

3/29/07

Nuclear Regulatory Commission, Region 1
Materials Licensing Section
475 Allendale Road
King of Prussia, PA 19406-1415
610-337-5309

RE: Radioactive materials license number 29-28041-01

030-30030

Request for amendment

NMSB2

Dear Sir or Madam:

Please amend the above referenced license in the following sections:

Section 12.B :


ADD: Authorized User

Material and Use

Adam Cohen, M.D.

35.200

I am enclosing a preceptorship letter and certificates of didactic coursework completion to document the Training and Experience of Adam Cohen, M.D.
Should you have any question regarding this amendment, please contact me at 303-541-0044.
Sincerely,


Charles H. Rose, MA MSPH D (ABSNM)
CEO/Administrator
PO Box 778
Red Bank, NJ 07701-0000

RECEIVED
REGION 1
2007 MAR 29 AM 10:45

140317

NMSS/RGNI MATERIALS-102



Adam J. Cohen, M.D.
 Carlos C. Marinelli, M.D.
 John D. Ramirez, M.D.
 Julian J. Nunez, M.D.
 Juliann M. Lain, P.A.-C

PRECEPTOR ATTESTATION

March 2, 2007

This letter is to verify and attest that **Adam J. Cohen, M.D.** has satisfactorily completed all training and experience requirements for Level 2 training in nuclear cardiology as outlined in the ACC/ASCN COCATS Guidelines [revised 2006].

Furthermore, Dr. Cohen has achieved a level of competency sufficient to function independently as an Authorized User under NRC 10 CFR 35.290 uses.

In more specific detail, Dr. Cohen's training and experience include, but are not limited to, the following:

<u>Training</u>	<u>Hours</u>	<u>Dates</u>
Radiation Physics and Instrumentation	-100 hours	01/20/07-01/28/07
Above includes Eluting Generators	- 10 hours	01/20/07-01/28/07
Radiation Protection	- 30 hours	08/12/06-08/20/06
Mathematics Pertaining to Radioactivity	- 20 hours	08/12/06-08/20/06
Radiopharmaceutical Chemistry	- 30 hours	08/12/06-08/20/06
Radiation Biology	- 20 hours	08/12/06-08/20/06
Total	-200 hours	

<u>Experience</u>	<u>Hours</u>	<u>Dates</u>
Ordering & Receiving Radioactive Material	- 50 hours	09/01/06-02/22/07
Calibrating & Using Radiation Instruments	- 50 hours	09/01/06-02/22/07
Calculating & Measuring Patient Dosages	-100 hours	09/01/06-02/22/07
Safe Use of Unsealed Radiation Sources	- 25 hours	09/01/06-02/22/07
Proper Spill & Decontamination Procedures	- 25 hours	09/01/06-02/22/07
Administering Radioactive Doses to Patients	- 50 hours	09/01/06-02/22/07
Didactic Discussions on Nuclear Patients	-200 hours	09/01/06-02/22/07
Above includes Interpretation of Studies	-500 hours	09/01/06-02/22/07
Total	-500 hours	

If any additional information is needed regarding this preceptorship attestation, I may be contacted at (813) 875-1177 during regular business hours.

Carlos C. Marinelli, M.D., FACC
 Tampa Heart Center, Inc
 Radiation Safety Officer & Authorized User
 State of Florida Radioactive Materials License Number 3223-1

STATEMENT OF TRAINING AND EXPERIENCE ELUTING GENERATOR

To whom it may concern:

This is confirm that Dr. Adam Cohen, M.D. has gained work experience at
GE HEALTHCARE (Name of Facility)

Address: 7802 Woodland Center Blvd

City: TAMPA State: FL Zip: 33614

Date: 3/24/07

The training/experiences involved the following:

Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluats for radionuclitic purity, and processing the eluats with reagent kits to prepare labeled radioactive drugs.

