

Dr. EDWIN SPATH
Dr. STEVEN COHEN
Dr. PETER WHITE
Dr. GLADYS KAGAOAN
1000 Asylum Ave Suite 4300
Hartford, CT 06105
Tel. (860)527-6247/ Fax (860)549-7936



Q-8
06-30812-01
03036246

Fax

To: USNRC REGION I OFFICE
MEDICAL LICENSING SECTION

From: EDWIN SPATH, MD

Fax: (610)337-5269

Pages: 10

Phone:

Date: 11/15/2004

Urgent For Review Please Comment Please Reply Please Recycle

RE: AMENDMENT OF NRC MATERIALS LICENSE #06-30812-01

ATTACHED HERewith IS A COMPLETED FORM 313A INCLUDING AMMENDMENTS TO ITEMS 12A, 12B, 12C, 12d and 12E AS PER YOUR INSTRUCTIONS.



Ms. Kim McCord

Practice Manager

Kim McCord
135663

NMSS/RGNI MATERIALS-002

GREATER HARTFORD CARDIOLOGY GROUP, PC

1000 Asylum Avenue, Suite 4300, Hartford, CT 06105 Tel 860-527-6247

To: USNRC, Region I Office
Medical Licensing Section
475 Allendale Road
King of Prussia, PA 19406

September 2, 2004

03036246

Re: Amendment of NRC Materials License #06-30812-01

Dear Sir or Madam:

This letter serves to request a license amendment for Greater Hartford Cardiology Group, PC.

ITEM 1

Gladys Kagaoan, MD is a physician having recently completed her training for nuclear cardiology. She has joined our group and we are enclosing documentation of her training and experience. We request that she be authorized for the materials and use listed in 10 CFR; 35.100, 35.200, and 35.300.

We appreciate your efforts to expedite the amendment and we look forward to a continued safe and effective materials program. Should you have any questions or desire additional information regarding our private, nuclear cardiology imaging office, please contact me at 860-527-6247. Thank you for your assistance.

Respectfully submitted,

Edwin A. Spath MD

Edwin A. Spath, MD

| | | |
|---|------------------------------------|---|
| NRC FORM 313A (10-2002) | U.S. NUCLEAR REGULATORY COMMISSION | APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2005 |
| TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT | | |

PART I - TRAINING AND EXPERIENCE

Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulations.

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

GLADYS A. KAGAOAN, MD

2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed

CT

3. CERTIFICATION

| Specialty Board | Category | Month and Year Certified |
|--------------------|-----------------|--------------------------|
| INTERNAL MEDICINE | } — pending — [| 10/2001 |
| CARDIOLOGY | | 11/2004 |
| NUCLEAR CARDIOLOGY | | 10/2004 |

Stop here when using Board Certification to meet 10 CFR Part 35 training and experience requirements.

4. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)

| Description of Training | Location | Clock Hours | Dates of Training |
|--|---|-------------|---------------------|
| Radiation Physics and Instrumentation | UNIV. OF CONNECTICUT & ST. FRANCIS HOSPITAL Hartford, CT | 100 | 7/2001 to 6/2004 |
| Radiation Protection | UNIV. OF CONNECTICUT & ST. FRANCIS HOSPITAL Hartford, CT | 30 | 7/2001 to 6/2004 |
| Mathematics Pertaining to the Use and Measurement of Radioactivity | UNIV. OF CONNECTICUT & ST. FRANCIS HOSPITAL Hartford, CT | 20 | 7/2001 to 6/2004 |
| Radiation Biology | UNIV. OF CONNECTICUT & ST. FRANCIS HOSPITAL Hartford, CT | 20 | 7/2001 to 6/2004 |
| Chemistry of Byproduct Material for Medical Use | UNIV. OF CONNECTICUT & ST. FRANCIS HOSPITAL Hartford, CT | 30 | 7/2001 to 6/2004 |
| OTHER | | | |

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TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

5a. WORK EXPERIENCE WITH RADIATION

| Description of Experience | Name of Supervising Individual(s) | Location and Corresponding Materials License Number | Dates and Clock Hours of Experience |
|--|---|---|-------------------------------------|
| PERFORMANCE & INTERPRETATION of CARDIAC STRESS & PERFUSION IMAGING | DR. RICHARD SOUCHER CO-PROGRAM DIRECTOR OF CARDIOLOGY FELLOWSHIP | Saint Francis Hospital 06-00854-03 | 7/1/2001 to 6/30/2004 |
| PERFORMANCE of CARDIAC CATHETERIZATION | DR. DANIEL DWOR (CARDIOLOGY CHAIRMAN & DIRECTOR of CATH LAB) | Saint Francis Hospital 06-00854-03 | 7/1/2001 to 6/30/2004 |
| Total time committed = 1300 hours minimum (Nuclear Lab) | | | |
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5b. SUPERVISED CLINICAL CASE EXPERIENCE

