

CARDIOVASCULAR CONSULTANTS, P.L.L.C

333 Laidley Street, Suite 402

Charleston, WV 25301

(304)-414-0423

RECEIVED
REGION I
2011 DEC -2 PM 12: 39

11/28/2011

Br. 1

Mr. Joseph Nick, Chief
Nuclear Medical Branch
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Rd.
King of Prussia, PA 19406-1415

**** Please EXPEDITE ****

Re: Request for Amendment of Radioactive Materials License
Number 47-30849-01

03036436

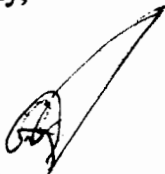
Dear Sir or Madam:

We are hereby submitting the forms required for the addition of Dr. Mohammad Hussan Pervaiz, M.D. to our License No. 47-30849-01 for Cardiovascular Consultants, PLLC, 333 Laidley Street, Suite 402, Charleston, WV 25301-1605.

The sources, possession limits, forms and uses for nuclear cardiology and cardiovascular imaging, as stated in the license, will be followed by Dr. Pervaiz. Dr. Pervaiz has privileges in our facility and has read and agreed to comply with the current license, license conditions, and other applicable operational conditions of the license. Dr. Pervaiz is licensed to provide medicine in New Jersey.

We authorize INME (Institute for Nuclear Medical Education) and NCS to respond to any inquiries concerning this amendment request. Please contact INME (NCS) at 1.8900.548.4024 for any additional information you may need.

Sincerely,



Bassam MoushMoush, M.D., F.A.C.C

Cc: file

Enclosures

576472
NMSS/RGN1 MATERIALS-002

**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
Mohammad Hassan Pervaiz, MD

State or Territory Where Licensed
West Virginia

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	-N/A-		

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	-N/A-		
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use (not required for 35.590)			
Radiation biology			
Total Hours of Training:			

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	See Preceptor Statement (Attached)	<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	-N/A-	<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 (<i>check one</i>).			
<input type="checkbox"/> 35.190 <input type="checkbox"/> 35.290 <input type="checkbox"/> 35.390 <input type="checkbox"/> 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
	-N/A-	

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

FORM 8888 (04/01/00)

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, oversees, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each that required to meet training requirements in 35.530.

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(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.

For 35.290

Board Certification

I attest that MOHAMMAD HASSAN PERVAIZ, 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(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.

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>GEORGE, S. ABELA, M.D.</u>	Signature <u>George S. Abela MD</u>	Telephone Number <u>517-432-9124</u>	Date <u>9-19-2011</u>
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License/Permit Number/Facility Name
MICHIGAN STATE UNIVERSITY CARDIOLOGY FELLOWSHIP, EAST LANSING, MI

17681 FOR HOP1 99:51 GBL 1102/51/60

Preceptor Letter

Date: 9/15/11

To Whom It May Concern:

This letter is to affirm that **MOHAMMAD HASSAN PERVAIZ, MD** M.D. received training and experience in Nuclear Cardiology at MICHIGAN STATE UNIVERSITY between 7/1/2007 - 6/30/2010 and 6/30/2010 and successfully completed this training program on 6/30/2010

During this training program, Dr. PERVAIZ received not less than 700 hours of supervised work experience. The experience of Dr. PERVAIZ was gained under the supervision of an Authorized User.

The supervised work experience included ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; Calibrating Instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; Calculating, measuring, and safely preparing patient or human research subject dosages; Using administrative controls to prevent medical events; Using procedures to safely contain spills and using proper decontamination procedures; Administering dosages of radioactive drugs to patients or human research subjects.

I certify that Dr. PERVAIZ has satisfactorily completed the requirements in 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 35.100 and 35.200.

Should you require any additional information please feel to contact me at 517-432-9124

Sincerely,

George S. Abrams

*Please
retype on
your letterhead*

Radioactive materials license number 21-00021

Telephone number: _____

**MICHIGAN STATE
UNIVERSITY**

October 21, 2011

To Whom It May Concern:

This letter is to confirm that **Mohammad Hassan Pervaiz, M.D.**, received training and experience in Nuclear Cardiology at Michigan State University between 7/1/2007 and 6/30/2010 and successfully completed this training program on 6/30/2010.

