HEART& VASCULAR CLINIC

620 Stanton Christiana Road
Suite 203
Newark, DE 19713
(302) 338-9444
www.heartandvascular.com

February 28, 2011

MS 16
J-2

U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

03038183

Dear License Reviewer,

01 Num

Please amend our Radioactive Materials License (#07-31394-~~09~~), Heart and Vacsular Clinic – 620 Stanton Christiana Road, Suite 203, Newark, DE 19713 to reflect the following:

1. Request to add as authorized user:
   Ashish Parikh, M.D. – an authorized user (see attached documentation) for materials use 35.100, 35.200
   Dr. Parikh also passed his Certification Board of Nuclear Cardiology on February 24, 2011. Please see attached documentation.

If you have any questions, please contact Adam M. Henry at 484.366.4054.

Sincerely,

Ashish Parikh, M.D.
Owner

2-28-11

574263

NMSS/RGN1 MATERIALS-002

CERTIFICATION BOARD OF NUCLEAR CARDIOLOGY

101 LAKEFOREST BOULEVARD • SUITE 401 • GAITHERSBURG, MARYLAND 20877
TEL: +240.631.8151 • FAX: +240.631.8152 • ADMINISTRATION@CBNC.ORG •
WWW.CBNC.ORG

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For Immediate Release

February 2011

ASHISH B. PARIKH MD,FACC ACHIEVES RECERTIFICATION IN NUCLEAR CARDIOLOGY

Gaithersburg, Maryland, USA – The Certification Board of Nuclear Cardiology (CBNC), a not-for-profit corporation established to develop and administer practice-related examinations in the field of Nuclear Cardiology, is pleased to announce that **Ashish B. Parikh MD,FACC of Greenville, DE** passed the recertification examination in December 2010. Dr. Parikh is entitled to designate him/herself as "Diplomate of the Certification Board of Nuclear Cardiology".

<< Diplomate to add his/her biographical information here >>

The purposes of the CBNC Certification Program are to establish the domain of the practice of Nuclear Cardiology for certification; to assess the level of knowledge demonstrated by Nuclear Cardiology specialists in a valid manner; to encourage professional growth in, and enhance the quality of, the practice of Nuclear Cardiology; to recognize formally individuals who meet the requirements set by CBNC; and to serve the public by encouraging quality patient care in the practice of Nuclear Cardiology.

CBNC has been recognized by the Nuclear Regulatory Commission (NRC) as meeting the requirements for the specialty board certification pathway under 10 CFR Part 35, Section 35.290.

About CBNC

The Certification Board of Nuclear Cardiology, a not-for-profit corporation established in 1996, is a fully autonomous entity, independent of any other association, society, or academy. This independence allows the CBNC to maintain integrity concerning policy matters related to certification. Since 2003, CBNC has collaborated with the European Council of Nuclear Cardiology (ECNC) to offer the examination in a European venue. ECNC has representation on the CBNC's Examination Committee.

To date, 8,334 physicians have been certified in nuclear cardiology.

For further information contact:

Helen Gootinag
Program Director
Certification Board of Nuclear Cardiology
101 Lakeforest Boulevard, Suite 401
Gaithersburg MD 20887 USA
Tel: +240.631.8151 • Fax: +240.631.8152
www.cbnc.org; gootinag@cbnc.org

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NRC FORM 313A (AUD) (3-2009) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.100, 35.200, and 35.600) [10 CFR 35.190, 35.290, and 35.590]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 3/31/2012

Name of Proposed Authorized User	State or Territory Where Licensed
ASHISH PARIKH, MD	Delaware

Requested Authorization(s) *(check all that apply)*

- [x] 35.100 Uptake, dilution, and excretion studies
- [x] 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)

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(3-2009)

