

THE HEART GROUP

LANCASTER MEDICAL CENTER, SUITE 200
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LANCASTER, PA 17603-2962
(717) 481-7391
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www.theheartgroup.com

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SETH J. WORLEY, M.D., F.H.R.S., F.A.C.C.

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SHERRI DELGADO, C.R.N.P.
DEANNA DUKES, C.R.N.P.
JON ECHTERLING, C.R.N.P.
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CONNIE KISER, C.R.N.P.

LISA RATHMAN, C.R.N.P.
JILL REPOLEY, C.R.N.P.
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KELLY TRYNOSKY, C.R.N.P.
JENNIFER WARDLE, C.R.N.P.
ALEXANDRA WYANT, C.R.N.P.
BRENDA YOUNG, C.R.N.P.

July 10, 2007

NMSB2

Ms. Michelle Beardsley
United States Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406

Dear Ms. Beardsley:

03034622

RE: Material License No. 37-30426-01

The Heart Group is requesting to add Gulpinder K. Chatha, M.D. to the group's Materials License. Enclosed is Dr. Chatha's Training and Experience and Preceptor Attestation certifying her training in an approved Cardiology Fellowship Program at Loyola University Medical Center.

Should you have any questions, please call me directly at 717-481-7391. Thank you for your time and consideration of this request.

Sincerely,

Shelvy J. Frank

Shelvy J. Frank
VP & Chief Operating Officer

Enclosures

Cc: Department of Environmental Protection

RECEIVED
REGION 1
2007 JUL 12 AM 10:22

140795
NMSS/RGN1 MATERIALS-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: 10/31/2008

Name of Proposed Authorized User

GURPINDER CHATHA

State or Territory Where Licensed

PENNSYLVANIA

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	INSTITUTE OF NUCLEAR MEDICAL EDUCATION (INME) CHICAGO, IL	100	3/18/06 to 3/26/06 AND 10/14/06 to 10/22/06
Radiation protection	INSTITUTE OF NUCLEAR MEDICAL EDUCATION (INME) CHICAGO, IL	30	3/18/06 to 3/26/06 AND 10/14/06 to 10/22/06
Mathematics pertaining to the use and measurement of radioactivity	INSTITUTE OF NUCLEAR MEDICAL EDUCATION (INME) CHICAGO, IL	20	3/18/06 to 3/26/06 AND 10/14/06 to 10/22/06
Chemistry of byproduct material for medical use (not required for 35.590)	INSTITUTE OF NUCLEAR MEDICAL EDUCATION (INME) CHICAGO, IL	30	3/18/06 to 3/26/06 AND 10/14/06 to 10/22/06
Radiation biology	INSTITUTE OF NUCLEAR MEDICAL EDUCATION (INME) CHICAGO, IL	20	3/18/06 to 3/26/06 AND 10/14/06 to 10/22/06
Total Hours of Training:			200

- 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	LOYOLA UNIVERSITY MEDICAL CENTER, MAYWOOD, IL 60153 IL - 01131-02	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	5/1/06 To 1/31/07
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	LOYOLA UNIVERSITY MEDICAL CENTER, MAYWOOD, IL 60153 IL - 01131-02	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	5/1/06 To 1/31/07

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	LOYOLA UNIVERSITY MEDICAL CENTER, MAYWOOD, IL 60153 IL - 01131-02	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	5/1/06 To 1/31/07
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	LOYOLA UNIVERSITY MEDICAL CENTER, MAYWOOD, IL 60153 IL - 01131-02	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	5/1/06 To 1/31/07
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	LOYOLA UNIVERSITY MEDICAL CENTER, MAYWOOD, IL 60153 IL - 01131-02	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	5/1/06 To 1/31/07
Administering dosages of radioactive drugs to patients or human research subjects	LOYOLA UNIVERSITY MEDICAL CENTER, MAYWOOD, IL 60153 IL - 01131-02	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	5/1/06 To 1/31/07
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	LOYOLA UNIVERSITY MEDICAL CENTER, MAYWOOD, IL 60153 IL - 01131-02	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	5/1/06 To 1/31/07