Dr. Karen L. Dorn
Name (Please Print)

[Signature]
Signature

Date: 3/24/2007 Title: Pharmacy Manager

Radioactive Materials License Number: 2133-1

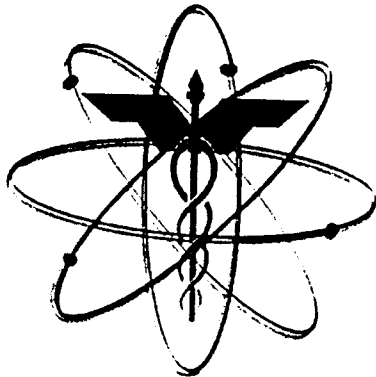
Telephone: 813-290-8747

FUNDAMENTALS
Radioisotope Handling
Attestation and Certification
Completion and Competency

This document is an affidavit that

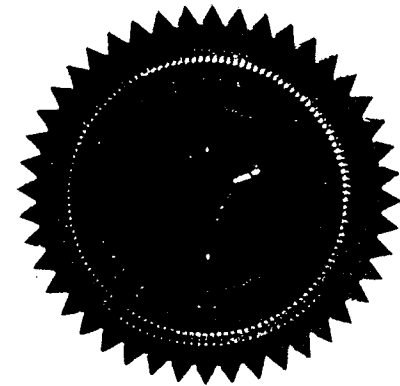
Adam Jay Cohen, M.D.

*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 (DII)
- In compliance with 10CFR35/AEA 73-689
- 100 Board Accepted Hours NUSPEX, NMTCB III b,
ABMRSO, ABR, ABNM, CBNC




Certifying Official

20 August 2006

Date Completed

203900

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.

INME1132-Class I-Compl&Comp 1/00

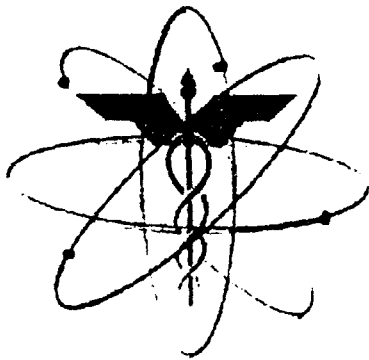
EXTENDED COMPREHENSIVE

Radioisotope Handling **Attestation and Certification Completion and Competency**

This document is an affidavit that

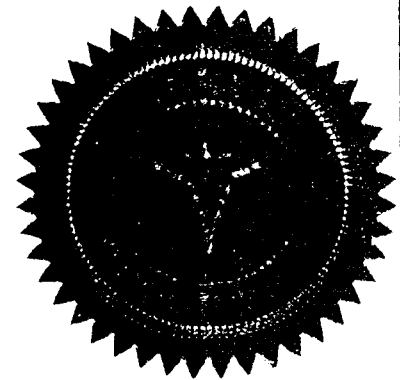
Adam Jay Cohen, M.D.

*has successfully completed the prescribed didactic program of
education and has achieved the objectives of this program
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- 100 Continuing Education Units (CEU)
- 100 Didactic Instructional Hours (DIH)
In compliance with 10CFR35/AEA 73-689
- 100 Board Accepted Hours NUSPEX, NMTCB III b,
ABMRSC, ABR, ABNM, CBNC




Certifying Official

January 28th, 2007

Date Completed

204016

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.

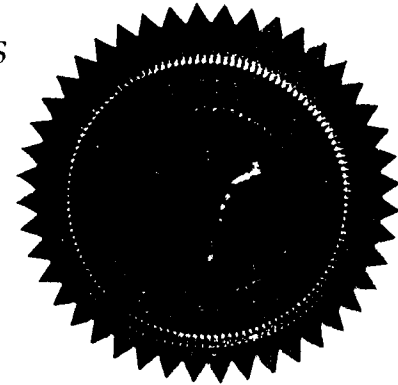
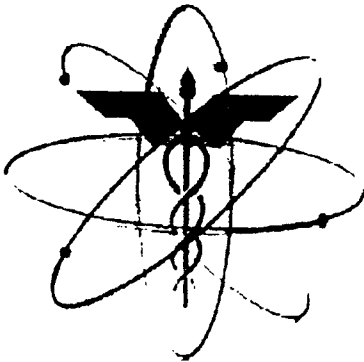
CERTIFICATE OF COMPLETION

HAZMAT TRAINING – RADIOACTIVE MATERIALS

This document is an affidavit that

Adam Jay Cohen, M.D.

Has received training and has been tested as required by 49CFR 172.704(d). This training was limited to diagnostic radioactive materials received or offered for shipment in approved Type A Packages, Class 7, UN2915, Yellow II.





Certifying Official

January 28th, 2007

Date Completed

203999

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.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

RADIOACTIVE MATERIALS LICENSE

Pursuant to Chapter 404, Florida Statutes, and Chapter 64E-5, Florida Administrative Code (F.A.C.), and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to receive, acquire, possess and transfer the radioactive material(s) designated below and to use such radioactive material(s) for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the state of Florida, Department of Health now or hereafter in effect and to any conditions specified below.

