

QUALITY CARDIOVASCULAR CARE, LLC

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MS 16
J-4

06-30966-01

Docket No. 030-36684
Control No. 140532

Michelle Beardsley
Senior Health Physicist
Division of Nuclear Materials Safety
Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

May 29, 2007

SUBJECT: ADDITIONAL INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO LICENSE No. 06-30966-01

Dear Ms. Beardsley:

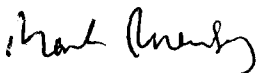
Enclosed please find Forms 313A (AUD) and 313A (RSO) in support of authorization of Dr. Lily Singhaviranon as Radiation Safety Officer and Authorized user for our Materials License.

Please let me know if any further information is necessary.

The best way to reach me is by cell phone (203-910-7470) or e-mail (gccmsr@sbcglobal.net)

Thank you for your prompt attention to this matter.

Sincerely,


Mark Rosenberg, MD
Managing Partner

RECEIVED
REGION 1
2007 MAY 31 PM 12: 59

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**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: 10/31/2008

Name of Proposed Authorized User

DR. LILY SINGHAVIRANON (M.D.)

State or Territory Where Licensed

CONNECTICUT

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

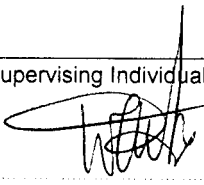
a. Authorized user on Materials License _____ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.

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

 Frans J Th Wachters, MD

License/Permit Number listing supervising individual as an authorized user

06-00819-03

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			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use <i>(not required for 35.590)</i>			
Radiation 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.)

Supervised Work Experience		Total Hours of Experience:	
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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	

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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Administering dosages of radioactive drugs to patients or human research subjects		<input type="checkbox"/> Yes <input type="checkbox"/> No	
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

License/Permit Number listing supervising individual as an authorized user

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)

First Section

Check one of the following for each use requested:

For 35.190

Board Certification

I attest that LILY SINGHAVIRANON 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 _____ 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 LILY SINGHAVIRANON 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 _____ has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

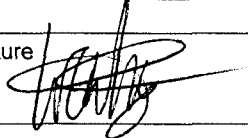
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

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 <u>Franco J Th Wachter, MD</u>	Signature 	Telephone Number <u>203-785 2384</u>	Date <u>5-23-2007</u>
License/Permit Number/Facility Name <u>06-00819-03</u>			

**RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION
[10 CFR 35.50]**

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2008

Name of Proposed Radiation Safety Officer

LILY SINGHAVIRANON

Requested Authorization(s) *The license authorizes the following medical uses (check all that apply):*

- 35.100
 35.200
 35.300
 35.400
 35.500
 35.600 (remote afterloader)
 35.600 (teletherapy)
 35.600 (gamma stereotactic radiosurgery)
 35.1000 (_____)

**PART I -- TRAINING AND EXPERIENCE
(Select one of the four 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. Use Table 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.
- c. Skip to and complete Part II Preceptor Attestation.

OR

2. Current Radiation Safety Officer Seeking Authorization to Be Recognized as a Radiation Safety Officer for the Additional Medical Uses Checked Above

- a. Use the table in section 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for the additional types of medical use for which recognition as RSO is sought.
- b. Skip to and complete Part II Preceptor Attestation.

OR

3. Structured Educational Program for Proposed Radiation Safety Officer

a. Classroom and Laboratory Training

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	Yale School of Medicine	50	2/01 - 2/02
Radiation protection	Yale School of Medicine	50	2/01 - 2/02
Mathematics pertaining to the use and measurement of radioactivity	YALE	50	2/01 - 2/02
Radiation biology	YALE	50	2/01 - 2/02
Radiation dosimetry	YALE	50	2/01 - 2/02
Total Hours of Training:		250 hrs	

