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May 19, 2008

NMSBZ

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

Ph: 610.337.5000

03030030

Re: License No. 29-28041-01

Dear Sir or Madam,

This is a request for an amendment to our NRC license to add Ms. Fong Mei Young Chang, M.D., as an Authorized User for cardiac procedures.

Copies of documents verifying Dr. Chang'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

142442
NMSS/RGN1 MATERIALS-002

NRC FORM 313A (AUD)
(10-2007)

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 35.590]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2008

Name of Proposed Authorized User

State or Territory Where Licensed

Fong Mei Young Chang

State of Florida

Requested Authorization(s) (check all that apply)

- 35.100 Uptake, dilution, and excretion studies
- 35.200 Imaging and localization studies
- 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.

- 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.
- 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.)

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:

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).

- 35.290
- 35.390 + generator experience in 32.290(c)(1)(ii)(G)

NRC FORM 313A (AUD) **U.S. NUCLEAR REGULATORY COMMISSION**
(10-2007) **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	04-28-08
Radiation protection	INME Training Class	15	04-28-08
Mathematics pertaining to the use and measurement of radioactivity	INME Training Class	10	04-28-08
Chemistry of byproduct material for medical use <i>(not required for 35.590)</i>	INME Training Class	15	04-28-08
Radiation biology	INME Training Class	10	04-28-08

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 safely 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 313A (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).
 35.190 35.290 35.390 35.390 + generator experience in 35.290(c)(1)(ii)(G)

c. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates
Coviden 46 Ci Generator Dry Column	Elution Generator Training	Advanced Specialty Pharmacy 2901 W. Busch Blvd. Tampa, Fl on 05-16-08

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 313A (AUD)
(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 _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

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 _____ has satisfactorily completed the 60 hours of training and
Name of Proposed Authorized User

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 _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

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 Fong Mei Young Chang has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

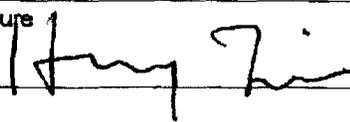
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

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	Signature	Telephone Number	Date
Huang-Ta Lin, M.D.		(727) 868-5404	05/20/2008

License/Permit Number/Facility Name
2723-1 Pasco Cardiology Center 14153 Yosemite Dr.#202 Hudson, Fl 34667

Preceptor Statement of Clinical and Work Experience

May 6, 2008

This letter is to affirm that Fong Mei Chang, 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, Fong Mei Chang, 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 Fong Mei Chang, 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



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., F.A.C.C.

Preceptor Statement of Clinical and Work Experience

May 6, 2008

To Whom It May Concern:

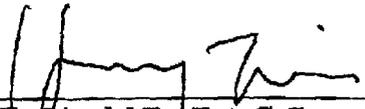
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Sincerely,



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

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	Name
64E-5.626 and 64E-5.627	Huang-Ta Lin, M.D. Werner Jauch, M.D.
64E-5.627 (except generators)	Charles E. Saniour, M.D.

B. The radiation safety officer is Huang-Ta Lin.

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

LICENSEE COPY
Page 1 of 2 Page(s)

Category: [5C]
Expiration Date: 11/30/2011a

FUNDAMENTALS

Radioisotope Handling

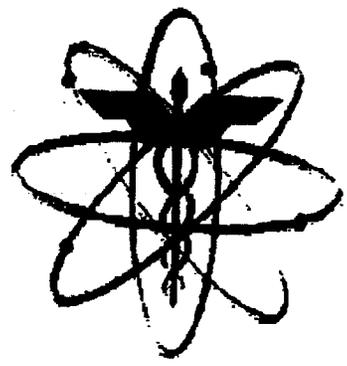
Attestation and Certification

Completion and Competency

This document is an affidavit that

Fong Mei Young Chang, 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/AEA 73-689
- 100 Board Accepted Hours NUSPEX, NMTCB
- ABMRSO, ABR, ABNM, CBNC



Certifying Official

28th April 2008

Date Completed

204160

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 Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.

CME CREDIT CERTIFICATE

This is to certify that

Fong Mei Young Chang, M.D.

Has completed up to

100 Hours

Of Category 1 CME credit through participation in the course(s)/activities conducted by the Institute for Nuclear Education (INME), April, 2008.

This CME activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) thru the Joint Sponsorship of the Institute for Medical Studies (IMS) and INME.

IMS is accredited by the ACCME to provide continuing medical education for physicians.

IMS designates this educational activity for a maximum of 100 credit hours AMA PRA Category 1 Credits™.

Participants should claim only those hours of credit that he/she actually spent in the activity as established by registration and attendance.

Please retain this Certificate for your records.

The Institute for Medical Studies
14 Monarch Bay Plaza, Suite 202
Monarch Bay, CA 92629

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

5/19/08, 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 142442.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.