



CARDIOVASCULAR SPECIALISTS, INC.

D. B. Chough, MD, FACC
Edward Skillen, Jr., DO, FACC
Jun K. Chung, MD, FACC
George A. Sarris, MD, FACC
Marc J. Rosenberg, MD
Calin V. Maniu, MD, FACC
Maria E. Pagtalunan, FNP-C
Daniel T. Thibodeau, PA-C
Amy C. Barco, PA-C
Gretchen A. Loyola, PA C

- Cardiovascular Consultation
- Cardiac and Peripheral Vascular Disease
Diagnosis and Treatment
- Cardiac Catheterization
- Cardiovascular Interventional Services
 - Coronary Angioplasty
 - Intracoronary Stent Therapy
 - Peripheral Vascular Angioplasty
 - Intravascular Ultrasound
 - Laser Atherectomy
 - Directional Coronary Atherectomy
 - Rotational Atherectomy
 - Transluminal Extraction Atherectomy
 - Renal Arterial Stent Angioplasty
- Electrophysiology
 - Pacemaker Follow-up Services
 - Temporary & Permanent Pacemaker
 - AICD/Defibrillator
- Heart Failure Evaluation & Treatment
 - Heart Failure Clinic
 - Heart Transplant
 - Endomyocardial Biopsy
- Echocardiography Services
 - Transthoracic
 - Transesophageal
 - Stress
 - Dobutamine
 - Contrast
- Cardiac Stress Testing
- Nuclear Cardiology
- ECG Services
 - Electrocardiography
 - Holter Monitoring
 - Event Recording
- Anticoagulation Management

3235 Academy Avenue
Suite 201
Portsmouth, VA 23703

Phone: 757-483-6420
Fax: 757-638-4519

Br. 2

October 21, 2008

Licensing Assistance Team
US Nuclear Regulatory Commission
Division of Nuclear Materials Safety
Region I
475 Allendale Road
King of Prussia, PA 19406

03034295

REFERENCE: Radioactive Materials License No. 45-25377-01

Dear Sir or Madam:

We would like to request that our radioactive materials license be amended to designate Marc J. Rosenberg, MD as our Radiation Safety Officer. Dr. Rosenberg is presently an authorized user on our license. Please find enclosed the training and experience and preceptor attestation required for this change.

Should there be any questions or if any further information be required, please contact our consulting physicist, Roy Heltzel, Jr. at 757-410-9051.

Sincerely,

Jun K. Chung, MD
President

2008 OCT 24 PM 12:46

RECEIVED
REGION I

142943
NRC/RM MATERIALS-002

**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

Marc J. Rosenberg, M.D.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**

- Provide a copy of the board certification.
- Use Table 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.
- 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**

- 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.
- Skip to and complete Part II Preceptor Attestation.

OR☐ **3. Structured Educational Program for Proposed Radiation Safety Officer**

- 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			
Radiation biology			
Radiation dosimetry			

Total Hours of Training:

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		
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides		
Securing and controlling byproduct material		
Using administrative controls to avoid mistakes in administration of byproduct material		
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures		
Using emergency procedures to control byproduct material		
Disposing of byproduct material		
Licensed Material Used (e.g., 35.100, 35.200, etc.)+ 		

+ 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	License/Permit Number listing supervising individual as a Radiation Safety Officer
<p>This license authorizes the following medical uses:</p> <div style="display: flex; flex-wrap: wrap;"> <div style="width: 50%;"><input type="checkbox"/> 35.100</div> <div style="width: 50%;"><input type="checkbox"/> 35.200</div> <div style="width: 50%;"><input type="checkbox"/> 35.300</div> <div style="width: 50%;"><input type="checkbox"/> 35.400</div> <div style="width: 50%;"><input type="checkbox"/> 35.500</div> <div style="width: 50%;"><input type="checkbox"/> 35.600 (remote afterloader)</div> <div style="width: 50%;"><input type="checkbox"/> 35.600 (teletherapy)</div> <div style="width: 50%;"><input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery)</div> <div style="width: 50%;"><input type="checkbox"/> 35.1000 (_____)</div> </div>	

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		
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses		
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - teletherapy uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - remote afterloader uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - gamma stereotactic radiosurgery uses		
Radiation safety, regulatory issues, and emergency procedures for 35.1000, specify use(s):		

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 *If 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

Dae Been Chough, M.D.

45-25377-01

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. *45-25377-01*
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 _____ 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 Marc J. Rosenberg, MD 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 Marc J. Rosenberg, MD 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 Marc J. Rosenberg, MD 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

Cardiovascular Specialists, Inc.
Name of Facility

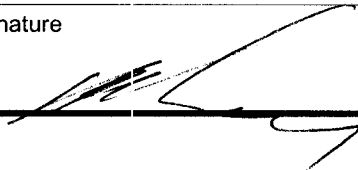
License/Permit Number:

45-25377-01

Name of Preceptor

Dae Been Chough, M.D.

Signature



Telephone Number

757-483-6420

Date

10/08/08

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

10/21/08, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amendment C45-25377-01
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** 142943.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.