

Heart Care Imaging Inc.
3301 New Mexico Avenue, NW, Suite 316
Washington, D.C.

Br. 2

October 3, 2008

Licensing Assistance Section
Nuclear Medicine Safety Branch
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

RECEIVED
REGION I
2008 NOV 17 PM 12:20

RE: Heart Care Imaging, Inc.
License Number: 08-31211-01 03037382
Amendment Application

Dear License Reviewer:

Please amend our byproduct material license to add Ramin Oskoui, M.D. as an authorized user for all procedures and material listed in 10 CFR 35.100 and 10 CFR 35.200. Documentation attesting to his training and experience are enclosed in the attachment section of this correspondence.

If you have additional questions, please contact Michael W. Lairmore or myself. Mr. Lairmore may be contacted at (201) 693-2277.

We thank you in advance for your assistance with this licensing action.

Sincerely,



Administrative Representative
Cesar Milla

143015
NRS/RGNI MATERIALS-002

Attachment A

NRC FORM 313A (AUD)
(10-2007)

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. 3160-0120
EXPIRES: 10/31/2008

Name of Proposed Authorized User

State or Territory Where Licensed

Ramin Oskoui

Washington, D.C.

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)

NRC FORM 313A (AUD)
(10-2007)

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	Corscan and the University of Toledo, Authorized User Classroom and Laboratory and Training Program Online	16	Completion date: 8/20/08
Radiation protection	Corscan and the University of Toledo, Authorized User Classroom and Laboratory and Training Program Online	16	Completion date: 8/20/08
Mathematics pertaining to the use and measurement of radioactivity	Corscan and the University of Toledo, Authorized User Classroom and Laboratory and Training Program Online	16	Completion date: 8/20/08
Chemistry of byproduct material for medical use (not required for 35.590)	Corscan and the University of Toledo, Authorized User Classroom and Laboratory and Training Program Online	16	Completion date: 8/20/08
Radiation biology	Corscan and the University of Toledo, Authorized User Classroom and Laboratory and Training Program Online	16	Completion date: 8/20/08
Total Hours of Training: 80			

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:	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	Steven Walter, M.D. Authorized User, NRC # 37-31143-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Completion date: 08/13/08	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Steven Walter, M.D. Authorized User, NRC # 37-31143-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Completion date: 08/13/08	

NRC FORM 313A (AUD)
(10-2007)

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	Steven Walter, M.D. Authorized User, NRC # 37-31143-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Completion date: 08/13/08
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Steven Walter, M.D. Authorized User, NRC # 37-31143-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Completion date: 08/13/08
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Steven Walter, M.D. Authorized User, NRC # 37-31143-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Completion date: 08/13/08
Administering dosages of radioactive drugs to patients or human research subjects	Steven Walter, M.D. Authorized User, NRC # 37-31143-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Completion date: 08/13/08
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	Steven Walter, M.D. Authorized User, NRC # 37-31143-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Completion date: 08/13/08

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Steven W. Walter, M.D.	NRC # 37-31143-01

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)
(10-2007)

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	Corscan and the University of Toledo, Authorized User Classroom and Laboratory and Training Program Online	16	Completion date: 8/20/08
Radiation protection	Corscan and the University of Toledo, Authorized User Classroom and Laboratory and Training Program Online	16	Completion date: 8/20/08
Mathematics pertaining to the use and measurement of radioactivity	Corscan and the University of Toledo, Authorized User Classroom and Laboratory and Training Program Online	16	Completion date: 8/20/08
Chemistry of byproduct material for medical use (not required for 35.590)	Corscan and the University of Toledo, Authorized User Classroom and Laboratory and Training Program Online	16	Completion date: 8/20/08
Radiation biology	Corscan and the University of Toledo, Authorized User Classroom and Laboratory and Training Program Online	16	Completion date: 8/20/08
Total Hours of Training: 80			

**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:	650	
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	Esma Akin, M.D., Authorized User NRC # 08-31211-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	9/1/07 -	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Esma Akin, M.D., Authorized User NRC # 08-31211-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	9/1/07	

NRC FORM 313A (AUD)
(10-2007)

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	Esma Akin, M.D., Authorized User NRC # 08-31211-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	9/1/07 -
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Esma Akin, M.D., Authorized User NRC # 08-31211-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	9/1/07 -
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Esma Akin, M.D., Authorized User NRC # 08-31211-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	9/1/07 -
Administering dosages of radioactive drugs to patients or human research subjects	Esma Akin, M.D., Authorized User NRC # 08-31211-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	9/1/07 -
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 Esma Akin, M.D.	License/Permit Number listing supervising individual as an authorized user NRC # 08-31211-01
--	--

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.

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 _____ 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 Ramin Oskoui, M.D. 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 Ramin Oskoui, M.D. has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

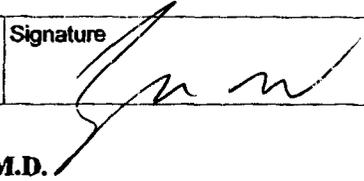
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

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
Esmā Akin, M.D.		2027155212	10/6/08
License/Permit Number/Facility Name			
NRC # 08-31211-01/ Ramin Oskoui, M.D.			

Certificate of Completion *Authorized User Classroom and Laboratory* *Training Program*

Ramin Oskoui, M.D.

has successfully completed 80 hours of classroom and laboratory training that included:

- Radiation physics and instrumentation
- Radiation protection
- Mathematics pertaining to the use and measurement of radioactivity
- Chemistry of byproduct material for medical use
- Radiation biology, Generator elution for ¹⁰⁹Cd/²⁰³Pb (G) and
- Review of regulations regarding the medical use of radionuclides

Corscan
 The Nuclear Imaging Company
 www.corscanplus.com

Steven W. Walter, MD

August 13, 2008

Steven W. Walter, MD
 Medical Director
 Corscan Medical, LLC
 13752
 01052-125

Date

UNIVERSITY OF TOLEDO

Center for Continuing Medical Education

This certifies that

Ramin Oskoui, M.D.

has participated in the educational activity

Authorized User Classroom and Laboratory Training Program Online

on

8/20/2008

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of the University of Toledo and Corscan. The University of Toledo and St. Vincent Mercy Medical Center are accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The University of Toledo and St. Vincent Mercy Medical Center awards this educational activity
55 AMA PRA Category 1 Credits™

Actual credits awarded for this educational activity: 55



William J. Davis, D.D.S., M.S.
Associate Dean
Continuing Medical Education

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

10/3/08, and to inform you that the initial processing which includes an administrative review has been performed.

- Amendment (08-31211-01) 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** 143015.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.