Supervising Individual

ROBERT WAGNER MD

License/Permit Number listing supervising individual as an authorized user

IL - 01131-02

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)

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 Gurpinder Chatha 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

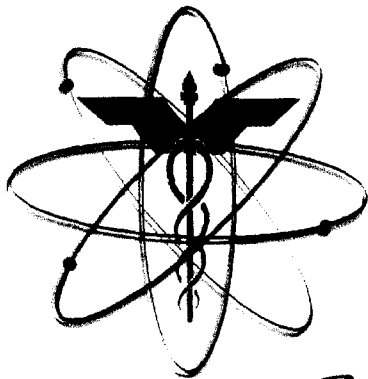
Name of Preceptor <u>Robert Wagner, M.D.</u>	Signature <u>[Signature]</u>	Telephone Number <u>708-216-8667</u>	Date <u>6/27/07</u>
License/Permit Number/Facility Name <u>IL-01131-02 Loyola Univ. Med. CTR.</u>			

FUNDAMENTALS
Radioisotope Handling
Attestation and Certification
Completion and Competency

This document is an affidavit that

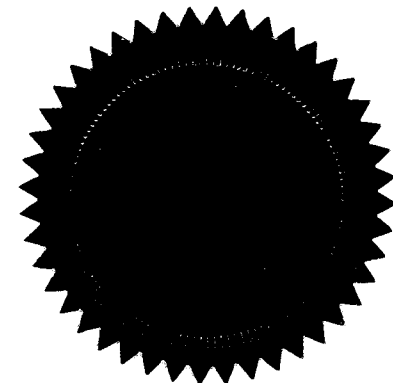
Gurpinder Chatha, M.D.

*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

- 10.0 Continuing Education Units (CEU)
- 100 Didactic Instructional Hours (DIH)
In compliance with 10CFR35/AEA 73-689
- 100 Board Accepted Hours NUSPEX, NMTCB III b,
ABMRSO, ABR, ABNM, CBNC




Certifying Official

26 March 2006

Date Completed

203754

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.

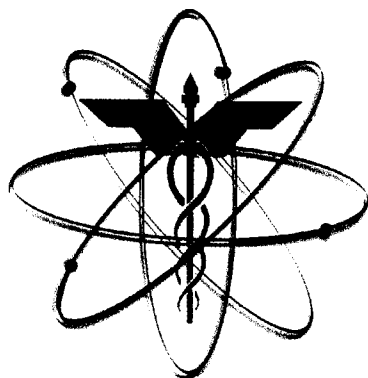
INME1132-Class I-Compl&Comp 1/00

EXTENDED COMPREHENSIVE
Radioisotope Handling
Attestation and Certification
Completion and Competency

This document is an affidavit that

Gurpinder Chatha, M.D.

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



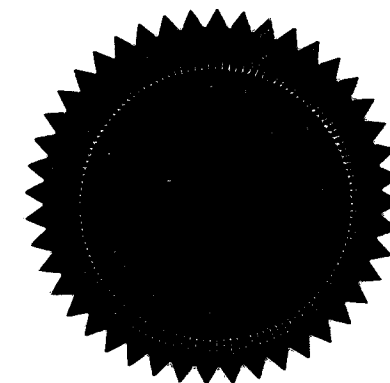

Certifying Official

This Program provides the following levels of documented accomplishment

- 10.0 Continuing Education Units (CEU)
- 100 Didactic Instructional Hours (DIH)
In compliance with 10CFR35 / AEA 73-689
- 100 Board Accepted Hours NUSPEX, NMTCB III b,
ABMRSO, ABR, ABNM, CBNC
- 6.0 Semester Hours American Council on
Education (ACE), American Association for
Collegiate Registrars

22 October 2006

Date Completed



203958

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.

