

QUALITY CARDIOVASCULAR CARE, LLC

1389 West Main Street
Tower One, Suite 106
Waterbury, CT 06708
203-591-1998
Fax 203-591-8163

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2009 APR 15 PM 12:26

RECEIVED
REGION 1

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

April 12, 2009

03036684

RE: License No. **06-30966-01**

To Whom It May Concern:

I would like to add myself as an authorized user to the Materials License (No. 06-30966-01) for Quality Cardiovascular Care, LLC.

Enclosed please find Form 313A (AUD) and a copy of my board certification (certificate number 6602) issued by the *Certification Board of Nuclear Cardiology*.

The following is a summary of my continuing education and experience related to uses 35.100 and 35.200:

Course Title	Date	Sponsor	Location	Credits
Basic Radioisotope Handling Course	November 2005	Consultants in Nuclear Medicine	Chicago, IL	100
Nuclear Cardiology Board Exam Preparation Course	July 2008	American Society of Nuclear Cardiology	Chicago, IL	15.75
Nuclear Cardiology Self-Assessment Program	September 2008	American Society of Nuclear Cardiology	Internet-Based	7

I thank you in advance for your attention to this matter.

Sincerely,



Mark Rosenberg, MD
Managing Partner
Quality Cardiovascular Care, LLC
1389 West Main Street
Tower One, Suite 106,
Waterbury, CT 06708
Voice: 203-591-1998
Fax: 203-591-8163

143649

NMSS/RCN1 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. 3150-0123
EXPIRES: 10/31/2008

Name of Proposed Authorized User

Mark S. Rosenberg

State or Territory Where Licensed

Connecticut

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	Clock	Dates of
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use (not required for 35.590)			
Radiation biology			
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:	
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		<input 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		<input 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		Dates of Experience
Calculating, measuring, and safely preparing patient or human research subject dosages		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Administering dosages of radioactive drugs to patients or human research subjects		<input 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		<input 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

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)

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 Mark S. Rosenberg 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 Mark S. 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 _____ 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>LILY SINGH AVIRANON, MD</u>	Signature <u>Lily Singha</u>	Telephone Number <u>203-591-</u>	Date <u>3/30/09</u>
License/Permit Number/Facility Name <u>06-30966-01</u>		<u>Quality Cardiovascular Care, LLC</u>	

Certification Board of Nuclear Cardiology

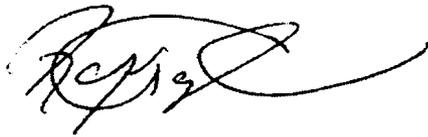
Incorporated 1996

Certifies that

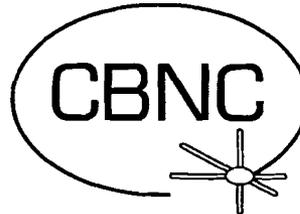
Mark S. Rosenberg, MD

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD
FOR PHYSICIANS TRAINED IN THE UNITED STATES
AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION,
IS HEREBY DESIGNATED
A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF
NUCLEAR CARDIOLOGY

FOR THE PERIOD 2008 - 2018



President



Secretary



CERTIFICATE NUMBER: 6602

*Consultants in Nuclear Medicine
2910 W. Estes Avenue
Chicago, IL 60645*

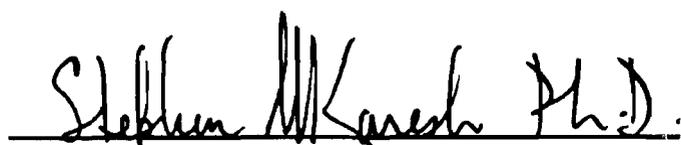
This certificate verifies that on November 6, 2005

*Dr. Mark Rosenberg
SS # 124-36-6302*

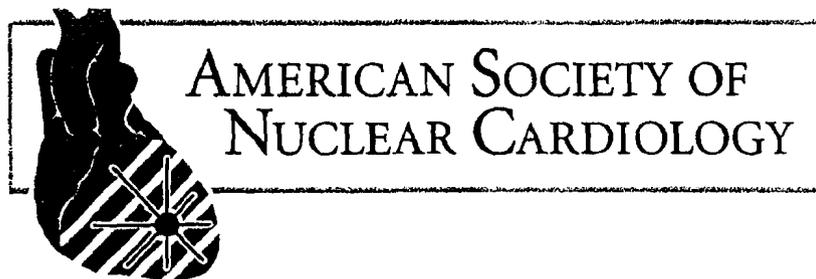
*completed 100 hours of the
Basic Radioisotope Handling Course,
covering the topics of*

