



Tara L. Weidner  
Health Physicist/Medical Branch  
United States Nuclear Regulatory Commission  
Region I  
475 Allendale Road  
King of Prussia, PA 19406-1415

Br. 1

September 12, 2011

RE: NRC license # 37-30120-01

03033422

Dear Ms. Weidner:

In our last conversation regarding the addition of Thomas Komorowski, M.D. to our license as an authorized user, 35.200; you had stated he would need NRC Form 313 (AUD) completed in addition to his preceptor paperwork and hours of cardiovascular fellowship and imaging training, both clinical and didactic. As you will see per the attachment, this has been completed in its entirety.

Therefore, please amend our Nuclear Regulatory Materials License (37-30120-01) to reflect the inclusion of an additional authorized user, 35.200; In vitro studies, for Thomas Komorowski, M.D. Attached you will find the documentation as described above.

Please contact me at your earliest convenience with any questions.

Thank you for your prompt attention in this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Lon P. Wilson", written in a cursive style.

Lon P Wilson, CNMT  
President - Nuclear Operations  
Radiation Safety Officer

CDL Nuclear Technologies, Inc.  
6400 Brooktree Court, Wexford PA 15090  
724 - 933 - 5570

REC'D IN LAT

9/14/11

575994  
NMSS/RGN1 MATERIALS-002



Division of Nuclear Medicine  
560 First Avenue, New York, NY 10016  
Phone: (212) 263-7410  
Fax: (212) 263-7519

July 18, 2005

To Whom it May Concern;

This letter is to affirm that Dr. Thomas W. Komorowski gained clinical experience at our institution in nuclear cardiology. The preceptorship began 7/1/2000 and continued through 6/30/2003. During this period Dr Thomas W. Komorowski actively participated in the following number of procedures:

- 600 Stress myocardial perfusion procedures
- 600 Rest myocardial perfusion procedures
- 100 Myocardial viability procedures
- 700 Ejection fraction calculation and wall motion evaluation procedures

During this time Dr. Thomas W. Komorowski also acquired expertise in health physics, radiopharmaceutical preparation, technical and administrative procedures of our facility, as well as general operations as stipulated by our license conditions. Dr. Thomas W. Komorowski also gained experience in preparation of radiopharmaceutical kits during this period, and eluted <sup>99m</sup>Tc/<sup>99</sup>Mo generator. The hours of nuclear cardiology clinical and work experience accrued during this period total 1200 hours.

Dr. Thomas W. Komorowski has completed a training program in nuclear cardiology that meets the requirements as outlined in the ACC/ASNC COCATS Guidelines [revised 2000] for Level II training in nuclear cardiology. Dr. Thomas W. Komorowski is competent to independently function as an authorized user under NRC 10 CFR 35.290 uses.

Sincerely,

Mariano J. Rey, MD  
Professor of Medicine and Physiology  
New York University  
NYC Department of Health, Bureau of Radiological Health,  
User # 75-2955-01

I hereby certify that this is a true copy of the original document.  
Sworn to before me this 18th day of July 2005.

SHARON WALDEN  
Notary Public, State of New York  
No. 24-4653681  
Qualified in Kings County  
Commission Expires Nov 23, 06



DIVISION OF NUCLEAR MEDICINE

August 19, 2009

To: Certification Board of Nuclear Cardiology

Dr. Thomas W. Komorowski has completed a training program in nuclear cardiology that meets the requirements as outlined in ACC/ASNC COCATS Guidelines (2000).

Dr. Thomas W. Komorowski is competent to independently function as an authorized user under NRC10CFR 35.290 uses.

Sincerely,

A handwritten signature in black ink, appearing to read "Kent Friedman" with "MD" written to the right.

Kent Friedman, M.D.  
Assistant Professor of Radiology  
Section Chief, Nuclear Medicine  
NYU Langone Medical Center  
Department of Radiology  
User#75-2955-01

# AMERICAN BOARD OF INTERNAL MEDICINE

INCORPORATED 1936

ATTESTS THAT

## Thomas Wojciech Komorowski

HAS MET THE REQUIREMENTS OF THIS BOARD AND IS HEREBY  
CERTIFIED FOR THE PERIOD 2004 THROUGH 2014

AS A DIPLOMATE IN

### CARDIOVASCULAR DISEASE



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CHAIR  
AMERICAN BOARD OF INTERNAL MEDICINE

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*Michael R. Zile*

OCEAN HEART GROUP

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VERONICA FORD

NRC FORM 313A (AUG) (3-2009) 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 DMS: NO. 1160-0120 EXPIRES: 3/31/2012

Name of Proposed Authorized User: Thomas Kowalski State or Territory Where Licensed: NJ

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 32.280(c)(1)(ii)(G)

NRC FORM 313A (AUG 12-2004) U.S. NUCLEAR REGULATORY COMMISSION  
AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

2. 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	NYU Hospitals	20	7-2000 → 6-2003
Radiation protection	NYU Hospitals	15	7-2000 → 6-2003
Mathematics pertaining to the use and measurement of radioactivity	NYU Hospitals	15	7-2000 → 6-2003
Chemistry of byproduct material for medical use (not required for 35.590)	NYU Hospitals	15	7-2000 → 6-2003
Radiation biology	NYU Hospitals	15	7-2000 → 6-2003
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.)

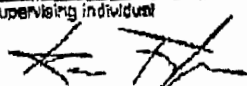
Supervised Work Experience		Total Hours of Experience:
		1,200
Description of Experience Must include:	Location of Experience/License or Permit Number of Facility	Confirm Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	NYU Hospitals	<input checked="" type="checkbox"/> Yes 7/00- <input type="checkbox"/> No 6/03
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	NYU Hospitals	<input type="checkbox"/> Yes 7/00 <input checked="" type="checkbox"/> No -6/03

NRC FORM 312A (AUB) (5-2009) 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	NYU Hospitals	<input type="checkbox"/> Yes <input type="checkbox"/> No	7/00 -6/03
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	NYU Hospitals	<input type="checkbox"/> Yes <input type="checkbox"/> No	7/00 -6/03
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	NYU Hospitals	<input type="checkbox"/> Yes <input type="checkbox"/> No	7/00 -6/03
Administering dosages of radioactive drugs to patients or human research subjects	NYU Hospitals	<input type="checkbox"/> Yes <input type="checkbox"/> No	7/00 -6/03
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclitic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs	NYU Hospitals	<input type="checkbox"/> Yes <input type="checkbox"/> No	7/00 -6/03

Supervising individual:  License/Permit Number listing supervising individual as an authorized user: 75-2955-01

Supervisor meets the requirements below, or equivalent Agreement State requirements (check one).  
 35.190  35.290  35.390  35.290 + 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 users only, stop here. For 35.100 and 35.200 users, skip to end complete Part II Preceptor Attestation.

OCEAN HEART GROUP  
VERONICA FORD

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NRC FORM 370A (AUB) (3-7579) U.S. NUCLEAR REGULATORY COMMISSION  
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 35.530)

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(e)(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 6 hours of classroom and laboratory training, required by 10 CFR 35.190(e)(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(e)(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 Thomas Komoroski 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(e)(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:

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

Kent Erdman MD

[Signature]

212 263 7410

7/11/11

License/Permit Number/Facility Name

75-2955-01 NYU Hospitals Center

PAGE 4



This is to acknowledge the receipt of your letter application dated

9/12/2011, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (37-30120-01) 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** 575994.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.