| Radionuclide | Type of Use | No. of Cases Involving Personal Participation | Name of Supervising Individual | Location and Corresponding Materials License Number | Dates and Clock Hours of Experience |
|--|----------------------|---|--|---|-------------------------------------|
| Tc99m sestamibi | MYOCARDIAL PERFUSION | 71 cases injected | GARY V. HELLER, MD | % UNIV. OF CONNECTICUT 06-13022-02 | 10/1/2003 to 10/31/2003 |
| Tc99m MIBI | MYOCARDIAL PERFUSION | >800 cases performed & interpreted | RICHARD SOUCHER, MD & GARY V. HELLER, MD & MOZAFAR KARIMEDDINI, MD | Saint Francis Hospital 06-00854-03 | 7/1/2001 to 6/30/2004 |
| Total time committed = 3100 hours (clinical case experience) | | | | | |
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U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

6. FORMAL TRAINING (applies to Medical Physicists and Therapy Physicians)

| Degree, Area of Study or Residency Program | Name of Program and Location with Corresponding Materials License Number | Dates | Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490) |
|--|--|-------|---|
| | | | |

7. RADIATION SAFETY OFFICER -- ONE-YEAR FULL-TIME WORK EXPERIENCE

YES Completed 1-year of full-time radiation safety experience (in areas identified in item 5a) under supervision of _____ the RSO for License No. _____

N/A

8. MEDICAL PHYSICIST -- ONE-YEAR FULL-TIME TRAINING/WORK EXPERIENCE

YES Completed 1-year of full-time training in therapeutic radiological physics under the supervision of _____ who meets requirements for Authorized Medical Physicists; and

N/A

YES Completed 1-year of full-time work experience (for areas identified in item 5a) for _____ who meets requirements of Authorized Medical Physicists for _____ modality(ies).

N/A

9. SUPERVISING INDIVIDUAL -- IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet requirements in 10 CFR 35, provide the following information for each) :

A. Name of Supervisor

B. Supervisor is:

- Authorized User
- Radiation Safety Officer
- Authorized Medical Physicist
- Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) _____

for medical uses in Part 35, Section(s) _____

D. Address

E. Materials License Number

NRC FORM 913A
(10-2003)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

PART II -- PRECEPTOR STATEMENT

Note: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet the training requirements in 10 CFR 35.590.

Item 10 must be completed for Nuclear Pharmacists meeting the requirements of 10 CFR Part 35, Subpart J. Preceptors do not have to complete items 11a, 11b, or the certifying statements for other individuals meeting the requirements of 10 CFR Part 35, Subpart J.

YES 10. The individual named in item 1 has satisfactorily completed the training requirements in 10 CFR 35.980 and is competent to independently operate a nuclear pharmacy.
 N/A

YES 11a. The individual named in item 1 has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 35.100 & 35.200, 35.910 & 35.920.
 N/A

YES 11b. The individual named in item 1 is competent to independently function as an authorized _____ for _____ uses (or units).
 N/A

12. PRECEPTOR APPROVAL AND CERTIFICATION

I certify the approval of item 10 and certify I am an Authorized Nuclear Pharmacist;

or

I certify the approval of items 11a and 11b, and certify I am an Authorized Nuclear Pharmacist;

or

I certify the approval of items 11a and 11b, and I certify that I meet the requirements of 35.200 or equivalent Agreement State requirements to be a preceptor authorized USER

for the following uses (or units) of byproduct material: Imaging and localization studies
35.100 and 35.200

A. Address
UNIVERSITY OF CONNECTICUT HEALTH CENTER
DIVISION OF NUCLEAR MEDICINE FM 042
FARMINGTON, CT 06030-2804

B. Materials License Number
06-13022-02

C. NAME OF PRECEPTOR (print clearly)
DR. MOZAFAR KARIMEDDINI

D. SIGNATURE -- PRECEPTOR
M. Karimeddini

E. DATE
* 11/15/04

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* Please see enclosed supporting documentation

NRC FORM 313A
(10-2002)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

PART II - PRECEPTOR STATEMENT

Note: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet the training requirements in 10 CFR 35.590.

Item 10 must be completed for Nuclear Pharmacists meeting the requirements of 10 CFR Part 35, Subpart J. Preceptors do not have to complete items 11a, 11b, or the certifying statements for other individuals meeting the requirements of 10 CFR Part 35, Subpart J.

YES 10. The individual named in item 1 has satisfactorily completed the training requirements in 10 CFR 35.880 and is competent to independently operate a nuclear pharmacy.

N/A

YES 11a. The individual named in item 1 has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 35.100 & 35.200, 35.910 & 35.920

N/A

YES 11b. The individual named in item 1. is competent to independently function as an authorized _____ for _____ uses (or units).

N/A

12. PRECEPTOR APPROVAL AND CERTIFICATION

I certify the approval of item 10 and certify I am an Authorized Nuclear Pharmacist;

OR

I certify the approval of items 11a and 11b, and certify I am an Authorized Nuclear Pharmacist;

OR

I certify the approval of items 11a and 11b, and I certify that I meet the requirements of 35.200 or equivalent Agreement State requirements to be a preceptor authorized _____ for the following uses (or units) of byproduct material: Imaging & Localization studies 35.100 & 35.200

A. Address HARTFORD HOSPITAL
80 SEYMOUR ST
HARTFORD, CT 06102

B. Materials License Number 06-00253-04

C. NAME OF PRECEPTOR (Print clearly) GARY V. HELLER, MD

D. SIGNATURE OF PRECEPTOR 

E. DATE Nov 12, 2004

← PLEASE SEE SUPPORTING DOCUMENTATION - ENCLOSED



THE UNIVERSITY OF CONNECTICUT HEALTH CENTER

DEPARTMENT OF DIAGNOSTIC IMAGING & THERAPEUTICS
DIVISION OF NUCLEAR MEDICINE FM 042
FARMINGTON, CONNECTICUT 06030-2804

Tel: (860) 679-3120
Fax: (860) 679-2164

July 15, 2004

Re: GLADYS A. KAGAOAN, M.D.

To Whom It May Concern:

This is to verify that the above student has satisfactorily attended the training in Basic Nuclear Medicine Science from September 2003 to February 2004 during her cardiology fellowship at the University of Connecticut Health Center.

John Vento, MD and Ronald Weiner, PhD, taught the Basic Science Course in Nuclear Medicine at the University of Connecticut Health Center. The course consisted of 100 contact hours and covered topics in Radiopharmacy, Radiochemistry, Radiopharmacology, Nuclear Medicine Physics, Radiation Protection, Health Physics, Instrumentation, and Statistics.

In addition I have supervised Dr. Kagaoan in the interpretation of at least 100 clinical nuclear cardiology cases during her cardiovascular fellowship from July 2001 to June 2004.

The University of Connecticut Health Center has a Broad Scope Human Use License (06-13022-02) to use radioactive materials, which expires December 1, 2013. The Radiation Safety committee of the Health Center authorizes individual users of radioactivity.

Please do not hesitate to contact Dr. Weiner or myself for any further questions.
Phone: 860-679-3793, FAX: 860-679-2164.

Sincerely,

Mozafar Karimeddini, MD
Associate Professor of Diagnostic Imaging
Clinical Chief, Nuclear Medicine Division
Authorized User, University of Connecticut Health Center



June 8, 2004

To Whom It May Concern:

RE: Gladys Kagaoan, MD

This is to certify that Dr. Kagaoan has participated in the interpretation of over 600 nuclear cardiology studies of which angiographic correlation was possible in at least 100 patients. Dr. Kagaoan also has training to Level 2 in Nuclear Cardiology (2000 ACC/ASNC training guidelines).

Dr. Kagaoan's training and experience fully meets the requirements as outlined in the ACC/ASNC COCATS Guidelines shown on page 16 of the 2004 Candidate Bulletin. She has achieved a level of competence sufficient to function independently as an authorized user for the medical uses authorized under NRC Subpart E-imaging and localization.

If I can be of any further assistance, please do not hesitate to contact me.

Sincerely,

Gary V. Heller, MD, Ph.D., FACC
Associate Director, Division of Cardiology
Director, Nuclear Cardiology Laboratory
CBNC # 06-00253-04
Director, Cardiovascular Fellowship Program
Hartford Hospital
Professor of Medicine and Nuclear Medicine
University of Connecticut School of Medicine

GVH/bd





SAINT FRANCIS

Hospital and Medical Center

Department of Medicine
Section of Cardiology

11+ Woodland Street
Hartford, Connecticut
06105-1299

860 714-5900
Fax 860 714-8001

July 12, 2004

To Whom It May Concern:

**Re: Gladys Kagaoan, MD
Training in Nuclear Cardiology**

I am the Co-Director of the Cardiology Fellowship Training Program at the University of Connecticut, and I have directly supervised the training of Dr. Kagaoan, for the past three years during her cardiology fellowship program.

This letter will certify that **Gladys Kagaoan, MD** has satisfactorily completed six months of formal nuclear cardiology training under the auspices of the Cardiology Fellowship at our institution between July 2001 and June 2004. This training consisted of 200 hours of didactic training in radiation safety as outlined:

| | |
|--|-----------|
| Radiation physics and instrumentation | 100 hours |
| Radiation protection | 30 hours |
| Mathematics pertaining to the use and measurement of radioactivity | 20 hours |
| Radiation biology | 20 hours |
| Radiopharmaceutical chemistry | 30 hours |

During her training, she provided services for over 300 nuclear cardiology cases. In more than 30 of these cases, there was angiographic correlation. She meets the requirements as outlined in the ACC/ASNC COCATS Guidelines shown on page 13 of the 2001 Candidate Bulletin. In addition, she has achieved a level of competence sufficient to function independently as an authorized user for the medical uses authorized under NRC 35.100 and 35.200.

Please contact me if I can provide any further information.

Sincerely,


 Richard J Soucier, MD, FACC
 Co-Director of Cardiology Fellowship, University of CT
 CCNC Diplomat #1213