



B.1

03014390

REC RG1 0618 13 0716

Date: May 29, 2013

US Nuclear Regulatory Commission, Region II
475 Allendale, Road
King of Prussia, PA 19406-1415

To Whom It May Concern:

Re: Amendment to Radioactive Materials License 47-18046-01

We request an amendment to the above material license to have
Dr. Melaku G. Demede added for parts 35.200.
This will allow him to read his own Cardiolite and or Thallium stress test.

Thank you for your attention to this request. If you have any questions
Regarding this matter please contact JAMES MILLER, Nuclear Medicine
Supervisor at 304-256-4126, or JAMES.MILLER@LPNT.net, or Fax 304-256-4038.

Sincerely,

David Darden
President/Chief Executive Officer

581169

NMSS/RGN1 MATERIALS-002

Certification Board of Nuclear Cardiology

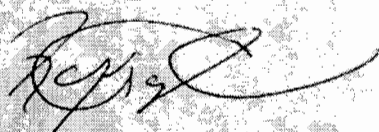
Incorporated 1996

Certifies that

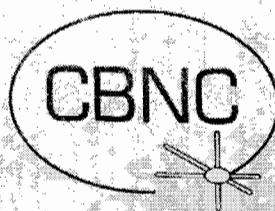
Melaku Gebremariam Demede, MD

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

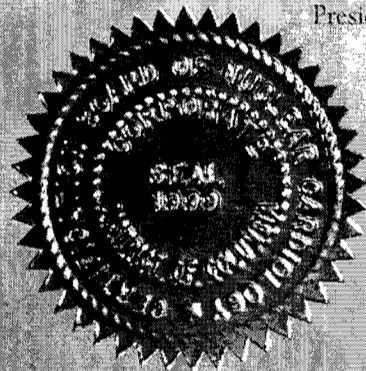
FOR THE PERIOD 2010 - 2020



President



Secretary



CERTIFICATE NUMBER: 7610



STATE UNIVERSITY OF NEW YORK DOWNSTATE MEDICAL CENTER

THE DEPARTMENT OF RADIOLOGY AND RADIATION PHYSICS HEREBY
CERTIFIES THAT

MELAKU DEMEDE M.D.

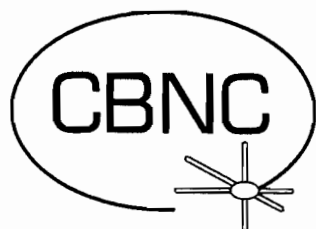
successfully completed a Radiation Physics courses designed specifically for the education in the use of radioactive materials in humans for diagnostic imaging. This certificate is awarded only after the physician has attended the classroom and laboratory instruction and passed a rigorous three hour written exam

The course consisted of 80 hours of classroom and laboratory instruction specifically covering:

RADIATION PHYSICS
RADIATION PROTECTION
RADIATION BIOLOGY
RADIATION MEASUREMENTS

ARTHUR OLSON, RADIATION SAFETY OFFICER
DIRECTOR RADIATION PHYSICS
CERTIFIED BY THE AMERICAN BOARD OF RADIOLOGY

July 19, 2010
JULY 2010



Certification Board of Nuclear Cardiology

A Division of the Council for Certification in CardioVascular Imaging

EXPERT IMAGERS • QUALITY CARE

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Verification of TESTAMUR Status

To Whom It May Concern:

This letter confirms that the following individual passed the board examination in nuclear cardiology given by the Certification Board of Nuclear Cardiology. The current status of this candidate is Testamur[†]. He/she is eligible to become a Diplomate pending confirmation of passing the Cardiovascular Disease, Nuclear Medicine or Radiology Board.

Name: **Melaku G. Demede, MD**

Date Passed the CBNC Exam: **12/19/2010**

Attested by:

Dawn M. Edgerton, Chief Executive Officer

Date: April 27, 2012

[†] **Testamur** - An individual who has successfully passed the CBNC examination but has not documented either full medical licensure and/or board certification in Cardiovascular Disease, Nuclear Medicine or Radiology. Testamurs must provide documentation of full medical licensure and board certification in Cardiovascular Disease, Nuclear Medicine or Radiology in order to be granted Diplomate status, and this must happen within six (6) years of passing the CBNC exam.



A Diverse Legacy, A Bright Future

College of Medicine

College of Nursing

College of Health Related Professions

School of Graduate Studies

School of Public Health

Jason M. Lazar, MD, MPH

Director, Non-Invasive Cardiology

Director, Cardiovascular Medicine Fellowship Training Program

Clinical Assistant Dean, College of Medicine

Associate Professor of Medicine

July 30, 2010

Certification Board of Nuclear Cardiology
101 Lake Forest Boulevard, Suite 401
Gaithersburg, MD 20877

Re: Melaku Demede, MD
ID #894

Dear Sir/Madam:

Dr. Melaku Demede, MD has completed a nuclear cardiology training program that meets the requirements for level 2 as outlined in the *ACCF/ASNC COCATS Guidelines for Training in Nuclear Cardiology, revised 2008*, within an accredited fellowship program.

Dr. Demede completed level 2 Nuclear Cardiology training between the dates of 07/01/08 and 07/30/10.

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

Dr. Demede completed a minimum of 80 hours of classroom and laboratory training that meets the Nuclear Regulatory Commission (NRC) requirements as an INTEGRAL part of his fellowship program.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jason M. Lazar'.

Jason M. Lazar, MD, MPH
Director, Cardiovascular Medicine
Fellowship Training Program
NRC License#: 75-2934-01-202

/dv



College of Medicine

College of Nursing

College of Health Related Professions

School of Graduate Studies

School of Public Health



A Diverse Legacy. A Bright Future

Jason M. Lazar, MD, MPH

Director, Non-Invasive Cardiology

Director, Cardiovascular Medicine Fellowship Training Program

Clinical Assistant Dean, College of Medicine

Associate Professor of Medicine

July 30, 2010

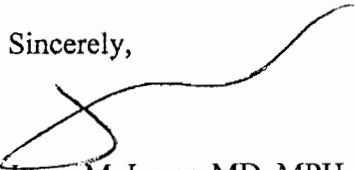
Certification Board of Nuclear Cardiology
101 Lake Forest Boulevard, Suite 401
Gaithersburg, MD 20877

Re: Melaku Demede, MD
ID #894

Dear Sir/Madam:

Dr. Melaku Demede, MD is a third year Cardiology Fellow in good standing in the Division of Cardiovascular Medicine Fellowship Training Program at the State University of New York Downstate Medical Center, Brooklyn, New York. His training dates are from 07/01/08 to 06/30/11.

Sincerely,



Jason M. Lazar, MD, MPH
Director, Cardiovascular Medicine
Fellowship Training Program
NRC License#: 75-2934-01-202

/dv

**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: (05/31/2015)

Name of Proposed Authorized User

Dr. Melaku G. Demede

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			

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			
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		<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 (<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

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, 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. (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 DR DEMEDZ 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 Dr. DEMEDÉ 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 Dr. Melaku G. Demede has satisfactorily completed the requirements in

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. DEMEDE 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 Thir Bingham	Signature 	Telephone Number 304-254-0892	Date 6/6/2
License/Permit Number/Facility Name NRC# 47-18046-01		Raleigh General Hospital	

This is to acknowledge the receipt of your letter application dated

05-29-13, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amend: 47-18046-01
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** 581169.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.