

# ADVANCED CARDIOVASCULAR ASSOCIATES, PLC

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GERIANNE MALIK, PA-C  
CHRISTOPHER DAVIS, PA-C

August 23, 2016

UNITED STATES NUCLEAR REGULATORY COMMISSION  
Region III, Materials Licensing Section  
2443 Warrenville Road  
Suite 210  
Lisle, IL 60532-4352

**Re: Amendment for License No. 21-25912-01, Advanced Cardiovascular Associates, PLC**

Please amend our license to add Fadi Al-Qas Hanna, M.D. to our license for 10CFR35.200. Please find enclosed a copy of his CBNC board certification and preceptor form.

Thank you for your cooperation.



Kathy Powers  
Practice Administrator  
Advanced Cardiovascular Associates, PLC

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Sterling Heights, MI 48314

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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: 06/30/2019

Name of Proposed Authorized User

Fadi Al-Qas Hanna, M.D.

State or Territory Where Licensed

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 \_\_\_\_\_ 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 Fadi Al-Qas Hanna, M.D. 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

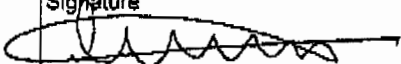
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

**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	Signature	Telephone Number	Date
Lalitha Rudraiah, M.D.		(986) 731-7000	8/29/16
License/Permit Number/Facility Name			
21-25912-01 / Advanced Cardiovascular Associates, PLC			

P 1/1

# Certification Board of Nuclear Cardiology

Incorporated 1996

A Division of the Council for Certification in Cardiovascular Imaging

Certifies That

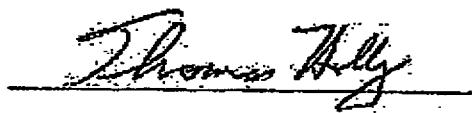
1 >>

## Fadi Al-Qas Hanna, MD

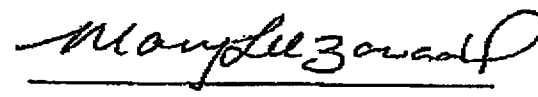
HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD FOR PHYSICIANS  
TRAINED IN THE UNITED STATES AND HAVING SATISFACTORILY PASSED  
THE REQUIRED EXAMINATION, IS HEREBY DESIGNATED  
A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF  
NUCLEAR CARDIOLOGY

VALID: JANUARY 1, 2015 — MARCH 1, 2025

1586-294-5333



President



Secretary



CERTIFICATE NUMBER: 9712

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MATTHEW FORCINA, M.D., FACC

GERIANNE MALIK, PA-C  
CHRISTOPHER DAVIS, PA-C

## FAX COVER SHEET

DATE: 8/30/16. Total Pages Including Cover: \_\_\_\_\_  
TO: U.S. NRC - ATTN: MATERIAL LICENSING.  
PHONE/FAX: (630) 515-1078  
FROM: JOYCE BIELA, RT(W) ADV. CARD. ASSOC.  
URGENT \_\_\_\_\_ FOR REVIEW \_\_\_\_\_ PLEASE REPLY \_\_\_\_\_  
REGARDING: LICENSE AMENDMENT

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