

Physicians Imaging Center  
New Jersey

August 13, 2009

K-4  
MS-16

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

Attn: Steven Courtemanche

Ph: 610.337.5000

Re: License No. 29-28041-01 63030030

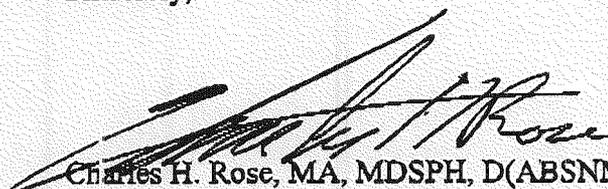
Dear Mr. Courtemanche,

Enclosed you will find new documentation for Narendra Upadhyaya, M.D.

Please disregard the previous submission of Handling Experience as the current documents are simplified and, as attested by Dr. Cicio, current.

We apologize for the confusion and will now be more attentive in providing clear, valid documentation.

Sincerely,



Charles H. Rose, MA, MDSPH, D(ABSNM)

Administrator  
Physicians Imaging Center  
180 Avenue at the Common  
Shrewsbury, NJ 07702

Cc: file

Enclosures

143961  
NRC/RGNI MATER.ALS-002

**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: 3/31/2012

Name of Proposed Authorized User <b>Narendra Upadhyaya, M.D.</b>	State or Territory Where Licensed
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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	See Attachment A		

**Total Hours of Experience:**

Supervising Individual <b>Modesto R. Quintero, RPh, WP Radiopharmacist, GE HealthCare</b>	License/Permit Number listing supervising individual as an authorized user <b>FL MP 209 &amp; PS 14894</b>
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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	INME 5660 Airport Blvd, Ste. 101 Boulder, CO 80301 1.800.548.4024	150	
Radiation protection	Same as above	45	Certification Attached 1993 -- 1994 -- 2009
Mathematics pertaining to the use and measurement of radioactivity	Same as above	30	
Chemistry of byproduct material for medical use (not required for 35.590)	Same as above	45	
Radiation biology	Same as above	30	
<b>Total Hours of Training:</b>		300 hrs	

**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:	See Attachment B	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	See Attachment B	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

**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	See Attachment B	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	See Attachment B	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	See Attachment B	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Administering dosages of radioactive drugs to patients or human research subjects	See Attachment B	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
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	GE HealthCare See Attachment A	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Supervising Individual \_\_\_\_\_ License/Permit Number listing supervising individual as an authorized user \_\_\_\_\_

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
	N/A	

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

U.S. NUCLEAR REGULATORY COMMISSION

NRC FORM 5130 (2007)  
 (2-1000) **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 exceeding to the individual's "general clinical competency."

**First Section**

Check one of the following for each use requested:

For 35.191

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 35.200

Board Certification

I attest that

\_\_\_\_\_ Name of Proposed Authorized User

has satisfactorily completed the requirements in

10 CFR 35.200(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

Narendra Upadhyaya, 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 35.200(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.

**NON  
DATE**

**Second Section**

Complete the following for preceptor attestation and signature:

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

- 35.190     35.200     35.380     35.390 + generator experience

Name of Preceptor <b>William Cicio, M.D.</b>		Signature 	Telephone Number <b>860.350.7724</b>	Date <b>8/12/09</b>
License/Permit Number/Facility Name <b>2816-2, 4093-1, 06-17892-01 (See Attachment B)</b>				

Attachment A



GE Healthcare

10725 MARKS WAY  
MIRAMAR, FL 33025  
USA

T+1 954 432 4255  
F+1 954 432 4920

July 22, 2009

Dr. Narendra R. Upadhyaya MD  
2301 N. University Drive  
Suite 108  
Pembroke Pines, FL 33024

Dear Dr. Upadhyaya,

This document is to certify, that Dr. Narendra R. Upadhyaya M.D., has under my immediate supervision and observation, properly eluted a molybdenum/technetium generator at least twice, and was present during the preparation of multiple radiopharmaceutical kits.

During his visit he was fully trained in the area of molybdenum breakthrough and Aluminum testing of Tc99 Eluate.

Also during his visit at GE Healthcare, he was present under the supervision of two nuclear pharmacists and saw the dispensing of doses to medical facilities

He was also present as quality control testing was performed on the radiopharmaceutical kits.

During his two-hour visit, Dr Upadhyaya was present while delivery personnel were preparing doses for delivery, following the DOT guidelines.

Sincerely,

A handwritten signature in black ink, appearing to read 'Modesto R. Quintero'.

Modesto R. Quintero RPh, NP  
Radiopharmacist  
Pharmacy Manager  
GE Healthcare

Dr. Narendra Upadhyaya, M.D.

