

Cardiovascular Associates of Puerto Rico
CARDIOVASCULAR CONSULTANTS

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René E. Pérez-Ríos, M.D.
Luis Ortiz Muñoz, M.D.

February 10, 2010

US Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia
Pennsylvania, 19406-1415

Br 1

03036419

RE: Byproduct Materials
License number: 52-30841-01

Gentlemen:

We hereby you include Dr. Luis Ortiz Muñoz as an authorized user on our NRC license.
Enclose please find Dr. Ortiz preceptor attestation statement and copy of the board certificate.

Thanking you for your prompt attention to this request, we remain,

Humberto O. Quintana Irazola, MD, FACC, CCDS

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REGION I
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AMERICAN SOCIETY OF
NUCLEAR CARDIOLOGY

The American Society of Nuclear Cardiology

certifies that

Luis Ortiz, MD

has participated in an educational activity titled

"Nuclear Cardiology Physics Course"
held from November 13 - 14, 2009 in Baltimore, MD

The American Society of Nuclear Cardiology designates this
educational activity for a maximum of *16.00 AMA PRA Category 1 Credit(s)TM*.

Physicians should only claim credit commensurate with
the extent of their participation in the activity.

The American Society of Nuclear Cardiology
is accredited by the Accreditation Council for
Continuing Medical Education to provide continuing medical
education for physicians.

James A. Arrighi, MD
Chairman, ASNC Education Committee

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Certification Board of Nuclear Cardiology

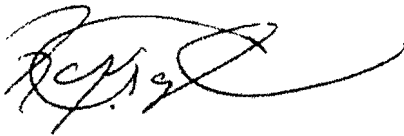
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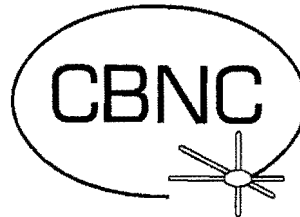
Luis Ortiz-Munoz, MD

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD
FOR PHYSICIANS TRAINED IN THE UNITED STATES
AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION,
IS HEREBY DESIGNATED
A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF
NUCLEAR CARDIOLOGY

FOR THE PERIOD 2007 - 2017



President



Secretary



CERTIFICATE NUMBER: 5571

**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: **Ortíz Muñoz Luis** State or Territory Where Licensed: **Puerto Rico**

- 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)

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	Corscan Authorized User and Laboratory Training Program, UCLA	20	6/13/2007-6/15/2007
Radiation protection	Corscan Authorized User and Laboratory Training Program, UCLA	20	6/13/2007-6/15/2007
Mathematics pertaining to the use and measurement of radioactivity	Corscan Authorized User and Laboratory Training Program, UCLA	10	6/13/2007-6/15/2007
Chemistry of byproduct material for medical use (not required for 35.590)	Corscan Authorized User and Laboratory Training Program, UCLA	15	6/13/2007-6/15/2007
Radiation biology	Corscan Authorized User and Laboratory Training Program, UCLA	15	6/13/2007-6/15/2007
Total Hours of Training: 80			

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 ⁷⁰⁰ 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	Cleveland Clinic Weston Florida	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	5/1/07-11/1/07
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Cleveland Clinic Weston Florida	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	5/1/07-11/1/07

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	Cleveland Clinic Weston Florida	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	5/1/07-11/1/07
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Cleveland Clinic Weston Florida	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	5/1/07-11/1/07
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Cleveland Clinic Weston Florida	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	5/1/07-11/1/07
Administering dosages of radioactive drugs to patients or human research subjects	Cleveland Clinic Weston Florida	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	5/1/07-11/1/07
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	Cleveland Clinic Weston Florida	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	5/1/07-11/1/07

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Michael Shen, MD	ME-87992/64E-5-626, 64E-5-627/38711

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

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

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 Luis Ortíz Muñoz 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 Luis Ortiz Munoz 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
MICHAEL SHEN, MD	<i>Michael Shen</i>	754-659-5311	1/28/2010

License/Permit Number/Facility Name
ME87992/64E-5.626 & 64E-5.627/ Cleveland Clinic Florida

3871-1

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

2/10/2010, and to inform you that the initial processing which includes an administrative review has been performed.

- AMEND. 52-30861-01 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** 144449.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.