

May 4th, 2011

Sent via email to sandra.gabriel@nrc.gov

Ms. Sandra Gabriel, Senior Health Physicist
U.S. NRC Region I
Nuclear Materials Section B
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

K-8

03019530

RE: Amendment Request for NRC Radioactive Materials License#: 47-19919-01
Logan Regional Medical Center, 20 Hospital Drive, Logan, WV 25601

Dear Sandy:

We wish to add the following individual as an Authorized User on our Radioactive Materials License:

Authorized User	Authorized Material & Uses	Training & Experience
Kozhaya Mallah, MD	10 CFR 35.200	NRC 313A (AUD) preceptor form, Attestation of supervised experience, Attestation of competency

Supporting documentation is enclosed. Dr. Mallah attended a course provided by the Institute on Nuclear Medicine Education (INME) for 9 days from 2/13/10 – 2/21/10 and obtained 100 CME hours of classroom and laboratory training to include HAZMAT training in radioactive materials. It appears that the course actually provided 80 hours of in-class training. No other supporting documentation from INME is available.

We are aware that the 313 form does not indicate the total number of supervised work experience hours in Section 3b. The number of supervised work experience hours is included in the attestation letter signed by Dr. Fayez Shamoan documenting 600 hours of supervised clinical experience obtained at St. Michael's and St. Joseph's Medical Centers. The letter refers to Illinois Title 32 regulations in Section 335.9040 which are compatible with 10 CFR 35.290. The training and attestation letter signed by Dr. Elie Gharib documents competency and an additional 22.5 hours of supervised clinical experience obtained at Logan Regional Medical Center and the completion of at least 700 hours of training and experience.

This request has been reviewed and approved by senior management and the facility Radiation Safety Officer.

575112

REC'D IN LAT MAY 10 2011

NMSS/RGN1 MATERIALS-002



Logan Regional
Medical Center

20 Hospital Drive
Logan, WV 25601

We appreciate your consideration of this amendment request. If you have any questions regarding this request or should you need any further information, please do not hesitate to contact us.

Sincerely,

A handwritten signature in black ink, appearing to read 'Nancy Godby', with the date '05/10/11' written to the right of the signature.

Nancy Godby MS, MA, RT (R) (M)
Chief Operating Officer
304-831-1120
Nancy.Godby@LPNT.net

A handwritten signature in black ink, appearing to read 'James Norweck', written over a horizontal line.

James Norweck, MS, DABR
Radiation Safety Officer
304-710-0172
jnorweck@radiology-inc.com

**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

Dr. Kozhaya Mallah, M.D.

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	Not Applicable		

Total Hours of Experience:

Supervising Individual

N/A

License/Permit Number listing supervising individual as an authorized user

N/A

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	Institute For Nuclear Medical Education, (INME) Secaucus, NJ	50	Feb 13-21, 2010
Radiation protection	INME, as above	15	Same as Above
Mathematics pertaining to the use and measurement of radioactivity	INME, as above	10	Same as Above
Chemistry of byproduct material for medical use (not required for 35.590)	INME, as above	15	Same as Above
Radiation biology	INME, as above	10	Same as Above
Total Hours of Training:		100 hrs Total	

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	St. Michael's and St. Joseph's Medical Center, Newark, NJ #29/101-91-02	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/07 to 06/30/10
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Same as above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Same

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	Same as above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Same
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Same as above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Same
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Same as above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Same
Administering dosages of radioactive drugs to patients or human research subjects	Same as above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Same
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	Same as above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Same

Supervising Individual

Dr. Faye Shamoon, M.D.

License/Permit Number listing supervising individual as an authorized user

NRC 29-101-91-02

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
N/A	Not Applicable	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.

NRC FORM 313A (AUG) 0-90001

U.S. NUCLEAR REGULATORY COMMISSION

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(e)(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 _____ 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 Dr. K. Mallah, M.D. 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

FAYEZ SHAMOUN

973 877 5160

8/24/10

License/Permit Number/Facility Name

NRC 29-10191-02

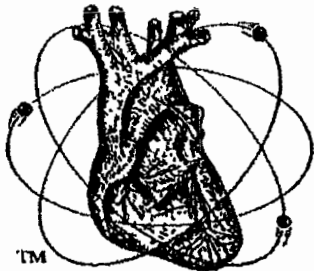
19919-01

Medical Radioisotope Handling Attestation and Certification Completion and Competency

This document is an affidavit that, as evidenced by written examination,

Kozhaya Mallah, M.D.

has successfully completed this formal academic program of didactic classroom and laboratory experience and has demonstrated competency in the objectives of this program through formal, written, examination.