**Attachment B**  
(For NRC 313A 3.b, Pages 2 and 3)

1. 1991 - 1994  
Mt. Sinai Medical Center  
4300 Alton Road  
Miami Beach, FL 33140

2. Florida Institute of Cardiovascular Care, PA  
2845 ~~Aventura Blvd.~~  
~~Miami~~, FL 33180

3702 Washington Street April 25 '20  
Hollywood, FL ~~July 2007 - July 2008~~  
33021 September 2008

License #2806-2

3. Oct 28, 2008 - Present  
Upa Cardiology, Inc.  
2301 N. University Drive  
Suite 106  
Pembroke Pines, FL 33024

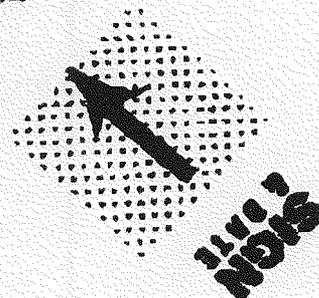
License #4093-01

William Cicio, M.D.

Y12log

Date

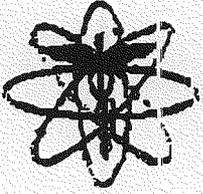
Authorized User  
FL 2806-2  
FL 4093-1  
06-17892-01



FAX REC

AUG 12 2009

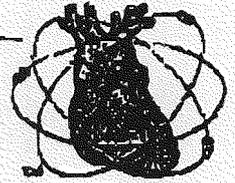
BY: SN



# INME

## Institute for Nuclear Medical Education

Approved and Regulated by The D.P.D.S., Department of Higher Education in CO



August 12, 2009

Licensed  
Nuc Reg Comm (NRC)  
Agreement State

Validated  
US Dept Education  
Am Council Education  
NUSPEX-BPSIA/PA

Accepted  
USNRC  
10 CFR 19  
10 CFR 20  
10 CFR 35  
274b AEC79  
Agreement State  
Rad Medical Equip  
Am Assoc Colls Joint Reg

Credits Provided  
University  
College  
CME  
NRC  
State  
NIM/29  
CEU/HACET  
RSD

Dr. Cicio:

We are working with Dr. Narendra Upadhyaya, M.D. to assist him in obtaining his license as an Authorized User (AU). We have some existing documentation signed by you; however, we need revision of those documents and new signatures.

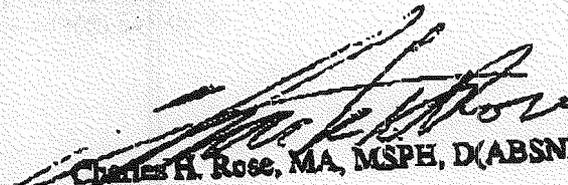
Please review the enclosed for accuracy and if incorrect, make the appropriate changes clearly on the document. Then sign and date where indicated, and fax back to our office.

**Action Required:**

- Review for accuracy
- Put dates in #2 of Attachment B
- Sign and date Attachment B
- Sign and date Page 4.

Please feel free to contact me at 303.541.0044 if you have any questions or need any additional information.

Sincerely,



Charles H. Rose, MA, MSPH, D(ABSNM)  
President

Cc: file

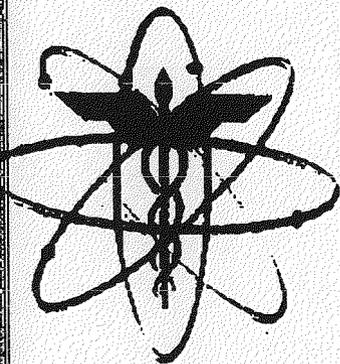
Enc.

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

*This document is an affidavit that*

**Narendra R. Upadhyaya, MD, FACC**

*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**

**January 23, 2009**

**Date Completed**

**204355**

**Certification**

**Institute for Nuclear Medical Education**

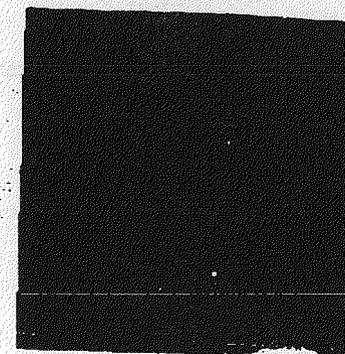
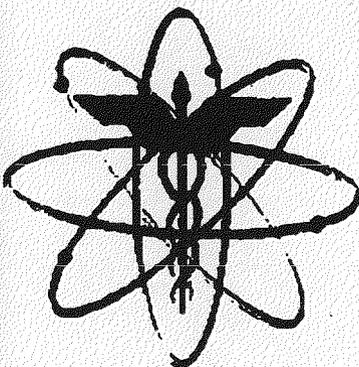
...ed, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the American Council on Educational Accreditation, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by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

**CERTIFICATE OF COMPLETION**  
**HAZMAT TRAINING – RADIOACTIVE MATERIALS**

*This document is an affidavit that*

*Narendra R. Upadhyaya, MD, FACC*

*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.*



*[Handwritten Signature]*

Certifying Official

January 19, 2009

Date Completed

204356

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.