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

b. Supervised Radiation Safety 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 Training/ License or Permit Number of Facility	Dates of Training*
Shipping, receiving, and performing related radiation surveys	YALE / 06-00819-03	2/01 - 2/02
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides	YALE / 06-00819-03	2/01 - 2/02
Securing and controlling byproduct material	YALE / 06 - 00819 - 03	2/01 - 2/02
Using administrative controls to avoid mistakes in administration of byproduct material	YALE / 06 - 00819 - 03	2/01 - 2/02
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures	YALE / 06 - 00819 - 03	2/01 - 2/02
Using emergency procedures to control byproduct material	YALE / 06 - 00819 - 03	2/01 - 2/02
Disposing of byproduct material	YALE / 06 - 00819 - 03	2/01 - 2/02
Licensed Material Used (e.g., 35.100, 35.200, etc.)+ 	YALE / 06 - 00819 - 03	2/01 - 2/02


+ Choose all applicable sections of 10 CFR Part 35 to describe radioisotopes and quantities used: 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 remote afterloader units, 35.600 teletherapy units, 35.600 gamma stereotactic radiosurgery units, emerging technologies (provide list of devices).

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

b. Supervised Radiation Safety Experience (continued)

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervising Individual 	FRANS J.Th. WACKERS, MD	License/Permit Number listing supervising individual as a Radiation Safety Officer 06-00819-03
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This license authorizes the following medical uses:

- | | | | |
|---|--|---|---------------------------------|
| <input checked="" type="checkbox"/> 35.100 | <input checked="" type="checkbox"/> 35.200 | <input type="checkbox"/> 35.300 | <input type="checkbox"/> 35.400 |
| <input type="checkbox"/> 35.500 | <input type="checkbox"/> 35.600 (remote afterloader) | <input type="checkbox"/> 35.600 (teletherapy) | |
| <input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery) | <input type="checkbox"/> 35.1000 () | | |

c. Describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

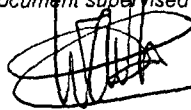
Description of Training	Training Provided By	Dates of Training*
Radiation safety, regulatory issues, and emergency procedures for 35.100, 35.200, and 35.500 uses	YALE - DR. WACKERS et al	2/01 - 2/02
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses	YALE - DR. WACKERS	2/01 - 2/02
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses	YALE - DR. WACKERS	2/01 - 2/02
Radiation safety, regulatory issues, and emergency procedures for 35.600 - teletherapy uses	YALE - DR. WACKERS	2/01 - 2/02
Radiation safety, regulatory issues, and emergency procedures for 35.600 - remote afterloader uses	YALE - DR. WACKERS	2/01 - 2/02
Radiation safety, regulatory issues, and emergency procedures for 35.600 - gamma stereotactic radiosurgery uses	YALE - DR. WACKERS	2/01 - 2/02
Radiation safety, regulatory issues, and emergency procedures for 35.1000, specify use(s):	YALE - DR. WACKERS	2/01 - 2/02

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

c. Training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license (continued)

Supervising Individual *training was provided by supervising RSO, AU, AMP, or ANP. (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)* License/Permit Number listing supervising individual

 **FRANS J. TH. WACKERS, MD** 06-00819-03

License/Permit lists supervising individual as:

- Radiation Safety Officer Authorized User Authorized Nuclear Pharmacist
- Authorized Medical Physicist

Authorized as RSO, AU, ANP, or AMP for the following medical uses:

- 35.100 35.200 35.300 35.400
- 35.500 35.600 (remote afterloader) 35.600 (teletherapy)
- 35.600 (gamma stereotactic radiosurgery) 35.1000 (_____)

d. Skip to and complete Part II Preceptor Attestation.

OR

4. Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist identified on the licensee's license

- a. Provide license number.
- b. Use the table in section 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.
- c. Skip to and complete Part II Preceptor Attestation.

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.

First Section

Check one of the following:

1. Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Radiation Safety Officer
10 CFR 35.50(a)(1)(i) and (a)(1)(ii); or 35.50 (a)(2)(i) and (a)(2)(ii); or 35.50(c)(1).

OR

2. Structured Educational Program for Proposed Radiation Safety Officers

I attest that LILY SINGHAVIRANON has satisfactorily completed a structural educational
Name of Proposed Radiation Safety Officer
program consisting of both 200 hours of classroom and laboratory training and one year of full-time radiation safety experience as required by 10 CFR 35.50(b)(1).

