HOWARD UNIVERSITY

RADIATION SAFETY OFFICE

Br.1
03001321

September 19, 2018

U.S. Nuclear Regulatory Commission - Region -1
Medical Branch, Division of Nuclear Material Safety
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406 – 2713
Attn: Ms. Donna Janda, Branch Chief

Subject: **Amend license # 08-03075-07 to remove Dr. Charu Gandotra's name and add Dr. Isaac Opoku-Asare as an Authorized User**

The Howard University Radiation Safety Committee is requesting an amendment to License No. 08-03075-07 to add Isaac Opoku-Asare, MD for imaging and localization studies as permitted under 10 CFR 35.200. Dr. Opuku-Asare has provided the following supporting documents for consideration.

1. Authorized User Training and Experience and Preceptor Attestation Form (*NRC FORM 313 A- AUD*).
2. Board Certification
3. DC Health Medical license.
4. Certification Board of Nuclear Cardiology
5. Training and Experience for proposed authorized user

The committee is also requesting to remove Dr. Charu Gandotra as an authorized user from the license since she separated from this Institution.

Please do not hesitate to contact me at my e- mail (satya.bose@howard.edu) or phone (202-806-7216) should you require any further information.

Sincerely,

Satya Ranjan Bose

Satya R. Bose, Ph. D., DABR
Director of Radiation Safety, Radiation Safety Officer &
Chief Medical Physicist

cc: Alice A. Mahan
Management Representative to RSC

Sergei A. Nekhai, Ph.D., Professor
Chair, Radiation Safety Committee

2041 Georgia Avenue, NW
Cancer Center, Room 323
Washington, DC 20060

p: (202) 806-7216
f: (202) 806 -5432

610154
NMSS/RGN1 MATERIALS-002

REC'D IN LAT 10/05/2018

NRC FORM 313A (AUD)
(06-2016)

U.S. NUCLEAR REGULATORY COMMISSION

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	State or Territory Where Licensed
Isaac Opoku-Asare, M.D.	Washington D.C.

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	TRAINING CERTIFICATE- ATTACHED	40	See attached
Radiation protection	-ATTACHED	15	See attached
Mathematics pertaining to the use and measurement of radioactivity	- ATTACHED	15	See attached
Chemistry of byproduct material for medical use *(not required for 35.590)*	- ATTACHED (Hours combined with Radiation Protection)		See attached
Radiation biology	-ATTACHED	10	See attached
	Total Hours of Training: 80		

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		☐ Yes ☐ No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		☐ Yes ☐ No	

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		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		☐ Yes ☐ No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		☐ Yes ☐ No	
Administering dosages of radioactive drugs to patients or human research subjects		☐ Yes ☐ 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		☐ Yes ☐ No	

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Andre Duerinckx, M.D..	08-03075-07

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.

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 Isaac Opoku-Asare, M.D. 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 Isaac Opoku-Asare, 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 Isaac Opoku-Asare, 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
Andre Duerinckx, M.D.		(202) 865-1572	9/19/2018

License/Permit Number/Facility Name

License# 08-03075-07, Howard University Hospital, Washington, D.C. 20060

Council for Certification in
CCCVI Cardiovascular
IMAGING
Expert Imagers - Quality Care

CARDIOVASCULAR IMAGING CERTIFICATIONS

NOTE: For questions or further clarification, please call our office at 240.631.8151.

- Cardiovascular Computed Tomography
- Nuclear Cardiology

Certification recognizes those physicians who have demonstrated knowledge and skills in their respective fields by documenting appropriate training and/or experience and successfully passing a written examination.

Search Results

Search Again

1 results found

Name/Location	Status	Information
Dr. Isaac Opoku-Asare [redacted] CBNC	DIPLOMATE	Certificate Number: 8429 Certified in Nuclear Cardiology on 1/1/2012. This certification is valid from 1/1/2012-3/1/2022.

THE AMERICAN BOARD OF INTERNAL MEDICINE

INCORPORATED 1936

Attests that

Isaac Opoku-Asare

Has met the requirements of this board
and is hereby certified as a diplomate in

Interventional Cardiology

Ongoing certification is contingent upon meeting the requirements of Maintenance of Certification.
Please visit www.abim.org to verify current certification status.

BOARD OFFICERS

CHAIR | CHAIR-ELECT | SECRETARY | TREASURER | PRESIDENT | CEO AND EXECUTIVE VICE PRESIDENT

CARDIOLOGY BOARD INTERVENTIONAL CARDIOLOGY EXAM COMMITTEE

CHAIR

NUMBER 283682

2014

THE

AMERICAN BOARD OF INTERNAL MEDICINE

INCORPORATED 1936

ATTESTS THAT

Isaac Opoku-Asare

HAS MET THE REQUIREMENTS OF THIS BOARD AND IS HEREBY
CERTIFIED FOR THE PERIOD 2012 THROUGH 2022
AS A DIPLOMATE IN

CARDIOVASCULAR DISEASE

Robert M. Wachter
CHAIR
AMERICAN BOARD OF INTERNAL MEDICINE

David H. Johnson
CHAIR-ELECT
AMERICAN BOARD OF INTERNAL MEDICINE

Stuart L. Linas
SECRETARY TREASURER
AMERICAN BOARD OF INTERNAL MEDICINE

PRESIDENT
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SUBSPECIALTY BOARD ON CARDIOVASCULAR DISEASE

William C. Little
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Alice K. Jacobs

A. Jeffrey Mandell

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Jae K. Oh

Andrea M. Russo

Thomas Ryan

Paul D. Thompson

NUMBER 283682

2012

PERSONAL INFORMATION WAS REMOVED
BY NRC. NO COPY OF THIS INFORMATION
WAS RETAINED BY THE NRC.