<p style="text-align: center;">Licensee</p> <p>1. Name: TAMPA HEART CENTER, INC.</p>	<p>3. License Number: 3223-1</p> <p><i>is hereby amended in its entirety, with reference to correspondence dated November 1, 2006.</i></p>
<p>2. Address: Suite 800 2727 West Martin Luther King Boulevard Tampa, FL 33607</p>	<p>4. Expiration Date: 3/31/2011</p> <p>5. Category: 5C</p>

6. Radioactive Material (element and mass number)	7. Chemical And/Or Physical Form	8. Maximum Quantity Licensee May Possess At Any One Time
A. Any radioactive material described in section 64E-5.627, F.A.C.	A. Any radiopharmaceutical for diagnostic use involving imaging and localization as described in section 64E-5.627, F.A.C., except gases, aerosols, generators, reagent kits, and NaI in quantities greater than 30 microcuries	A. As necessary, except for NaI-123, NaI-125 or NaI-131, in quantities greater than 30 microcuries

<p>9. Authorized Use</p> <p>A. Any medical use described in section 64E-5.627, F.A.C., except gases, aerosols, generators, reagent kits, and NaI in quantities greater than 30 microcuries.</p>

CONDITIONS

10. The authorized place of use is the licensee's facility located at the address in Item 2.
11. Failure to comply with the provisions of this license is a felony of the third degree pursuant to section 404.161, Florida Statutes. Also, violations may warrant an administrative fine of up to \$1,000.00 per violation per day, pursuant to section 404.162, Florida Statutes.

License Number: 3223-1
 Amendment No.: 7
 Control Number: 20061107-1802

LICENSEE COPY

Page 1 of 3 Page(s)

Category: [5C]
 Expiration Date: 3/31/2011

STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

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

Authorized Material and Uses as Described in Items 6, 7, 8, and 9	Names
64E-5.627 (except generators and reagent kits)	John D. Ramirez, M.D. Carlos C. Marinelli, M.D.

- B. The radiation safety officer is Carlos C. Marinelli, M.D.
- 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.
13. Radioactive material transported on public thoroughfares shall be packaged, prepared for shipment, and transported in accordance with Title 49, Code of Federal Regulations and Chapter 64E-5, F.A.C.
14. Sealed sources containing licensed material shall not be opened.
15. The licensee shall not authorize release from confinement for medical care any patient administered a radiopharmaceutical until:
- A. The dose rate is less than 5 millirem (50 microsieverts) per hour at a distance of 1 meter; or
- B. The amount of radioactive material in the patient is less than 30 millicuries.
16. A. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, 8, and 9 of this license in accordance with statements, representations and procedures contained in the licensee's application dated February 15, 2006 signed by Carlos C. Marinelli, M.D., President.

License Number: 3223-1
Amendment No.: 7
Control Number: 20061107-1802

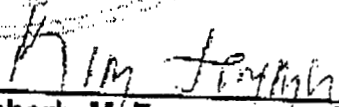
LICENSEE COPY
Page 2 of 3 Page(s)

Category: [5C]
Expiration Date: 3/31/2011

STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

16. B. The licensee shall comply with all applicable requirements of Chapter 64E-5, Florida Administrative Code, and these regulations shall supersede the licensee's statements in applications or correspondence, unless the statements are more restrictive than the regulations.

For the Bureau of Radiation Control:



Kimberly M. Farmer
Regulatory Specialist I
4052 Bald Cypress Way - Bin C21
Tallahassee, FL 32399-1741
(850) 245-4545

Issuance Date: DEC 01 2006

A party whose substantial interest is affected by this order may petition for an administrative hearing pursuant to sections 120.569 and 120.57, Florida Statutes. Such proceedings are governed by Rule 28-108, 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 850-487-1448. A copy of the petition should also be sent to: Bureau Chief, Bureau of Radiation Control, 4052 Bald Cypress Way, BIN # C21, Tallahassee, FL 32399-1741. 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 120.68, 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 fees required by law, 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: 3223-1
Amendment No.: 7
Control Number: 20061107-1802

LICENSEE COPY

Category: [5C]

Page 3 of 3 Page(s)

Expiration Date: 3/31/2011

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

3/29/2007, and to inform you that the initial processing which includes an administrative review has been performed.

Account 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** 140317.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.