

Heart Care Imaging, Inc.  
c/o Ramin Oskoui, M.D.  
3301 New Mexico Avenue, NW, Suite 316  
Washington, D.C. 20016

*NMSB2*

**FEDERAL EXPRESS**

April 12, 2007

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

*03037382*

Re: **Heart Care Imaging, Inc.**  
**License Number: 08-31211-01**  
**Amendment Application**

Dear License Reviewer:

Please amend our byproduct material license to add Lindsey White, M.D. as an authorized user for all procedures and material listed on the byproduct material license. 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. Larimore or myself. Mr. Larimore may be contacted at (201) 693-2277.

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

Sincerely,



Robert J. Stille  
President  
Heart Care Imaging, Inc.  
(561) 746-6125

Encl:

RECEIVED  
REGION 1  
2007 APR 19 AM 10:32

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NMSS/RGN1 MATERIALS-002

**Attachment A**

**MEDICAL USE TRAINING AND EXPERIENCE  
AND PRECEPTOR ATTESTATION**

**PART I – TRAINING AND EXPERIENCE**

**Note:** Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulation (10 CFR Part 35)

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

Lindsey White, M.D.



2. For Physicians, Podiatrists, Dentists, Pharmacists – State or Territory Where Licensed

State of North Carolina

**3. CERTIFICATION**

- a. Provide a copy of the board certification. (Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(a); continue if applying under other subparts.)
- b. Provide documentation in appropriate items 4 through 10 of training or clinical case work required by 35.50(e); 35.51(c); 35.290(c)(1)(ii)(G) for AU seeking 35.200 authorization; 35.390(b)(1)(ii)(G); 35.396(d)(1) and 35.396(d)(2); 35.590(c); or 35.690(c).
- c. Provide completed Part II Preceptor Attestation, Items 11a through 11d.  
Stop here after completing items 3a, 3b, and 3c when using board certification to meet 10 CFR Part 35 training and experience requirements.

**4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO), AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICISTS (AMP), OR AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS**

- a. Provide a copy of the license or broadscope permit listing the current authorization **and** (b) or (c)
- b. Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to meet requirements for: RSO in 35.50(c)(2) or 35.50(e); or AU in 35.290(c)(1)(ii)(G) or 35.390(b)(1)(ii)(G) or 35.590(c) or 35.690(c); or AMP under 35.51(c).
- c. Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).

**5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)**

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	CorScan/Authorized User Classroom and Laboratory Training Program. Toledo, OH. NRC #47-25351-01	20 hours	Completion Date: October 3, 2006
Radiation Protection	CorScan (Please see Certificate)	20 hours	Completion Date: October 3, 2006
Mathematics Pertaining to the Use and Measurement of Radioactivity	CorScan	10 hours	Completion Date: October 3, 2006
Radiation Biology	CorScan	20 hours	Completion Date: October 3, 2006
Chemistry of Byproduct Material for Medical Use	CorScan	10 hours	Completion Date: October 3, 2006
OTHER			

**MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**6a. WORK OR PRACTICAL EXPERIENCE WITH RADIATION**

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
Dedicated Nuclear Cardiology supervised training experience.	Agnieszka J. Silbert, M.D.	Eastern Carolina Cardiovascular License#070-1282-1 NC	1000 hours
Ordering, receiving, unpacking radioactive materials safely and performing related radiation surveys	Steven Walter, M.D./Authorized User CorScan training program	NRC # 47-25351-01	10 hours
Calibrating instruments and performing quality control procedures used to determine the activity of doses and performing checks with survey meters	Steven Walter, M.D./Authorized User CorScan training program	NRC # 47-25351-01	20 hours
Calculating, measuring and safely preparing human subject doses	Steven Walter, M.D./Authorized User CorScan training program	NRC # 47-25351-01	15 hours
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material.	Steven Walter, M.D./Authorized User CorScan training program	NRC # 47-25351-01	10 hours
Using procedures to safely contain spilled radioactive material and using proper decontamination procedures	Steven Walter, M.D./Authorized User CorScan training program	NRC # 47-25351-01	10 hours
Administering dosages of radioactive drugs to patients of human research subjects	Steven Walter, M.D./Authorized User CorScan training program	NRC # 47-25351-01	10 hours
Generator Elution systems: 10CFR35.290(ii) (G) preparing of radioactive drugs for imaging, measuring and testing eluate.	Steven Walter, M.D./Authorized User CorScan training program	Mallincrodt Nuclear Pharmacy, Toledo, OH NRC # 47-25351-01	5 hours

**6b. SUPERVISED CLINICAL CASE EXPERIENCE (describe experience elements in 6a)**

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
Tc99m	Cardiac Imaging	200	Agnieszka J. Silbert, M.D.	NC 070-1282-1, NC	3/21/05-3/21/07

**MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**6c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), or 35.690(c)**

Training Element	Type of Training *	Location and Dates

\* Types of training may include supervised (complete item 10 for 35.50(e), 35.51(c), and 35.690(c)), didactic, or vendor training.

