

HCI

Heart Care Imaging, Inc.

"Your Link to the World of Imaging"

MS16
J-4

45-30909-01

03036560

FACSIMILE

To: <u>Lizette</u>	Date: <u>18 May 07</u>
From: <u>Jackie Graham</u>	
Telephone: _____	Pages: <u>9</u>
Fax: <u>610.337.5269</u>	
Re: <u>Control Number: 140168</u>	

If you do not receive all the pages, please call (561) 746-6125.

Thank you!

[REDACTED]

[REDACTED]

725 North A1A, Suite B-105, Jupiter, FL 33477

140168

NMSS/RGN1 MATERIALS-002

ROGAN & O'BRIEN
CARDIOVASCULAR ASSOCIATES, P.C.
3299 WOODBURN ROAD, SUITE 200
ANNANDALE, VIRGINIA 22003

John T. O'Brien, M.D., F.A.C.C.
Kevin M. Rogan, M.D., F.A.C.C.
Jun Anthony Quion, M.D., F.A.C.C.

Tel: 703-573-0740
Tel: 703-698-6255
Fax: 703-207-8561

17 May 2007

Dear Colleague,

I am an Authorized User and Radiation Safety Officer listed on the Radioactive Materials License of Rogan & O'Brien Cardiovascular Associates, P.C., license number 45-30909-01. In addition I am an Authorized User listed on the Radioactive Materials License of Woodbridge Cardiovascular Center, P.L.C., license number 45-30953-01. This letter is to attest that Kevin Rogan, M.D., has successfully completed all training requirements set forth by the Nuclear Regulatory Commission section 35.290, paragraph c (1) from August 2004 to present, May 2007. I attest that he has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under the NRC guidelines 35.200.

Dr. Kevin Rogan has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. This training and experience included a minimum of the following:

- A. 1) 80 hours of classroom and laboratory training in the following areas:
- a) Radiation physics and instrumentation;
 - b) Radiation protection;
 - c) Mathematics pertaining to the use and measurement of radioactivity;
 - d) Chemistry of byproduct material for medical use;
 - e) Radiation biology
 - f) Generator Elution
- 2) Work experience, under the supervision of authorized user Jun Anthony Quion, MD, which meet the requirements in §§ 35.290, involving:
- a) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - b) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - c) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;



- d) Calculating, measuring, and safely preparing patient or human research subject dosages;
- e) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
- f) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
- g) Administering dosages of radioactive drugs to patients or human research subjects; and
- h) 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

I certify that Dr. Kevin Rogan has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under the NRC regulations CFR 35.290.

Preceptor Signature :  _____

Date : 17 May 2007 _____

NRC FORM 813A (REV. 11-2006) 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 35.100, 35.200, and 35.500)		APPROVED BY OIR: NO. 3750-012 EXPIRES: 10/31/2008	
Name of Proposed Authorized User Kevin Rogan, MD		State or Territory Where Licensed Virginia	
Requested Authorization(s) (check all that apply)			
<input checked="" type="checkbox"/> 35.100 Uptake, dilution, and excretion studies <input checked="" type="checkbox"/> 35.200 Imaging and localization studies <input type="checkbox"/> 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.			
<input type="checkbox"/> 1. <u>Board Certification</u>			
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, stop to and complete Part II Preceptor Attestation.			
<input type="checkbox"/> 2. <u>Current 35.200 Authorized User Seeking Additional 35.200 Authorization</u>			
a. Authorized user on Materials License _____ meeting 10 CFR 35.200 or equivalent Agreement State requirements seeking authorization for 35.200. 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, assaying and testing the eluate for radiochemical 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).			
<input type="checkbox"/> 35.200 <input type="checkbox"/> 35.200 + generator experience in 32.280(a)(1)(B)(G)			

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			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use (not required for 35.500)			
Radiation biology			

Total Hours of Training:

**b. Supervised Work Experience (completion of this table is not required for 35.500).
 (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
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	Rogan O'Brien Cardiovascular Associates, PC NRC License # 45-30909-01	100	08/04 to 08/06
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	NRC License # 45-30909-01	100	08/04 to 08/06
Calculating, measuring, and safely preparing patient or human research subject dosages	NRC License # 45-30909-01	100	08/04 to 08/06

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	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Rogan ? O'Brien Cardiovascular Associates, P.C. NRC License 45-30909-01	100	08/04 to 05/06
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	NRC License 45-30909-01	100	08/04 to 05/06
Administering dosages of radioactive drugs to patients or human research subjects	NRC License 45-30909-01	150	08/04 to 05/06
Using generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radiochemical purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			
Total Hours of Experience: 650			
Supervising Individual Jon Anthony V. Quinn, MD		License/Permit Number listing supervising individual as an authorized user NRC # 45-30909-01	
Supervisor meets the requirements below, or equivalent Agreement State requirements (check one).			
<input checked="" type="checkbox"/> 35.190 <input checked="" type="checkbox"/> 35.290 <input type="checkbox"/> 35.290 <input type="checkbox"/> 35.330 + generator experience in 35.290 (X)(U)(C)			

c. For 35.290 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, stop to and complete Part II Preceptor Attestation.

ROGAN OBRLEN

HCI
 HCI

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	Check Hours	Dates of Training
Radon physics and instrumentation			
Radon protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use (not required for 35.590)			
Radon 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.)

Description of Experience	Location of Experience/Plant or Firm Number of Facility	Check Hours	Dates of Experience
Ordering, receiving, and unloading radioactive materials safely and performing the related radiation surveys	Co Scan Plus NRC # 47-25351-01	6	7/16/06 to 8/23/06
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Co Scan Plus NRC # 47-25351-01	6	7/26/06 to 8/23/06
Calculating, measuring, and safely preparing patient or human research subject dosages	Co Scan Plus NRC # 47-25351-01	9	07/26/06 to 08/23/06

NRC Form 30A (AUG 1999) 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	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	NRC# 47-25351-01	6	07/26/06 to 08/23/06
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	NRC# 47-25351-01	6	07/26/06 to 08/23/06
Administering dosages of radioactive drugs to patients or human research subjects	NRC# 47-25351-01	6	07/26/06 to 08/23/06
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radioisotopic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs	Mallinckrodt Nuclear Pharmacy Toledo, OH NRC# 47-25351-01	20	07/26/06 to 08/23/06

Total Hours of Experience: **56**

Supervising Individual: **Steven Walter, MD**
 License/Permit Number listing supervising individual as an authorized user: **NRC# 47-25351-01**

Supervisor meets the requirements below, or equivalent Agreement State requirements (check one).
 35.190 35.290 35.390 35.390 + generator experience in 35.280(c)(1)(i)(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 35.980)

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 Kevin Rogan, MD 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 Kevin Rogan, MD has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

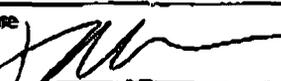
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

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
- 35.980 + generator experience

Name of Preceptor <u>Jon Anthony V. Quinn, MD</u>	Signature 	Telephone Number <u>703-573-0140</u>	Date <u>17 May 2007</u>
License/Permit Number/Facility Name <u>NRC # 45-30909-01</u>		Preceptor's Name <u>Rogan & O'Brien Cardiovascular Associates, P.C.</u>	