

September 6, 2017

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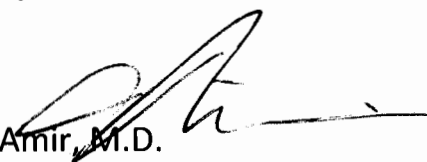
U.S. Nuclear Regulatory Commission  
Region 1  
2100 Renaissance Boulevard  
Suite 100  
King of Prussia, PA 19406-2713

Dear Sir/Madam:

License No. 06-28615-01 / 103032088

We wish to appoint Irma Fotjadhi, M.D. as an authorized user on the above license. A copy of her board certification and application form 313A (AUD) has been included with this letter

Sincerely,

  
Doron Amir, M.D.  
Radiation Safety Officer  
Authorize User

601035  
NMSC/EGNI MATERIALS-002

REC'D 09 19 17 AM 07:07



**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 Irma Fotjadhi, M.D.	State or Territory Where Licensed Connecticut
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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
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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 Irma Fotjadhi, 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

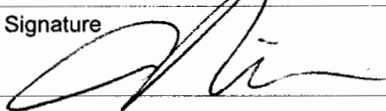
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

**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
Doron Amir, M.D.		2033342100	09/06/2017
License/Permit Number/Facility Name			
06-28615-01			

# Certification Board of Nuclear Cardiology

Incorporated 1996

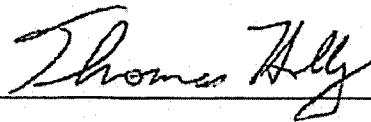
A Division of the Council for Certification in Cardiovascular Imaging

Certifies That

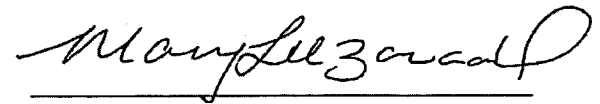
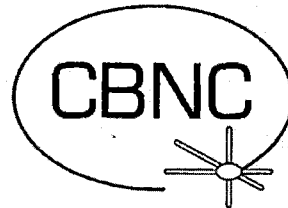
## Irma Mece Fotjadhi, MD

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, 2016 – MARCH 1, 2026



President



Secretary



CERTIFICATE NUMBER: 10396



**ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE**

<b>Name and Address of Applicant and/or Licensee</b>  Advanced Cardiovascular Specialists ATTN: Doron Amir, M.D., Radiation Safety Officer 439 Mill Hill Avenue Bridgeport, CT 06610	<b>Date</b> September 26, 2017
	<b>License Number(s)</b> 06-28615-01
	<b>Mail Control Number(s)</b> 601035
	<b>Licensing and/or Technical Reviewer or Branch</b> Medical Branch (Branch 1)

This is to acknowledge receipt of your:  Letter and/or  Application Dated: 09/06/2017

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:  
 [Empty box for listing omissions]

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, or (610) 337-5239