**7. FORMAL TRAINING Physicians (for uses under 35.400 and 35.600) and Medical Physicists**

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Number	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)

**8. RADIATION SAFETY OFFICER (RSO) – ONE-YEAR FULL-TIME EXPERIENCE**

- YES Completed 1 year of full-time radiation safety experience (in areas identified in item 6a) under supervision.
- N/A of \_\_\_\_\_ the RSO for License No. \_\_\_\_\_

**9. MEDICAL PHYSICIST – ONE-YEAR FULL-TIME TRAINING/WORK EXPERIENCE**

- YES Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics (35.961) or medical physics (35.51) under the supervision of \_\_\_\_\_
- N/A who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51);

**and**

- YES Completed 1 year of full-time work experience (at location providing radiation therapy services described and for topics identified in item 6a) for (specify use or device) \_\_\_\_\_
- N/A under the supervision of \_\_\_\_\_ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device) \_\_\_\_\_

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

10. SUPERVISING INDIVIDUAL – IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet requirements in 10 CFR Part 35, provide the following information for each) :

A. Name of Supervisor

Agnieszka J. Silbert, M.D.

B. Supervisor is:

Authorized User

Authorized Medical Physicist

Radiation Safety Officer

Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 35.190, 35.290, 35.50

for medical uses in Part 35, Section(s) 35.100, 35.200

D. Address

1134 North Road Street, Building 9  
Elizabeth City, NC 27909

E. Materials License Number

070-1282-1 (North Carolina)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet training requirements in 35.590 or Part 35, Subpart J (except 35.980).

I attest the individual named in Item 1:

11a.

has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 35.100, 35.200, as documented in section(s) 6a, 6b of this form.

11b. Select one

meets the requirements in  35.50(e)  35.51(c)  35.390(b)(1)(ii)(G)  35.690(c) for

N/A types of use, as documented in section(s) of this form.

11c.

has achieved a level of competency sufficient to independently operate a nuclear pharmacy (for 35.980); **OR**

has achieved a level of competency sufficient to function independently as an authorized User for 35.100, 35.200 uses (or units); **OR**

has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee ; **OR**

N/A

11d.

I am an Authorized Nuclear Pharmacist; **OR**  I am a Radiation Safety Officer; **OR**

I meet the requirements of 35.190, 35.290 section(s) of 10 CFR Part 35

or equivalent Agreement State requirements to be a preceptor  AU or  AMP

for the following byproduct material uses (or units): Any byproduct material permitted in 35.100, 35.200

A. Address

1134 North Road Street, Building 9  
Elizabeth City, nC 27909

B. Materials License Number

070-1282-1 (North Carolina)

C. NAME OF PRECEPTOR (print clearly)

AGNIESZKA J. SILBERT

D. SIGNATURE – PRECEPTOR



E. DATE

03.29.07



January 20, 2005

Candidate Number: 112532

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[www.abim.org](http://www.abim.org)

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A Member Board of the  
American Board of  
Medical Specialties (ABMS)

Dr. Lindsey Lee White  
Attention: Kathy Harvey  
Building 9  
1134 North Road Street  
Elizabeth City, NC 27909-3365

Dear Dr. White:

Congratulations! The Board is pleased to inform you that you passed the November 2004 Cardiovascular Disease Examination and are now certified as a Diplomate in Cardiovascular Disease. Your certification will remain valid through the year 2014.

The following information regarding your certification is attached:

- Score Report
- Description of the Score Report
- Form to order your Certificate(s)

The Board's Web site <[www.abim.org](http://www.abim.org)> includes a page to verify certification status and information about the ABIM and its activities. In 10 days, the ABIM verification of certification web page will be updated to indicate that you are certified.

To ensure that you receive timely information from the Board about maintaining your certification, please notify us of any changes in contact information, including an e-mail address. You can update contact information online through the ABIM Web site.

Your name will be provided to the American Board of Medical Specialties for listing in *The Official ABMS Directory of Board Certified Medical Specialists*. You will receive a form from the ABMS, the publisher of the directory, soliciting the information to appear in your listing.

To maintain your certification beyond its 10-year limit you must complete the ABIM Maintenance of Certification program, Continuous Professional Development (CPD). Details about the CPD program can be found on the ABIM website, and the Board will inform you by mail about your CPD status annually.

The Board wishes you continued success.

Most sincerely,

F. Daniel Duffy, M.D.

# UNIVERSITY OF TOLEDO

## Center for Continuing Medical Education

*This certifies that*

**Lindsey White, M.D.**

*has participated in the educational activity*

**Authorized User Classroom and Laboratory Training Program Online**

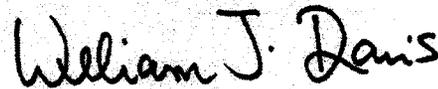
*on*

**October 4, 2006**

The University of Toledo and St. Vincent Mercy Medical Center are accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians.

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

Actual credits awarded for this educational activity: 55



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

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

*Lindsey White, 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](http://www.corscanplus.com)

*Steven W. Walter, MD*

Steven W. Walter, MD  
Program Director  
General Manager and CEO  
Corcan  
910 528 6251  
Authorized User and RSO NRC No. 47-25351-01

October 3, 2006

Date

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

4/12/2007, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 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

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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** 140406.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.