This individual is entitled to full recognition as meeting or exceeding the requirements established by the U.S. Nuclear Regulatory Commission (NRC) in,
10 CFR 35.190(c)(1)(A-E) 10 CFR 35.290(c)(1)(i)(A-E) 10 CFR 35.390(b)(1)(i)(A-E)
10 CFR 35.392(c)(1)(i-v) 10 CFR 35.394(c)(1)(i-v) 10 CFR 35.396(d)(1)(i-v)



This program also provides,
100 Hours Category I CME AMA (PRA), Institute of Medical Studies
100 Hours College/University Credit American Council on Education (ACE)
100 Hours Board Exam Accepted Hours, NMTCB, ABR, ABNM, CBNC, et. al.


Certifying Official

February 13-21st, 2010
Date Completed

205024
Certification

Institute for Nuclear Medical Education

Validated by the American Council on Education (ACE), recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education.

CME CREDIT CERTIFICATE

This is to certify that
Kozhaya Mallah, M.D.

Has completed up to
100 Hours

Of Category 1 CME credit through participation in the Medical Radioisotope Handling conducted by the Institute for Nuclear Medical Education (INME) from February 13-21, 2010 in Secaucus, NJ.

This CME activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) thru the Joint Sponsorship of the Institute for Medical Studies (IMS) and INME.

IMS is accredited by the ACCME to provide continuing medical education for physicians.

IMS designates this educational activity for a maximum of 100 credit hours AMA PRA Category 1 Credits™.

Participants should claim only those hours of credit that he/she actually spent in the activity as established by registration and attendance.

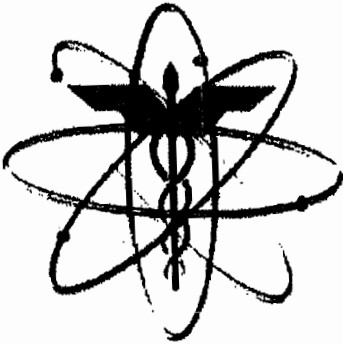
Please retain this Certificate for your records.

The Institute for Medical Studies
14 Monarch Bay Plaza, Suite 202
Monarch Beach, CA 92629

CERTIFICATE OF COMPLETION HAZMAT TRAINING – RADIOACTIVE MATERIALS

This document is an affidavit that

Kozhaya Mallah, M.D.



Has received training and has been tested as required by 49CFR 172.704(d). This training was limited to diagnostic radioactive materials received or offered for shipment in approved Type A Packages, Class 7, UN2915, Yellow II.



Certifying Official

February 21, 2010

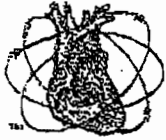
Date Completed

204112

Certification

Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the American Council on Education (ACE), recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.



INSTITUTE FOR NUCLEAR MEDICAL EDUCATION
INME
BASICS OF RADIOISOTOPE HANDLING
MEDICAL RADIOISOTOPE HANDLING

TOPIC/HOURS

CLASSROOM & LABORATORY TRAINING ⁽¹⁾ TOPIC	(1)		(2)		(3)	
	In-Class		Study		TOTAL	
Radiation Physics	24		6		30	
Instrumentation ⁽⁴⁾	16		4		20	
Radiation Protection ⁽⁴⁾	12		3		15	
Mathematics Pertaining to the Use and Measurement of Radiation and Radioactivity	8		2		10	
Chemistry of Byproduct Material for Medical Use Including Production, QC/QA and Control	12		3		15	
Radiation Biology	8		2		10	
	80		20		100	

(1) The program provides classroom-based training with a formal, didactic classroom experience of instruction and laboratory presentations. The identity and presence of the participants is established through physical supervision of the educational experience, multiple daily sign-in sheets, identity verification, in writing, and a photograph of the participant.

(2) The classes provide 8.5-9.0 hours of daily instruction for a total of 80 hours. An additional 20 hours may be obtained through documented exercises external to the classroom training.

(3) The total hours, if achieved by the participant, Category 1 CME and/or college/university credit, have been reviewed by external agencies and approved for 100 hours.

