

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

Br 2

September 25, 2009

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
2009 OCT -9 PM 12:19

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

Dear License Reviewer:

Please amend our byproduct material license to add Russell David Anderson, M.D. as an authorized user for all materials and procedures approved on our current license. Dr. Anderson is board certified by the Certification Board of Nuclear Cardiology. A copy of his certificate has been enclosed within Attachment A. In addition, an attestation statement has been completed by his preceptor authorized user and attached to this submission. Please refer to Attachment A for details.

If you have additional questions, please contact me. I may be reached at (201) 693-2277.

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

Sincerely,

Michael W. Lairmore, M.S.
Michael W. Lairmore, M.S.
Radiation Safety Officer

144230
NRC/RCNI MATER.ALS-002

Attachment A

**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: 3/31/2012

Name of Proposed Authorized User

R. David Anderson, M.D.

State or Territory Where Licensed

Florida

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 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: 9/22/08
Radiation protection	Corscan and the University of Toledo, Authorized User Classroom and Laboratory and Training Program Online	16	Completion Date: 9/22/08
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: 9/22/08
Chemistry of byproduct material for medical use (<i>not required for 35.590</i>)	Corscan and the University of Toledo, Authorized User Classroom and Laboratory and Training Program Online	16	Completion Date: 9/22/08
Radiation biology	Corscan and the University of Toledo, Authorized User Classroom and Laboratory and Training Program Online	16	Completion Date: 9/22/08
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: 09/20/08
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: 09/20/08

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: 09/20/08
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: 09/20/08
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: 09/20/08
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: 09/20/08
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: 09/20/08

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

Signature



Telephone Number
(352) 273-9075

Date

9/21/09

License/Permit Number/Facility Name

State of Fla Nuclear Med License # 31-3/University of Florida/R. David Anderson, M.D.

Certificate of Completion
Authorized User Classroom and Laboratory
Training Program

R. David Anderson, 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 10CFR35.290(ii) (G) and

Review of regulations regarding the medical use of radioisotopes.

Corscan

The Nuclear Imaging Company
www.corscanplus.com

Steven W. Walter, MD

Steven W. Walter, MD
Program Director
910 528 6251

Authorized User NRC No. 07-31237-01
NC RAM 053-1108-1

September 24, 2008

Date

Corscan

Steven W. Walter, MD

103 Grendon Place

Cary, NC 27519

910-528-6251

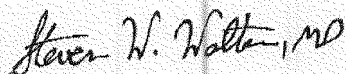
September 23, 2008

To whom it may concern:

R. David Anderson has completed our 55 hour online CME requirement and the hard copy certificate is pending from the University of Toledo Medical Center.

Feel free to contact me at 910-528-6251 or email at swalter@corscanplus.com.

Sincerely,

A handwritten signature in black ink that reads "Steven W. Walter, MD". The signature is written in a cursive, flowing style.

Steven W. Walter, MD

Corscan

General Manager and CEO

UNIVERSITY OF TOLEDO

Center for Continuing Medical Education

This certifies that

R. David Anderson, M.D.

has participated in the educational activity

Authorized User Classroom and Laboratory Training Program Online

on

9/22/2008

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.TM

Actual credits awarded for this educational activity: 55

William J. Davis

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

Certification Board of Nuclear Cardiology

Incorporated 1996

Certifies that

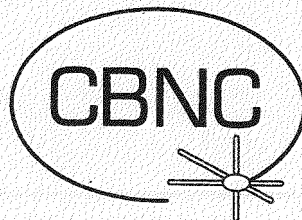
Russell David Anderson, MD

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

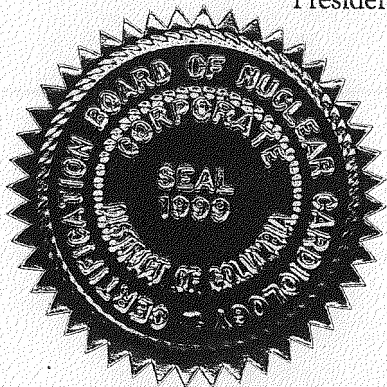
FOR THE PERIOD 2008 - 2018



President



Secretary



CERTIFICATE NUMBER: 5937

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

9/25/09, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amendment C08-31211-01
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 144230.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

Sincerely,
Licensing Assistance Team Leader