The
Cardiovascular
Group, P.C.

Fritz H. Andersen, M.D., F.A.C.C.
Anthony Chang, M.D., F.A.C.C., F.A.C.P.
Nicholas Cossa, M.D., F.A.C.C.
Stephen M. Day, M.D.
Richard F. Dietz, M.D., F.A.C.C.
Robert F. Herron, D.O., F.A.C.C., F.A.C.P.
Sara Kulangara, M.D.
Warren S. Levy, M.D., F.A.C.C.
Carey M. Marder, M.D., F.A.C.C.
J. Kenneth Marshall, M.D., F.A.C.C.
Francis J. McGrath, M.D., F.A.C.C.
Lawrence A. Miller, M.D., F.A.C.C.
Diane Mukherjee, M.D., F.A.C.C.
Pradeep R. Nayak, M.D., F.A.C.C.
Antonio R. Parente, M.D., F.A.C.C.
Dean M. Pollock, M.D., F.A.C.C.
Stephen P. Rosenfeld, M.D., F.A.C.C.
Anne M. Safko, M.D., F.A.C.C.
Harry Schwartz, M.D., F.A.C.C.
Stuart E. Sheifer, M.D.
Robert A. Shor, M.D., F.A.C.C.
Joseph M. Smith, M.D., Ph.D., F.A.C.C.
Mark P. Tanenbaum, M.D., F.A.C.C.

4660 Kenmore Ave., Suite 1200
Alexandria VA 22304
703-751-8111 ♥ Fax 703-751-1105

1635 N. George Mason Dr., Suite 190
Arlington VA 22205
703-524-7202 ♥ Fax 703-516-4501

611 S. Carlin Springs Rd., Suite 203
Arlington VA 22204
703-671-8200 ♥ Fax 703-379-9767

3700 Joseph Siewick Dr., Suite 102
Fairfax VA 22033
703-648-3266 ♥ Fax 703-648-3264

44055 Riverside Pkwy., Suite 200
Leesburg VA 20176
703-858-3050 ♥ Fax 703-858-3051

1830 Town Center Dr., Suite 201
Reston VA 22090
703-437-5977 ♥ Fax 703-478-2475

130 Park St. SE, Suite 100
Vienna VA 22180
703-281-1265 ♥ Fax 703-255-0571

3289 Woodburn Rd., Suite 375
Annandale VA 22003
703-573-3494 ♥ Fax 573-5353

July 18, 2008 Br. 2

Nuclear Regulatory Commission
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406

RE: The Cardiovascular Group
License Amendment
45-25533-01 03035466

To Whom It May Concern:

Please amend the above referenced license to add Rachel Berger, M.D. as authorized users to the above referenced license. Documentation in support of these physician's credentials is enclosed.

Any questions regarding this request may be directed to me at (703) 641-0500.

Sincerely,

Neil C. Smarte, C.N.M.T.
Radiation Safety Officer.

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NRC FORM 313A (AUD) (3-2007)

U.S. NUCLEAR REGULATORY COMMISSION

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: Rachel Berger, MD

State or Territory Where Licensed: Virginia

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: [signature]

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)

NRC FORM 313A (AUD) (3-2007) U.S. NUCLEAR REGULATORY COMMISSION

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	See enclosed letter New York University School of Medicine 550 1st Avenue, TCH-2, HW246 New York, NY 10016	80+	7/1/04 to 6/29/07
Radiation protection	See enclosed letter		
Mathematics pertaining to the use and measurement of radioactivity	See enclosed letter		
Chemistry of byproduct material for medical use *(not required for 35.590)*	See enclosed letter		
Radiation biology	See enclosed letter		
Total Hours of Training:			

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: + 1000 hours		
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	New York University School of Medicine 550 1st Avenue, TCH-2, HW246 New York, NY 10016	☒ Yes ☐ No	7/1/04 to 6/29/07
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	"	☒ Yes ☐ No	"

NRC FORM 313A (AUD) (3-2007) U.S. NUCLEAR REGULATORY COMMISSION

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	New York University School of Medicine 550 1st Avenue, Tech-2, HW246 New York, NY 10016	☒ Yes ☐ No	7/1/04 to 6/29/07
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	"	☒ Yes ☐ No	"
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	"	☒ Yes ☐ No	"
Administering dosages of radioactive drugs to patients or human research subjects	"	☒ Yes ☐ 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	"	☒ Yes ☐ No	"

Supervising Individual: Jennifer H. Mieres, MD, FASNC

License/Permit Number listing supervising individual as an authorized user: 75-2955-01

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.

NRC FORM 313A (AUD) (9-2007) U.S. NUCLEAR REGULATORY COMMISSION

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 Rachel Berger, MD 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
Jennifer H. Mieres, MD, FASNC		212-263-5672	2/20/08

License/Permit Number/Facility Name
75-2955-01 New York University School of Medicine

NEW YORK UNIVERSITY SCHOOL OF MEDICINE

Jennifer H. Mieres, M.D., FACC, FAHA, FASNC
Director, Nuclear Cardiology
Associate Professor of Medicine
Leon H. Charney Division of Cardiology

550 First Avenue, TCH-2, HW246
New York, NY 10016
Telephone: (212) 263-0672
Facsimile: (212)263-2908
E-mail: jennifer.mieres@med.nyu.edu

Certification Board of Nuclear Cardiology
19562 Club House Road
Montgomery Village MD 20886-3002

Dr. Rachel Berger has completed a nuclear cardiology training program that meets the requirements for Level 2 as outlined in the *ACCF/ASNC COCATS Guidelines for Training in Nuclear Cardiology, revised 2006* within an accredited fellowship program.

Dr. Berger completed Level 2 nuclear cardiology training between the dates of 7/1/2004 and 6/29/2007 .

I attest that Dr. Berger is competent to independently function as an authorized user under NRC 10 CFR 35.200 uses.

☐ The above-named applicant completed a minimum of 80 hours of classroom and laboratory training that meets the Nuclear Regulatory Commission (NRC) requirements as an INTEGRAL part of his/her fellowship/residency program.

☒ The above-named applicant completed a minimum of 80 hours of classroom and laboratory training that meets the NRC requirements external to his/her fellowship program.

☐ The above-named applicant is an Authorized User listed on a current Radioactive Materials Licence (RAM).

Sincerely,

(Signature Required)

Name of Preceptor: Jennifer H Mieres, MD, FASNC

Title/Relationship to Applicant: Director of Nuclear Cardiology NYU Medical Center

NRC/Agreement State License Number (on RAM License): 75-2955-01

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

7/18/08, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (45-25533-01)

[X] 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** 142632.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader