

Physicians Imaging Center
New Jersey

Br. J

Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region 1
475 Allendale Rd.
King of Prussia, PA 19406-1415

Ph: 610.337.5000

Re: License No. 29-28041-01 03030030

Dear Sir or Madam,

This is a request for an amendment to our NRC license to add Mr. Peter Rossi, M.D., as an Authorized User for cardiac procedures.

Copies of documents verifying Dr. Rossi's training and experience are enclosed.

Please feel free to contact us if you need any additional information.

Sincerely,



Charles H Rose, MA, MDSPH, D(ABSNM)
Administrator
Physicians Imaging Center
180 Avenue at the Common
Shrewsbury, NJ 07702

Cc: file

Enclosures

143094
NRC/SS/RGMI MATERIALS-002

U.S. NUCLEAR REGULATORY COMMISSION AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.100, 35.200, and 35.500) (10 CFR 35.190, 35.290, and 35.390)		APPROVED BY OMB: NO. 3180-0128 EXPIRES: 10/31/2008									
(Name of Proposed Authorized User) Peter A. Rossi M.D., F.A.C.C.	State or Territory Where Licensed State of Florida										
Requested Authorization(s) (check all that apply)											
<input type="checkbox"/> 35.100 Uptake, dilution, and excretion studies											
<input checked="" type="checkbox"/> 35.200 Imaging and localization studies											
<input type="checkbox"/> 35.500 Sealed sources for diagnosis (specify device _____)											
PART I - TRAINING AND EXPERIENCE (Select one of the three methods below)											
* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.											
<input type="checkbox"/> 1. Board Certification											
a. Provide a copy of the board certification.											
b. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.											
<input type="checkbox"/> 2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization											
a. Authorized user on Materials License _____ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.											
b. Supervised Work Experience. (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)											
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 40%;">Description of Experience</th> <th style="width: 30%;">Location of Experience/License or Permit Number of Facility</th> <th style="width: 10%;">Clock Hours</th> <th style="width: 20%;">Dates of Experience*</th> </tr> </thead> <tbody> <tr> <td style="height: 100px; vertical-align: top;"> Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs </td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*	Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs				Total Hours of Experience: _____		
Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*								
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs											
Supervising Individual _____		License/Permit Number listing supervising individual as an authorized user _____									
Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply).											
<input type="checkbox"/> 35.290 <input type="checkbox"/> 35.390 + generator experience in 32.290(c)(1)(ii)(G)											

NRC FORM 313A (AUG) (10-2007) U.S. NUCLEAR REGULATORY COMMISSION
AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training
Radiation physics and instrumentation	INME Training Class	50	June 22, 2008
Radiation protection	INME Training Class	15	June 22, 2008
Mathematics pertaining to the use and measurement of radioactivity	INME Training Class	10	June 22, 2008
Chemistry of byproduct material for medical use (not required for 35.590)	INME Training Class	15	June 22, 2008
Radiation biology	INME Training Class	10	June 22, 2008
Total Hours of Training: 100			

**b. Supervised Work Experience (completion of this table is not required for 35.590).
 (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)**

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safety and performing the related radiation surveys	Pasco Cardiology Center, Florida	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	see attached
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Pasco Cardiology Center, Florida	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	see attached

NRC FORM 819A (AUD) (10-2007) U.S. NUCLEAR REGULATORY COMMISSION
AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience. (continued)

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience:
Calculating, measuring, and safely preparing patient or human research subject dosages	Pasco Cardiology Center, Florida	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	see attached
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Pasco Cardiology Center, Florida	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	see attached
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Pasco Cardiology Center, Florida	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	see attached
Administering dosages of radioactive drugs to patients or human research subjects	Pasco Cardiology Center, Florida	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	see attached
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs	Advanced Specialty Pharmacy, Florida	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	see below

Supervising Individual: **Huang-Ta Lin, M.D.** License/Permit Number listing supervising individual as an authorized user: **2723-1**

