residents write the initial reports at this center, and these are then reviewed with the attending physician. The need for follow-up was pointed out, and mechanisms for accomplishing this were also reviewed (such as data from the referring health care worker).
4. Dr. Santiago has pointed out experience with more than 3 administrations of strontium-89. I checked the other hospitals and found this to be true.

FORM 313M SUPPLEMENT A

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER

Approved by OMB
3150-0041
Expires 6-30-89

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER

RICHARD P. SPENCER, MD, PHD

2. STATE OR TERRITORY IN
WHICH LICENSED TO
PRACTICE MEDICINE CT

3. CERTIFICATION

SPECIALTY BOARD

A

CATEGORY

B

MONTH AND YEAR CERTIFIED

C

NUCLEAR MEDICINE

7/ 1972

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES
RICARDO E. SANTIAGO MONTALVO

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

Univ of Connecticut Health Ctr
Farmington, CT
Sept/Oct/Nov/Dec 1993
Sept/Oct/Nov/Dec 1994

Total:
81

Total:
6

b. RADIATION PROTECTION

(same as above)

Total:
12

c. MATHEMATICS PERTAINING TO
THE USE AND MEASUREMENT
OF RADIOACTIVITY

(same as above)

Total:
12

d. RADIATION BIOLOGY

(same as above)

Total:
15

e. RADIOPHARMACEUTICAL
CHEMISTRY

(same as above)

Total:
111

Total:
6

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Tc-99m	1 curie (generator)	Univ. Connecticut Health Ctr. & Consortium Hospitals	2 years	Radiopharmaceut.
I-131	200 mCi	" "	" "	Diagnosis, Therapy
I-123	0.5 mCi	" "	" "	Diagnosis
Xe-133	40. mCi	" "	" "	Diagnosis
Tl-201	5. mCi	" "	" "	Diagnosis
Ga-67	10. mCi	" "	" "	Diagnosis
In-111	1. mCi	" "	" "	Diagnosis


**EXHIBIT 3
SUPPLEMENT B**

SUPPLEMENT		U. S. NUCLEAR REGULATORY COMMISSION	
PRECEPTOR STATEMENT			
<p><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></p>			
1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS		KEY TO COLUMN C PERSONAL PARTICIPATION SHOULD CONSIST OF:	
FULL NAME Ricardo E. Santiago Montalvo		1. Supervised examination of patients to determine the suitability for radiopharmaceutical diagnosis and/or treatment and recommendation for prescribed dosage.	
STREET ADDRESS Calle De Diego 123 Este		2. Collaboration in dose calibration and actual administration of dose to the patient including discussion of the radiation dose, related measurements and plotting of data.	
CITY STATE ZIP CODE Mayaguez P.R. 00680		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 <small>(Additional information or comments may be submitted in duplicate on separate sheets.)</small> D
	Thyroid scan	60	
	Thyroid uptake	40	
	Lung perfusion scan	180	
	Xenon ventilation study	150	
	Aerosol ventilation scan	30	
	Renal flow scan	80	
	Brain scan	5	
	Liver/spleen scan	45	
	Bone scan	220	
	Gastroesophageal study	30	
	LeVeen shunt study	2	
	Cystogram	10	
	Lacrystocystogram	1	
	Cardiac perfusion scan	140	
	Cardiac stress ventriculogram	40	
	Cardiac rest ventriculogram	105	
	Gallium scan	90	

EXHIBIT 3 (Continued)

PROPOSED PHYSICIAN USER			
RICARDO E. SANTIAGO MONTALVO			
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 sheet.) D
P-32 (Sodium)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	-	
P-32 (Cobalt)	INTRACAVITARY TREATMENT	-	
I-131	TREATMENT OF THYROID CARCINOMA	7	
	TREATMENT OF HYPERTHYROIDISM	25	
Au-198	INTRACAVITARY TREATMENT	-	
Co-60 or Cs-137	INTERSTITIAL TREATMENT	-	
	INTRACAVITARY TREATMENT	-	
I-125 or I-192	INTERSTITIAL TREATMENT	-	
Co-60 or Cs-137	TELETHERAPY TREATMENT	-	
Sr-90	TREATMENT OF EYE DISEASE	-	
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR	40	
Sr-90/ Y-90	GENERATOR	-	
Ti-99m	REAGENT KITS	40	
Other Sr-89	Therapy of bone metastases	2	

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING		
LOCATION	DATES	CLOCK HOURS OF EXPERIENCE
Univ. Connecticut Health Center Farmington, CT and consortium Hospitals	7/1/1993 - 6/30/95	3,500

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:		5. PRECEPTOR'S SIGNATURE	
a. NAME OF SUPERVISOR Richard P. Spencer, MD, PhD			
b. NAME OF INSTITUTION Univ. Connecticut Health Center			
c. MAILING ADDRESS 263 Farmington Avenue		7. PRECEPTOR'S NAME. (Please type or print)	
d. CITY Farmington, CT 06030		Richard P. Spencer, MD, PhD	
e. MATERIALS LICENSE NUMBER(S) 06-13022-02		8. DATE October 12, 1995	