

# Advanced Cardiology<sup>PLLC</sup>

November 9, 2009

Paul M. Zack, M. D.  
Radiation Safety Officer

Paul M. Zack, M.D., F.A.C.C.  
Mohan C. Madala, M.D.

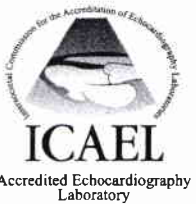
Re: Radiation Safety Officer/ Executive Management  
Letter of Understanding

Tracy Pride, PA-C  
Katherine Carlson, NP-C

Dear Dr. Zack:

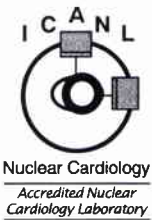
You have been appointed the Radiation Safety Officer (RSO) of this facility for our United States Nuclear Regulatory Commission Materials License. This "Letter of Understanding" is prepared to comply with Title 10 Code of Federal Regulations (CFR) Part 35.24(b). This section of the regulations requires that you agree in writing to the following:

- Assume responsibility for implementing the Radiation Protection Program
- Ensure that radiation safety activities are being performed in accordance with our own approved procedures and all regulatory requirements.



The executive management of this facility agrees to provide you as RSO:

- Specific written notation of your authority, duties and responsibilities, see attached.
- Sufficient authority, organizational freedom, time, resources and management prerogative to:
  1. Identify radiation safety problems;
  2. Initiate, recommend, or provide corrective actions;
  3. Stop unsafe operations; and,
  4. Verify implementation of corrective actions.



My signature noted below will attest to the issues noted above. Please make a copy of this document for your files.

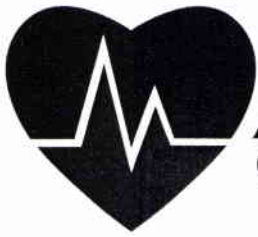
Sincerely,

Radiation Safety Officer and Executive Management

1200 E. Michigan Avenue  
Suite 780  
Lansing, MI 48912-1838

Telephone: (517) 484-9000  
Toll Free: (888) 448-4424  
Fax: (517) 267-9640

RECEIVED JAN 08 2010



**Advanced  
Cardiology** PLLC

November 9, 2009

United States Nuclear Regulatory Commission  
Region III, Materials Licensing  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4342

RE: Advanced Cardiology, PLLC  
License Amendment  
**NRC License No. 21-32569-01**

Dear Sir/Madam:

The purpose of this letter is to amend our current NRC license to reflect the following changes:

- Item #1:** Please Remove Robert Hills, D.O. as Radiation Safety Officer from our NRC license.
- Item #2:** Please remove Robert Hills, D.O. as an authorized user from our NRC license.
- Item #3:** Please list Paul M. Zack, M.D. as the Radiation Safety Officer on our NRC license. We have included Dr. Zack's NRC form 313A (RSO) and a copy of his CBNC board certificate.
- Item #4:** Please list Mohan C. Madala, M.D. as an authorized user for Groups 35, 100 and 35.200 on our NRC license. We have included the NRC for 313A (AU) and a copy of his CBNC board certificate.

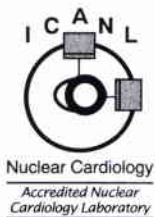
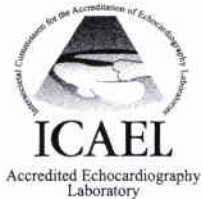
Thank you for your cooperation. If you have any questions or require additional information, please contact our physics consultant, Sharon Updike at 734-662-3197 or by email at [supdike@mpcphysics.com](mailto:supdike@mpcphysics.com).