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	CEDARS SINAI MEDICAL CENTER - LOS ANGELES CALIFORNIA 90048 RADIATION SAFETY ACADEMY 438 N. FREDERICK AVENUE, GAITHERSBURG MD 20877	100 19.5	1995 - 1996 OCT. 2009
Radiation protection	CEDARS SINAI MEDICAL CENTER - LOS ANGELES CALIFORNIA 90048 RADIATION SAFETY ACADEMY 438 N. FREDERICK AVENUE, GAITHERSBURG MD 20877	30 21.5	1995 - 1996 OCT. 2009
Mathematics pertaining to the use and measurement of radioactivity	CEDARS SINAI MEDICAL CENTER - LOS ANGELES CALIFORNIA 90048 RADIATION SAFETY ACADEMY 438 N. FREDERICK AVENUE, GAITHERSBURG MD 20877	20 2.5	1995 - 1996 OCT. 2009
Chemistry of byproduct material for medical use *(not required for 35.590)*	CEDARS SINAI MEDICAL CENTER - LOS ANGELES CALIFORNIA 90048	30	1995 - 1996
Radiation biology	CEDARS SINAI MEDICAL CENTER - LOS ANGELES CALIFORNIA 90048 RADIATION SAFETY ACADEMY 438 N. FREDERICK AVENUE, GAITHERSBURG MD 20877	20 1.5	1995 - 1996 OCT. 2009
Total Hours of Training: 245			

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 CEDARS SINAI/DR. D. GRUBBS	**Total Hours of Experience:** 700+		
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	37-31876-01 DR. DAVID GRUBBS - DELAWARE CEDARS SINAI MEDICAL CENTER - LOS ANGELES CALIFORNIA 90048	☑ Yes ☐ No	3/10 - PRESENT 1995-1996
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	37-31076-01 DR. DAVID GRUBBS - DELAWARE CEDARS SINAI MEDICAL CENTER - LOS ANGELES CALIFORNIA 90048	☑ Yes ☐ No	3/10 - PRESENT 1995-1996

NRC FORM 313A (AUD) U.S. NUCLEAR REGULATORY COMMISSION
(3-2009)

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	37-31076-01 DR. DAVID GRUBBS - DELAWARE CEDARS SINAI MEDICAL CENTER - LOS ANGELES CALIFORNIA 90048	☑ Yes ☐ No	3/10 - PRESENT 1995-1996
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	37-31076-01 DR. DAVID GRUBBS - DELAWARE 07-31374-01 HEART & VASC. CLINIC - DE CEDARS SINAI MEDICAL CENTER	☑ Yes ☐ No	3/10 - PRESENT 1995-1996
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	37-31076-01 DR. DAVID GRUBBS - DELAWARE 07-31374-01 HEART & VASC. CLINIC - DE CEDARS SINAI MEDICAL CENTER	☑ Yes ☐ No	3/10 - PRESENT 1995-1996
Administering dosages of radioactive drugs to patients or human research subjects	37-31076-01 DR. DAVID GRUBBS - DELAWARE 07-31374-01 HEART & VASC. CLINIC - DE CEDARS SINAI MEDICAL CENTER	☑ Yes ☐ No	3/10 - PRESENT 1995-1996
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	CEDARS SINAI MEDICAL CENTER - LOS ANGELES CALIFORNIA 90048	☑ Yes ☐ No	1995-1996

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
DR. DAVID GRUBBS DR. GERMANO DR. BERMAN	37-31076-01

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 35.690 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) U.S. NUCLEAR REGULATORY COMMISSION
(3-2009)

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 attesting to the individual's "general clinical competency."

First Section
Check one of the following for each use requested:

For 35.190

Board Certification

☑ I attest that Ashish Parikh (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 ASHISH PARIKH, MD (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 35.290

Board Certification

☑ I attest that Ashish Parikh (Name of Proposed Authorized User) has satisfactorily completed the requirements in 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 ASHISH PARIKH, MD (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 35.290(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
DR. DAVID GRUBBS, MD			2/25/11

License/Permit Number/Facility Name
37-31076-01 - DR. DAVID GRUBBS