Supervisor meets the requirements below, or equivalent Agreement State requirements (check one).
 35.180 35.290 35.390 35.390 + generator experience in 35.290(c)(1)(II)(G)

c. For 35.390 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates
Covidien 46Cl Generator Dry Column	Elution Generator Training	Advanced Specialty Pharmacy 2901 W. Beach Blvd. Tampa, FL on 08-01-08

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

NRC FORM STSA (ALU)
(10-2007)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II - PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (Not required to meet training requirements in 35.590)

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section

Check one of the following for each use requested:

For 35.190

Board Certification

I attest that

Name of Proposed Authorized User

has satisfactorily completed the requirements in

10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

OR

Training and Experience

I attest that

Name of Proposed Authorized User

has satisfactorily completed the 60 hours of training and

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

I attest that

Name of Proposed Authorized User

has satisfactorily completed the requirements in

10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

OR

Training and Experience

I attest that

Peter A. Rossi M.D.

Name of Proposed Authorized User

has satisfactorily completed the 700 hours of training

and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

Second Section

Complete the following for preceptor attestation and signature:

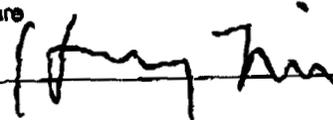
I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

35.190

35.290

35.390

35.390 + generator experience

Name of Preceptor Huang-Ta Lin, M.D.	Signature 	Telephone Number (727) 368-5404	Date 08/05/2008
License/Permit Number/Facility Name 2723-1 Pasco Cardiology Center 14153 Yosemite Dr. #202 Hudson FL 34667			



PASCO CARDIOLOGY CENTER

Mei Chang, M.D., F.A.C.C.
 Huang-Ta Lin, M.D., F.A.C.C.
 Peter A. Rossi, M.D., F.A.C.C.
 Werner Jauch, M.D., F.A.C.C.
 Charles Saniour, M.D.

Preceptor Statement of Clinical and Work Experience

July 15, 2008

To Whom It May Concern:

This letter is to affirm that Peter A. Rossi M.D. received training and experience at our institution, Pasco Cardiology Center, Inc. in imaging and localization studies. The Preceptorship began in October 1996 and continued until March 2008.

During this training program, Peter A. Rossi M.D. received not less than 500 hours of supervised work experience and not less than 500 hours of supervised clinical experience. The experience of Peter A. Rossi M.D. was gained under the supervision of an Authorized User.

The supervised work experience included ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters; calculating and safely preparing patient dosages; using administrative controls to prevent the misadministration of by-product material; using procedures to contain spilled byproduct material safely and using proper decontamination procedures.

The supervised clinical experience included examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications; selecting the suitable radiopharmaceuticals and calculating and measuring the dosages; administering dosages to patients and using syringe radiation shields; collaborating with the Authorized User in the interpretation of radioisotope test results and patient follow-up.

Sincerely,

Huang-Ta Lin M.D., F.A.C.C.
 Authorized User
 Florida RAM# 2723-1

Preceptor Statement of Clinical and Work Experience

July 15, 2008

To Whom It May Concern:

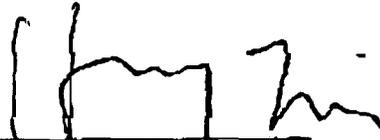
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Sincerely,



Huang-Ta Lin M.D., F.A.C.C.
Authorized User
Florida RAM# 2723-1

FUNDAMENTALS

Radioisotope Handling

Attestation and Certification

Completion and Competency

This document is an affidavit that

Peter Rossi, M.D.

has successfully completed the prescribed didactic program of education and has achieved the objectives of this program as evidenced by written examination



This Program provides the following levels of documented accomplishment

- 100** Continuing Education Units (CEU)
- 100** Didactic Instructional Hours (DIH)
- In compliance with 10CFR35/ABA 73-689
- 100** Board Accepted Hours NUSPEK, NMICB, ARMSO, ABR, ABNM, CBNC

Certifying Official

June 22nd, 2008

Date Completed

204329

Certification

Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the American Council on Education (ACE), recognized by the American Association for Collegiate Registrar Council on Post-Secondary Education. Licensed by MEC & Agreement States.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

RADIOACTIVE MATERIALS LICENSE
SUPPLEMENTAL SHEET

PASCO CARDIOLOGY CENTER, INC.
14153 Yosemite Drive, Suite 204
Hudson, FL 34667

With reference to correspondence received February 15, 2008, State of Florida Radioactive Material
License Number 2723-1 is hereby amended.

TO CHANGE CONDITION 12 TO READ:

12. A. The following individuals are authorized for the materials and uses as indicated:

Authorized Material and Uses as
Described in Items 5, 6, and 7

64E-5.626 and 64E-5.627

Henry Ts'Ch, M.D.
Werner Jauch, M.D.

64E-5.627 (except generators)

Charles E. Sanjour, M.D.

B. The radiation safety officer's initials

License Number: 2723-1
Amendment No.: 10
Control Number: 20080215-0238

LICENSEE COPY

Category: [5C]

Page 1 of 2 Page(s)

Expiration Date: 11/30/2011a

**STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL**

**RADIOACTIVE MATERIALS LICENSE
SUPPLEMENTAL SHEET**

12. C. Radiologic technologists who use and administer radioactive materials or perform brachytherapy or teletherapy procedures under the general supervision of an authorized user shall hold a valid certificate as required by Chapter 468, F.S.



For the Bureau of Radiation Control:

Issuance Date: MAR 10 2008

Kim Farmer
Kimberly M. Farmer
Regulatory Specialist I
4052 Bald Cypress Way - Bin C21
Tallahassee, FL 32309-1741
(850) 245-4545

Party whose substantial interest is affected by this order may petition for an administrative hearing pursuant to sections 120.559 and 120.57, Florida Statutes. Such proceedings are governed by Rule 28-106, Florida Administrative Code. A petition for administrative hearing must be in writing and must be received by the Agency Clerk for the Department, within twenty-one (21) days from the receipt of this order. The address of the Agency Clerk is: Agency Clerk, 4052 Bald Cypress Way, Bin # A02, Tallahassee, Florida 32309-1703. The Agency Clerk's facsimile number is 850-490-1448. A copy of the petition should also be sent to: Bureau Chief, Bureau of Radiation Control, 4052 Bald Cypress Way, Bin # C21, Tallahassee, FL 32309-1741. The Bureau Chief's facsimile number is 850-487-0435. Mediation is not available as an alternative remedy. Your failure to submit a petition for hearing within 21 days from receipt of this order will constitute a waiver of your right to an administrative hearing, and this order shall become a "final order." Should this order become a final order, a party who is adversely affected by it is entitled to judicial review pursuant to Section 120.58, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings may be commenced by filing one copy of a Notice of Appeal with the Agency Clerk of the Department of Health and a second copy, accompanied by the filing fee required by Rule 9.010, with the Court of Appeal in the appropriate District Court. The notice must be filed within 30 days of rendition of the final order.

License Number: 2723-1
 Amendment No.: 10
 Control Number: 20080215-0238

LICENSEE COPY

Category: [5C]

Page 2 of 2 Page(s)

Expiration Date: 11/30/2011a

FUNDAMENTALS
Radioisotope Handling
Attestation and Certification
Completion and Competency

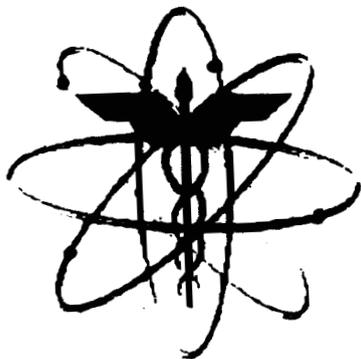
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- In compliance with 10CFR35/AEA 73-689
- 100 Board Accepted Hours NUSPEX, NMTCB
 ABMISO, ABR, ABNM, CBNC



Certifying Official

June 22nd, 2008

Date Completed

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Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the American Council on Education (ACE), recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.

This is to acknowledge the receipt of your letter/application dated

12/9/08, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (29-28041-01) There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 143094.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.