(4) The in-class program includes HAZMAT CERTIFICATION for the shipping and receiving of radioactive materials in compliance with the requirements of the DOT, other standards. An exam is given covering this HAZMAT material, which is separate from the program exam.

(5) The participant must pass a closed-book, written examination on the program content, administered under instructor, physical supervision, on the last day of the program.

For additional information, contact:

Institute for Nuclear Medical Education
5660 Airport Blvd, Suite 101
Boulder, CO 80301
Ph: 303.541.0044 Fax: 303.541.0066



August 24, 2010

Mr. James Norweck, MS., DABR
5112 US 60 East
Huntington, WV 25705

RE: Kozhaya Mallah, MD.


Dear Mr. Norweck:

Dr. Mallah has completed a nuclear cardiology training program that meets the requirements for Level 2 as outlined in the ACCF/ASNC COCATS Guidelines for Nuclear Cardiology, revised 2006, within the accredited fellowship or residency program.

Dr. Mallah completed level 2 nuclear cardiology training between the dates of 07/01/2007 and 06/30/2010.

I attest that Dr. Mallah is competent to independently function as an authorized user under NRC 10 CFR 35.200 uses.

Sincerely,



Faye Shamoan, MD., FACC, FACP, FSCAI
Cardiology Program Director
Radioactive material license# NRC 29-10191-02

Today's Date

To Whom It May Concern:

This letter is to affirm that Dr. K. ^{Mallah, M.D.} received training and experience in Nuclear Cardiology at: St. Michael's M.C. between 07/01/2007 and 08/30/2010 and successfully completed this training program on Nuclear cardiology located at St. Michael's / St. Joseph's * Medical Center

During this training program, Dr. Mallah received not less than 600 hours of supervised work experience. The experience of Dr. Mallah was gained under the supervision of an Authorized User.

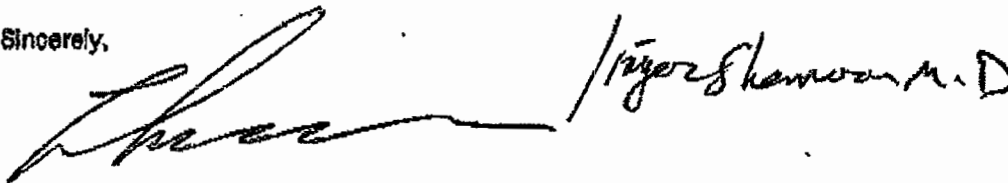
The supervised work experience included ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; Calculating, measuring, 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. Mallah has satisfactorily completed the requirements in 395.9040 subsection(c) and has achieved a level of competency sufficient to function independently as an Authorized User for the medical uses authorized under 395.4010 for those procedures not requiring a written directive.

Should you require any additional information please feel to contact me at

973 877 5160

Sincerely,



Radioactive materials license number NRC-27-101-91-02



RE: Letter of Attestation for Kozhaya Mallah, M.D.

To Whom It May Concern:

This letter is to attest that for the period from **October 18, 2010** through **March 18, 2011**, during which time Kozhaya Mallah, M.D. has interpreted a total of **219** studies.

I, (Elie Gharib, M.D.), have supervised the activities of Kozhaya Mallah, M.D. in the use of authorized material and uses authorized by 10CFR35.200 in **forty five (45)** of these 219 studies. This supervised work experience occurred at Logan Regional Medical Center. We estimate this clinical experience to be approximately equivalent to at least **twenty-two (22.5)** hours of practical radiation safety and radionuclide work experience. Please note that I am currently listed as an authorized user on NRC Radioactive Materials License No.: 47-19919-01 at Logan Regional Medical Center in Logan, WV.

Kozhaya Mallah, M.D. has demonstrated clinical proficiency in interpretation of nuclear cardiology studies along with an understanding of the essentials of radiation safety and the conditions of our license. We believe that Kozhaya Mallah, M.D. has satisfactorily completed the requirements of 10CFR35.290 and has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under 10CFR35.200.

I attest that Kozhaya Mallah, M.D. has satisfactorily completed the 700 hours of training 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 35.200.

Sincerely,

A handwritten signature in black ink, appearing to read "Elie Gharib", written over a horizontal line.

Elie Gharib, M.D.

A handwritten date "4/26/11" in black ink, written over a horizontal line.

Date

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

5/4/2011, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 47-19919-01
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** 575112.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.