Congratulations!
Here is your wall license and pocket identification card. If this is your initial license, your wall certificate will arrive under separate cover. If this is your renewal license, this is the only document you will receive. You must display the wall license below with your original wall certificate to show that your status is current.

In order to be sure that your next renewal notice is sent to you correctly, please notify the District of Columbia Department of Health of your name or address changes by writing to:

Government of the District of Columbia
Department of Health
899 North Capitol Street, NE – First Floor
Washington, DC 20002

PLEASE CAREFULLY DETACH AT PERFORATION

★★★ GOVERNMENT
[redacted] OF THE
[redacted]STRICT OF COLUMBIA

DISTRICT OF COLUMBIA

DEPARTMENT OF HEALTH
HEALTH REGULATION AND LICENSING ADMINISTRATION
BOARD OF MEDICINE

certifies that

Isaac Opoku-Asare

has met all requirements prescribed by law and regulations and is hereby licensed as a(n):

MEDICINE AND SURGERY
License Number: [redacted]

ISSUE DATE:01/01/2017 **EXPIRATION DATE: 12/31/2018**

LaQuandra S. Nesbitt MD
LaQuandra Nesbitt, M.D.
Director, Department of Health

Janis M. Orlowski MD
Janis Orlowski, MD

HUH
HOWARD
UNIVERSITY
HOSPITAL

2041 Georgia Avenue, N.W. (202) 865-6100
Washington, D.C. 20060 (202) 745-3731 Fax

Date: Sep 12, 2018

Certification Board of Nuclear Cardiology
1401 Rockville Pike, Suite 600
Rockville MD 20852

Dr. Isaac Opoku-Asare has completed a nuclear cardiology training program that meets the requirements for Level 2 as outlined in the ACC Core Cardiovascular Training Statement (COCATS) 4 Task Force 6: Training in Nuclear Cardiology, revised 2015, within an accredited program.

Dr. Isaac Opoku-Asare completed Level 2 nuclear cardiology training between the dates of 07/01/09 and 09/01/11 (use *MM/DD/YY*).

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

☐ The above-named applicant 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/her fellowship/ residency program.

☒ The above-named applicant completed a minimum of 80 hours of classroom and laboratory training that meets the NRC requirements EXTERNAL to his/her fellowship program. This training was taken in a course offered by HRSI *(course provider)* and was completed between the dates of 7/10/2011 and 9/06/2011 (use *MM/DD/YY*).

☒ I attest that the above-named applicant completed hands-on Laboratory training that meets the training and experience requirements of NRC 10 CFR 35.290 or Agreement State equivalent as part of his/her Nuclear Cardiology training and experience.

☐ The above-named applicant is an Authorized User listed on a current Radioactive Materials (RAM) License (if applicable).

Sincerely,

(Signature Required)

Name of Preceptor: Andre Duerinckx, MD

Title/Relationship to Applicant: Chair, Department of Radiology

☒ A statement regarding COCATS Level 2 Training in Nuclear Cardiology at our institution as well as my status as preceptor or nuclear cardiology program director is on file at the CBNC Office. The training of the above-named applicant complies with all components of the statement on file.

HOWARD UNIVERSITY HOSPITAL

2041 Georgia Avenue, N.W.
Washington, D.C. 20060

(202) 865-6100
(202) 745-3731 Fax

CLICK HERE TO PRINT
Must Print On Organizational Letterhead

Date: September 12, 2018

Certification Board of Nuclear Cardiology
1401 Rockville Pike, Suite 600
Rockville, MD 20852

To Whom It May Concern:

I am responsible for oversight of the Nuclear Cardiology rotation at Howard University Hospital. This program is affiliated with Howard University Hospital which is an ACGME or AOA accredited institution. I am an authorized user under U.S. Nuclear Regulatory Commission (NRC) 10 CFR 35.200 uses or Agreement State equivalent.

The program at our institution includes the following COCATS Level 2 Nuclear Cardiology Training that meets the NRC requirements outlined in 10 CFR 35.290 Training, or Agreement State equivalent:

Lectures and Self Study

☑ The didactic training should include in-depth details of all aspects of the procedures listed in Table 1 (see below). This program may be scheduled over a 12- to 36-month period concurrent and integrated with other fellowship assignments.

