

August 15, 2019

Licensing Assistance Team
Division of Nuclear Materials Safety
U. S. Nuclear Regulatory Commission, Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

Br. 1
03029521

REC RG 10829 19 AM0651

Re: License No. 07-27897-01 – Cardiovascular Consultants of Southern Delaware, LLC.

To Whom It May Concern,

We, Cardiovascular Consultants of Southern Delaware LLC, License Number 07-27897-01, wish to amend our radioactive materials license to reflect the following:

- We would like to name Ramon A. Rosa, MD as the radiation safety officer. Dr. Rosa is listed on the license as authorized user for 35.200 level use.
 - Dr. Rosa satisfies radiation safety officer training and experience as outlined in 10 CFR Part 35.50(c)(2). He has had experience in radiation safety aspects for 10 CFR Part 35.200 use – diagnostic use of radioactive material in nuclear cardiology.
 - I have reviewed with Dr. Rosa radiation safety, regulatory issues and emergency procedures for 10 CFR Part 35.200 as it applies to nuclear cardiology.
- Please see the attached 313A (RSO) paperwork.

If you have any questions regarding this amendment, please contact me at 302 645 1233.

Regards,

Barry S. Denenberg, M.D.
Radiation Safety Officer

Enclosure: Form 313A

614048
NMSS/RGN1 MATERIALS-002



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

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 06/30/2019

Name of Proposed Radiation Safety Officer

Ramon A. Rosa, MD

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			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			
Radiation dosimetry			
Total Hours of Training: <input type="text"/>			

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.)+ <div style="border: 1px solid black; height: 40px; width: 300px; margin-top: 5px;"></div>		

+ 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		
This license authorizes the following medical uses:			
<input type="checkbox"/> 35.100	<input 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	Barry S. Denenberg, MD	01/01/2012 - Current
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.)*

Barry S. Denenberg, MD

License/Permit Number listing supervising individual

Cardiovascular Consultants of S. Delaware / 07-27897-01

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.
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 Ramon A. Rosa, MD 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 _____ 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 Ramon A. Rosa, 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 Ramon A. Rosa, 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.

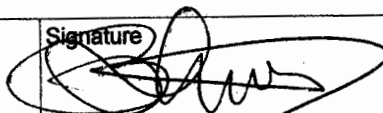
**Fourth Section
Complete the following for Preceptor Attestation and signature**

I am the Radiation Safety Officer for Cardiovascular Consultants of Southern Delaware, LLC
Name of Facility

License/Permit Number: 07-27897-01

Name of Preceptor
Barry S. Denenberg, MD

Signature



Telephone Number
302 645-1233

Date
8/8/19

Certification Board of Nuclear Cardiology

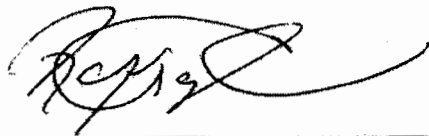
Incorporated 1996

Certifies That

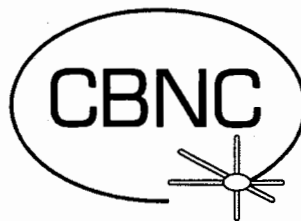
Ramon Alberto Rosa, MD

HAVING MET THE RECERTIFICATION 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 2009 - 2019



President



Secretary



CERTIFICATE NUMBER: 1501



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee Cardiovascular Consultants of Southern Delaware, LLC Attn: Barry S. Denenberg, M.D. 16704 Kings Highway Lewes, DE 19958	Date 09/05/2019
	License Number(s) 07-27897-01
	Mail Control Number(s) 614048
	Licensing and/or Technical Reviewer or Branch Medical Branch

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: 08/15/2019

The initial processing, which included an administrative review, has been performed.

☒ Amendment ☐ Termination ☐ New License ☐ Renewal

☒ There were no administrative omissions identified during our initial review.

☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

☐ Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
Follow the instructions on the form for submission.

☐ The following administrative omissions have been identified:

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
 U. S. Nuclear Regulatory Commission
 Division of Nuclear Materials Safety
 2100 Renaissance Boulevard, Suite 100
 King of Prussia, PA 19406-2713
 (610) 337-5260, (610) 337-5313,
 (610) 337-5398, (610) 337-5513 or (610) 337-5239