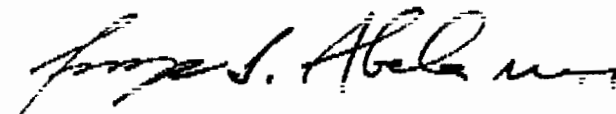
During this training program, Dr. Pervaiz received not less than 700 hours of supervised work experience. This experience of Dr. Pervaiz was gained under the supervision of an Authorized User.

The supervised work experience included ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; calculating, measuring and safely preparing patient or human research patient dosages; using administrative controls to prevent medical events; using procedures to safely contain spills and using proper documentation procedures; administering dosages of radioactive drugs to patients or human research subjects.

I certify that Dr. Pervaiz has satisfactorily completed the requirements in 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 35.100 and 35.200.

Should you require any additional information please feel free to contact me at 517-432-9124.

Sincerely,



George S. Abela, M.D., M.Sc., M.B.A., F.A.C.C.
Program Director, Cardiovascular Fellowship

Radioactive materials license number: 21-00021-29

Telephone number: 517-432-9124

**DEPARTMENT OF
MEDICINE****Division of Cardiology
College of Human Medicine**

Michigan State University
B208 Clinical Center
East Lansing, MI
48824-1313
517/353-4832
FAX: 517/432-4030

NRC FORM 374*

PAGE 1 OF 2 PAGES
Amendment No. 2

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p>Licensee</p> <p>1. Cardiovascular Consultants, PLLC</p> <p>2. 331 Laidley Street, Suite 402 Charleston, West Virginia 25301-1605</p>	<p>In accordance with the letter received May 14, 2010,</p> <p>3. License number 47-30649-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date December 31, 2013</p> <hr/> <p>5. Docket No. 03036436 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.200</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p>
<p>9. Authorized use:</p> <p>A. Any imaging and localization study permitted by 10 CFR 35.200</p>		

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at 331 Laidley Street, Suite 402, Charleston, West Virginia.
- 11. The Radiation Safety Officer for this license is Bassam Moushmoush, M.D.
- 12. Licensed material is only authorized for use by, or under the supervision of:
 - A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
 - B. The following individuals are authorized users for medical use as indicated:

<u>Authorized Users</u>	<u>Material and Use</u>
Bassam Moushmoush, M.D.	35.200
Ahmed M. Sakkal, M.D.	35.200

NRC FORM 374A

PAGE 2 OF 2 PAGES

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
47-30849-01

Order or Reference Number
03036436

Amendment No. 2

Authorized Users

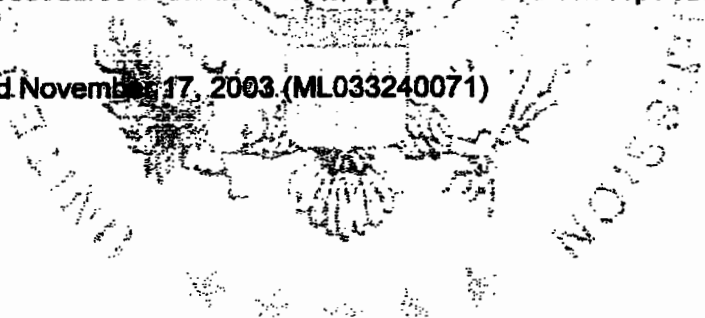
Material and Use

Mohammed Yaser Haffar, M.D.

35.200

- 13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
- 14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
- 15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated November 17, 2003 (ML033240071)



For the U.S. Nuclear Regulatory Commission

Date June 13, 2010

By *Sandra Gabriel*

Sandra Gabriel
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

Sunday, June 13, 2010 13:27:40

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

1/28/2011, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (47-30849-01)
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** 576472.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.