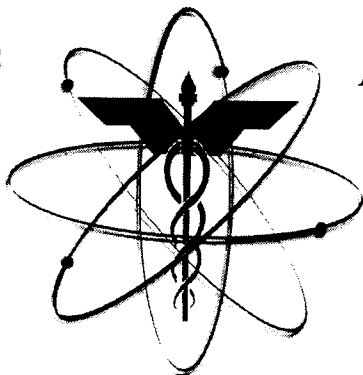
INME1132-Class I-Compl&Comp 1/00

CERTIFICATE OF COMPLETION

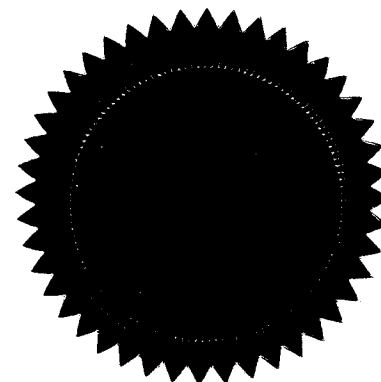
HAZMAT TRAINING - RADIOACTIVE MATERIALS

This document is to certify that

Gurpinder Chatha, 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

22 October 2006

Date Completed

203939

Certification

Training Materials and Records are located at

INME - Institute for Nuclear Medical Education • 5660 Airport Boulevard, Suite 101 • Boulder, Colorado 80301
(303) 541-0044 • (303) 541-0066 FAX • (800) 548-4024 • inme@nuclearcardiology.com • <http://www.nuclearcardiology.com/ncs>



LOYOLA
UNIVERSITY
CHICAGO

LOYOLA UNIVERSITY MEDICAL CENTER
Foster G. McGaw Hospital
Department of Radiology
Section on Nuclear Medicine

2160 S. First Avenue
Maywood, Illinois 60153

Telephone: (708) 216-8667
Fax: (708) 216-5813
Internet: rwagner@lumc.edu

June 27, 2007

To Whom It May Concern:

This letter is to confirm the training experience of Gurbinder Chatha, MD for the laboratory and clinical training in the diagnostic use of radioisotopes. She has received 200 hours of didactic/classroom training that are recognized by the ABR, ABNM and CBNC. This was completed on March 26th, 2006 and October 22nd, 2006.

Her clinical experience includes time spent in our radiopharmacy and supervision / interpretation of stress/rest myocardial perfusion studies. This clinical training included the interpretation of 1,090 studies at various periods from 5/06 through 1/07 and meets or exceeds the minimum of 700 hours total of training and experience in our department.

During the above time period, she spent time in our radiopharmacy where she was instructed and had experience in:

- a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- b. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- c. Calculating, measuring, and safely preparing patient or human research subject dosages;
- d. Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
- e. Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
- f. Administering dosages of radioactive drugs to patients or human research subjects; and
- g. Eluting generator systems appropriate for 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.

It has been a pleasure to have Dr. Chatha in our department and I believe that she is competent to act as a user for diagnostic cardiac studies.

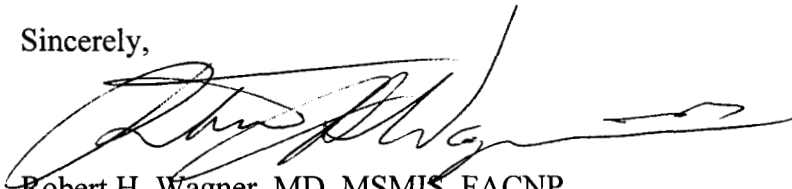
Dr. Chatha has completed a training program in nuclear cardiology that meets the requirements for Level 2 training as outlined in the ACC/ASNC COCATS Guidelines (Revised 2006) within an accredited fellowship program.

Dr. Chatha is competent to independently function as an authorized user under 10 CFR 35.290 uses.

I am an authorized user under a broad scope license at Loyola University Medical Center. This can be confirmed by contacting Dr. Kevin Corrigan at 708-216-9260. You can also request from that number a copy of our license.

Should you have any questions, please do not hesitate to contact me at 708-216-8667.

Sincerely,

A handwritten signature in black ink, appearing to read 'Robert H. Wagner', with a long horizontal flourish extending to the right.

Robert H. Wagner, MD, MSMIS, FACNP
Professor of Radiology and
Director, Section of Nuclear Medicine
Chairman, Radiation Safety Committee

Agreement State License Number IL-01131-02

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

7/10/2007, and to inform you that the initial processing which includes an administrative review has been performed.

☒ ATTEND. 37-30426-01 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** 140 795.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.