# NUCLEAR MEDICAL EDUCATION PROGRAM

## Affidavit of Academic Completion and Competency

*This document is to attest that*

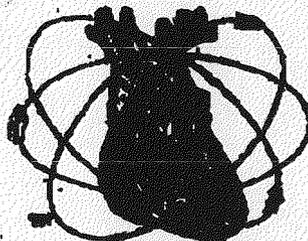
**NARENDRA R. UPADHYAYA, M.D.**

*has successfully completed the didactic program*

### **MEDICAL RADIATION INSTRUMENTATION**

*and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.*

*This program provides the following levels of accomplishment:*



- 80 Didactic Instructional Hours (DIH)  
(in compliance with IOCFRIS)
  - 5 Continuing Education Units (CEU)
  - 80 Continuing Medical Education (CME)
  - 80 Technical/Professional Credit specified by the American Pharmaceutical Association and the American Association of Health Physicians\*
- \*Additional documentation will be provided to regulatory agencies upon participant request.

**8 June 1994**

**Date Class Completed**

*[Signature]*  
Authorized Signature

190672  
Affidavit of Competency

## **INSTITUTE FOR NUCLEAR MEDICAL EDUCATION**

5171 Eldorado Springs Drive, Boulder, CO 80508 303-449-6034

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for College Reentry, Council on Post-Secondary Education.

# NUCLEAR MEDICAL EDUCATION PROGRAM

## Affidavit of Academic Completion and Competency

This document is to attest that

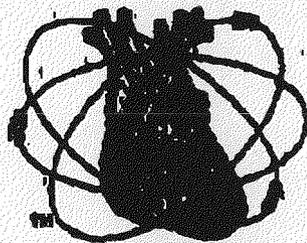
INDIRA K. PADHYA, M.D.

has successfully completed the didactic program

### RADIOPHARMACEUTICALS AND CHEMISTRY

and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.

This program provides the following levels of accomplishment:



- 60 Didactic Instructional Hours (DIH) (in compliance with 10CFR88)
  - 1 Continuing Education Units (CEU)
  - 12 Continuing Medical Education (CME)
  - 12 Technical/Professional Credit specified by the American Pharmaceutical Association and the American Association of Health Physicists
- Additional documentation will be provided to Regulatory Agencies upon request.

15 December 1993  
Date Class Commenced

*Cheryl E. Peace*  
Authorized Signature

**190492**

Affidavit of Competency

## INSTITUTE FOR NUCLEAR MEDICAL EDUCATION

6171 Eldorado Springs Drive, Boulder, CO 80503 303-443-4084

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Witnessed by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Witnessed by the American Council on Education, recognized by the American Association for College Re-accreditation. Council on Post-Secondary Education.

# NUCLEAR MEDICAL EDUCATION PROGRAM

## Affidavit of Academic Completion and Competency

*This document is to attest that*

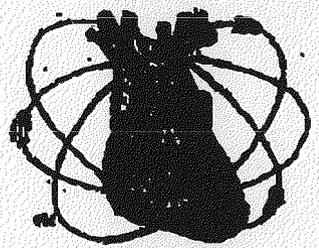
NARENDRA R. UPADHYAYA, M.D.

*has successfully completed the didactic program*

### PRINCIPLES OF RADIATION PHYSICS

*and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.*

*This program provides the following levels of accomplishment:*



- Didactic Instructional Hours (DIH)
- (in compliance with 10CFR233)
- Continuing Education Units (CEU)
- Continuing Medical Education (CME)
- Technical/Professional Credit specified by the American Pharmaceutical Association and the American Association of Health Physicists\*

\*Additional documentation will be provided to requesting agencies upon individual request.

4 June 1994

Date Class Completed

*Clide E. Kaur*  
Authorized Signatory

190757  
Attest of Competency

## INSTITUTE FOR NUCLEAR MEDICAL EDUCATION

5171 Eldorado Springs Drive, Boulder, CO 80509 303-549-4094

Certified, Approved and Regulated by the Division of Private Corporations, Department of Higher Education in Colorado. Validated by the American Commission on the Accreditation of Continuing Education, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for College Re-accreditation. Council on Post-Secondary Education.

# NUCLEAR MEDICAL EDUCATION PROGRAM

## Affidavit of Academic Completion and Competency

*This document is to attest that*

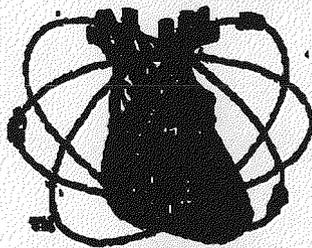
MARENDA R. UPDEHAYA, M.D.

*has successfully completed the didactic program*

### MEDICAL RADIATION PROTECTION

*and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.*

*This program provides the following levels of accomplishment:*



- 10 Didactic Instructional Hours (DIH) (in compliance with 10CFR20)
- 5 Continuing Education Units (CEU)
- 50 Continuing Medical Education (CME)
- 50 Technical/Professional Credit specified by the American Pharmaceutical Association and the American Association of Health Physicists\*

\*Additional documentation will be provided to Regulatory Agency upon participant request

11 December 1995  
Date Class Commenced

*Clare E. Rosen*  
Authorized Signature

190491

Affidavit of Competency

## INSTITUTE FOR NUCLEAR MEDICAL EDUCATION

5171 Eldorado Springs Drive, Boulder, CO 80508 303-443-6884

Certified, Approved and Registered by the Division of Private Occupational Systems, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Self-Study Institutions, Council on Postsecondary Education.