*Radiopharmacy, Radiation Biology, Physics and
Instrumentation, Radiation Protection, and the
Mathematics Associated with Radioactivity*

*and received a passing grade. This course is designed to
qualify a physician for the Nuclear Cardiology Board
Examination and to qualify a physician as an authorized
user of radiopharmaceuticals, generators, and reagent kit
and meets all requirements set forth by the US Nuclear
Regulatory Commission and all Agreement States as
outlined in the Code of Federal Regulations.*



Course Director



This Statement is for Enrollee's Records

Mark Rosenberg, MD

attended a continuing medical education program entitled

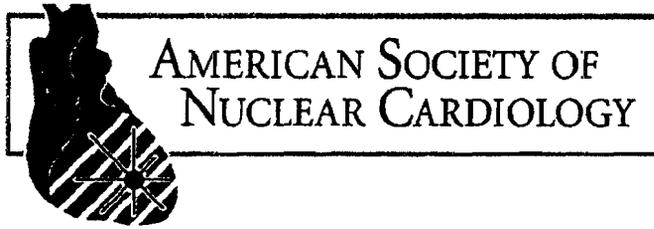
**2008 Nuclear Cardiology Board Exam Preparation Course
from July 19-20, 2008 in Chicago**

The American Society of Nuclear Cardiology is accredited
by the Accreditation Council for Continuing Medical Education to
sponsor continuing medical education for physicians.

The American Society of Nuclear Cardiology designates this
educational activity for a maximum of 15.75 AMA *PRA Category 1 Credit(s)*™.
Physicians **should only** claim credit commensurate with the
extent of their participation in the activity.

A handwritten signature in black ink, appearing to read "James A. Arrighi".

James A. Arrighi, MD
Chairman, ASNC Education Committee



American Society of Nuclear Cardiology

4550 Montgomery Ave., Suite 780 North
(301)215-7575
info@asnc.org

Bethesda, Maryland 20814-3304
FAX (301) 215-7113
www.asnc.org

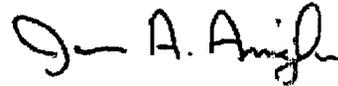
This Statement is for Enrollee's Records

Mark S. Rosenberg, MD

completed a continuing medical education activity entitled
"Nuclear Cardiology Knowledge Self Assessment Program" on
Saturday, September 13, 2008

The American Society of Nuclear Cardiology is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.

The American Society of Nuclear Cardiology designates this educational activity for a maximum of **7AMA PRA Category 1 Credit(s)TM**. Physicians should only claim credit commensurate with the extent of their participation in the activity.



James A. Arrighi, MD
Chairman, ASNC Education Committee

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MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee

1. Quality Cardiovascular Care, LLC

2. 1389 West Main Street
Tower I, Suite 106
Waterbury, Connecticut

In accordance with letter dated
June 12, 2007

3. License number 06-30966-01 is amended in its entirety to read as follows:

4. Expiration date November 30, 2014

5. Docket No. 030-36684
Reference No.

6. Byproduct, source, and/or special nuclear material

7. Chemical and/or physical form

8. Maximum amount that licensee may possess at any one time under this license

A. Any byproduct material permitted by 10 CFR 35.100

A. Any

A. As needed

B. Any byproduct material permitted by 10 CFR 35.200

B. Any

B. As needed

9. Authorized use:

A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.

B. Any imaging and localization study permitted by 10 CFR 35.200.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 1389 West Main Street, Waterbury, Connecticut.

11. Licensed material is only authorized for use by, or under the supervision of:

A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
06-30966-01Docket or Reference Number
030-36684

Amendment No. 2

B. The following individuals are authorized users for medical use as indicated:

<u>Authorized Users</u>	<u>Material and Use</u>
Lily Singhaviranon, M.D.	35.100, 35.200

12. The Radiation Safety Officer for this license is Lily Singhaviranon, M.D.
13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Letter dated September 30, 2004 [ML042820377]
 B. Facsimile dated November 5, 2004 [ML043200749]

For the U.S. Nuclear Regulatory Commission

Date June 26, 2007

By



Stephen Hammann
 Commercial and R&D Branch
 Division of Nuclear Materials Safety
 Region I
 King of Prussia, Pennsylvania 19406

Tuesday, June 26, 2007 9:51:32 AM

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

4/12/2009, and to inform you that the initial processing which includes an administrative review has been performed.

Approved. 06-30966-01
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 143649.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.