Sincerely,

Executive Management  
Advanced Cardiology, PLLC

1200 E. Michigan Avenue  
Suite 780  
Lansing, MI 48912-1838

Telephone: (517) 484-9000  
Toll Free: (888) 448-4424  
Fax: (517) 267-9640



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

APPROVED BY OMB: NO. 3150-0120  
EXPIRES: 3/31/2012

Name of Proposed Radiation Safety Officer

*Paul M. Zack 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**

- 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:**

**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
This license authorizes the following medical uses:	
<input type="checkbox"/> 35.100	<input type="checkbox"/> 35.200
<input type="checkbox"/> 35.500	<input type="checkbox"/> 35.600 (remote afterloader)
<input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery)	<input type="checkbox"/> 35.1000 ( _____ )
<input type="checkbox"/> 35.300	<input type="checkbox"/> 35.400
<input type="checkbox"/> 35.600 (teletherapy)	

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	Advanced Cardiology	6/06 THROUGH 6/08
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)

<p>Supervising Individual <i>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.)</i></p> <p style="font-size: 24pt; font-family: cursive;">Robert B. Hills D.O.</p>	<p>License/Permit Number listing supervising individual</p> <p style="font-size: 24pt; font-family: cursive;">21-32569-01</p>												
<p>License/Permit lists supervising individual as:</p> <p> <input checked="" type="checkbox"/> Radiation Safety Officer     <input checked="" type="checkbox"/> Authorized User     <input type="checkbox"/> Authorized Nuclear Pharmacist  <input type="checkbox"/> Authorized Medical Physicist </p> <p>Authorized as RSO, AU, ANP, or AMP for the following medical uses:</p> <table style="width: 100%;"> <tr> <td><input checked="" type="checkbox"/> 35.100</td> <td><input checked="" type="checkbox"/> 35.200</td> <td><input type="checkbox"/> 35.300</td> <td><input type="checkbox"/> 35.400</td> </tr> <tr> <td><input type="checkbox"/> 35.500</td> <td><input type="checkbox"/> 35.600 (remote afterloader)</td> <td><input type="checkbox"/> 35.600 (teletherapy)</td> <td></td> </tr> <tr> <td><input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery)</td> <td><input type="checkbox"/> 35.1000 ( _____ )</td> <td></td> <td></td> </tr> </table>		<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 ( _____ )		
<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 ( _____ )												

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 \_\_\_\_\_ 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 Paul M. Zack 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 Paul M. Zack M.D. 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 Paul M. Zack M.D. 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 Advanced Cardiology  
Name of Facility

License/Permit Number: 21-32569-01

Name of Preceptor	Signature	Telephone Number	Date
Robert B. Hills D.O.	Robert B. Hills D.O.	(616) 450-0680	11/30/09



**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: 3/31/2012

Name of Proposed Authorized User State or Territory Where Licensed

Mohan C. Madala M.D. Michigan

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 32.290(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			
<b>Total Hours of Training:</b>			

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)

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 Mohan C. Madala M.D. 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 Mohan C. Madala MD 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>Paul M. Zack M.D.</u>	Signature <u>[Signature]</u>	Telephone Number <u>517-484-9000</u>	Date <u>11/30/09</u>
License/Permit Number/Facility Name <u>21-32569-01</u>			

# Certification Board of Nuclear Cardiology

Incorporated 1996

Certifies that

**Paul M. Zack, MD**

HAVING MET THE 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 2008 - 2018**



President



Secretary



CERTIFICATE NUMBER: 6808

# Certification Board of Nuclear Cardiology

Incorporated 1996

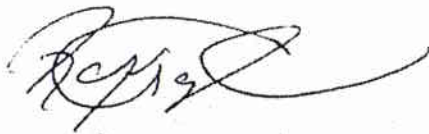
Certifies that

## Mohan Chand Madala, MD

HAVING MET THE 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 2007 - 2017**



President



Secretary



CERTIFICATE NUMBER: 5485



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# Advanced Cardiology<sup>PLLC</sup>

Sparrow Professional Building  
1200 E. Michigan Ave., Suite 780  
Lansing, MI 48912-1838

United States Nuclear Regulatory Commission  
Region III, Office of Materials Licensing  
2443 Warrenville Rd. Suite 210  
Lisle, IL 60532-4352

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