OR

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

Check one of the following:

3. Additional Authorization as Radiation Safety Officer

I attest that _____ is an
Name of Proposed Radiation Safety Officer

Authorized User

Authorized Nuclear Pharmacist

Authorized Medical Physicist

identified on the Licensees license and has experience with the radiation safety aspects of similar type of use of byproduct material for which the individual has Radiation Safety Officer responsibilities

AND

Second Section

Complete for all (check all that apply):

I attest that LILY SINGHAVIRANON has training in the radiation safety, regulatory issues, and
Name of Proposed Radiation Safety Officer

emergency procedures for the following types of use:

35.100

35.200

35.300 oral administration of less than or equal to 33 millicuries of sodium iodide I-131, for which a written directive is required

35.300 oral administration of greater than 33 millicuries of sodium iodide I-131

35.300 parenteral administration of any beta-emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

35.300 parenteral administration of any other radionuclide for which a written directive is required

35.400

35.500

35.600 remote afterloader units

35.600 teletherapy units

35.600 gamma stereotactic radiosurgery units

35.1000 emerging technologies, including:

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

AND

Third Section
Complete for ALL

I attest that LILY SINGHAVIRANON has achieved a level of radiation safety knowledge
Name of Proposed Radiation Safety Officer
sufficient to function independently as a Radiation Safety Officer for a medical use licensee.

Fourth Section
Complete the following for Preceptor Attestation and signature

I am the Radiation Safety Officer for Yale New Haven Hospital Nuclear Cardiology
Name of Facility

License/Permit Number: 06-00819-03

Name of Preceptor
Frans J.H. Wachter, MD

Signature

Telephone Number

Date

283
783-3178

5/29/
2007

Yale University

Department of Diagnostic Radiology



SCHOOL OF MEDICINE
333 CEDAR STREET
P.O. BOX 208042
NEW HAVEN, CONNECTICUT 06520-8042

(203) 785-4915 or (203) 785-4114
Fax (203) 737-2160
Email: frans.wackers@diagrad.med.yale.edu

FRANS J. TH WACKERS, M.D.
Director, Cardiovascular Nuclear Imaging

April 30, 2001

Certification Board of Nuclear Cardiology
9111 Old Georgetown Road
Bethesda, MD 20814

RE: Lily Singhaviranon, M.D.

To Whom It May Concern:

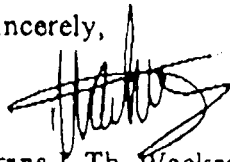
This letter is written to state that Dr. Lily Singhaviranon, who is applying to take the Certification Examination in Nuclear Cardiology, meets the eligibility criteria as stated in the Candidate Bulletin.

At the time of the examination, Dr. Lily Singhaviranon will have completed Level II training in Nuclear Cardiology at Yale University. She has taken a physics course consisting of at least 200 hours of classroom teaching and 1000 hours of clinical and hands on experience.

Dr. Lily Singhaviranon is Board Certified in Thailand in Cardiology. In particular, I can attest to the fact that Dr. Singhaviranon has interpreted at least 300 nuclear cardiology studies, of which at least 42 had angiographic correlation.

Please do not hesitate to contact me if you have any further questions.

Sincerely,



Frans J. Th. Wackers, M.D.
Professor of Diagnostic Radiology
and Medicine
Director, Cardiovascular Nuclear Imaging
and Exercise Laboratories

THE CERTIFICATION BOARD OF NUCLEAR CARDIOLOGY

Incorporated 1996

CERTIFIES THAT

Lily Singhaviranon, MBBS

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD FOR PHYSICIANS RESIDING
IN THE UNITED STATES AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION,

IS HEREBY DESIGNATED

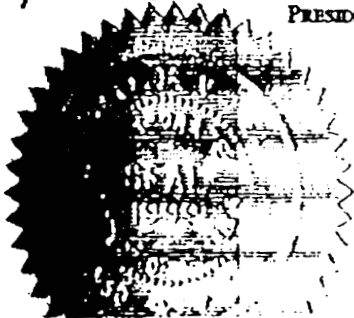
A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF

NUCLEAR CARDIOLOGY

FOR THE PERIOD 2001 THROUGH 2011

Manoel D. Cerqueira MD
PRESIDENT

C. Gerry Calvey MD
SECRETARY



CERTIFICATE # 2208



OCTOBER 28, 2001