Classroom and Laboratory Training (CLT) (Check Box if this is part of your Training Curriculum)

☑ Classroom and laboratory training needs to include extensive review of radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of byproduct material for medical use, radiation biology, the effects of ionizing radiation and radiopharmaceuticals. There should be a thorough review of regulations dealing with radiation safety for the use of radiopharmaceuticals and ionizing radiation. This experience should total a minimum of 80 hours and be clearly documented.

These CLT hours are obtained as follows (Check the Appropriate Box)

- ○ Internally within the Fellowship/Residency (conducted in house by personnel from our institution); OR
- ○ Externally to the Fellowship (conducted externally or in house by contracted personnel); OR
- ◉ A combination of Internal/External and may differ by individual trainee

Interpretation of Clinical Cases

☑ Fellows should participate in the interpretation of all nuclear cardiology imaging data for the 4-6 month training period. It is imperative that the fellows have experience in correlating catheterization or CT angiographic data with radionuclide-derived data in a minimum of 30 patients. A teaching conference in which the fellow presents the clinical material and nuclear cardiology results is an appropriate forum for such an experience. A total of 300 cases should be interpreted under preceptor supervision, from direct patient studies.

Hands-on Experience

☑ Clinical Cases: Hands-on supervised experience in a minimum of 30 patients: 25 patients with myocardial perfusion imaging and 5 patients with radionuclide angiography. Such experience should include pretest patient evaluation, radiopharmaceutical preparation (including experience with relevant radionuclide generators and CT systems), performance of studies with and without attenuation correction, administration of the dosage, calibration and setup of the gamma camera and CT system, setup of the imaging computer, processing the data for display, interpretation of the studies and generating clinical reports.

☑ Clinical and Work Experience: a minimum of 620 hours acquired continuously during training in the clinical environment where radioactive materials are being used and under the supervision of an authorized user who meets the NRC requirements of 10 CFR Part 35.290 or Part 35.290(c)(ii)(G) and 35.390 or the equivalent Agreement State requirements, including each of the experiences listed in a, b, c, d, e, f, g as follows:

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
(C) Calculating, measuring, and safely preparing patient or human research subject dosages;
(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
(F) Administering dosages of radioactive drugs to patients or human research subjects; and
(G) Eluting generator systems appropriate for 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

Additional Experience

☑ The training program for Level 2 training must also provide experience in computer methods for analysis. This should include perfusion and functional data derived from thallium or technetium agents and ejection fraction and regional wall motion measurements from radionuclide angiographic studies.

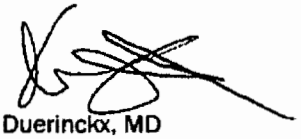
☑ **Table 1 Classification of Nuclear Cardiology Procedures**

A. Procedures in which competency should be achieved during Level 2 training
   1. Myocardial perfusion imaging
      a. SPECT, with or without attenuation correction
      b. ECG gating of perfusion images
      c. Stress protocols (exercise and pharmacologic)
      d. Viability assessment using SPECT and/or PET
   2. Radionuclide angiography
   3. Use of methods for acquisition, reconstruction, and quantitative analysis of images
   4. Appropriate radiation safety and quality improvement programs
   5. Use of radiation monitoring instruments

B. Procedures in which medical knowledge should be demonstrated and achievement of competency may be accomplished during or after fellowship
   1. PET Myocardial perfusion imaging
   2. Myocardial blood flow quantification
   3. Cardiac planar imaging
   4. Hybrid PET/CT and SPECT/CT
   5. Myocardial innervation
   6. Myocardial metabolism

☑ I attest that trainees at our institution must complete hands-on laboratory activities and that documentation o the dates and specific activities the whole of their nuclear cardiology training are maintained as part of each trainee's data record, and available for audit.

Sincerely,



Name: Andre Duerinckx, MD Title: Professor & Chair, Depart. of Radiology

Radioactive Materials (RAM) License Number 08-03075-07

Certified by:

☑ CBNC ☐ ABNM ☐ ABR ☐ AOBNM ☐ AOBR ☐ Other: _____

HOWARD UNIVERSITY

OFFICE OF THE PROVOST AND CHIEF ACADEMIC OFFICER

Radiation Safety Office

This is to certify that

Isaac Opoku-Asare, M.D.

has successfully completed the

Basic Radiation Safety Training Conducted by the

Howard University Radiation Safety Officer on July 11, 2018.

Satya Ranjan Bose

Satya R. Bose, Ph. D., DABR
Director of Radiation Safety
Radiation Safety Officer,
&
Chief Medical Physicist
Department of Radiation Oncology

NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Howard University Hospital
ATTN: Anthony K. Wutoh, Ph.D., R.Ph, Provost
& Chief Academic Officer
2041 Georgia Avenue, N.W.
Washington, DC 20060

Date
October 10, 2018

License Number(s)
08-03075-07

Mail Control Number(s)
610154

Licensing and/or Technical Reviewer or Branch
Medical Branch

This is to acknowledge receipt of your: ☑ **Letter and/or** ☐ **Application** **Dated:** 09/19/2018

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:**

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