New Brunswick
Cardiology Group, P.A.

Anthony J. Passannante, Sr., M.D., FACP, FACC
Anthony J. Passannante, Jr., M.D., FACC
John L. Dorazio, M.D., FACC
jack A. Stroh, M.D., FACP, FACC, FSCAI, RVT
Anand U. Kulkarni, M.D., FACC

Clifford D. Gladstone M.D., FACC
Sheldon J. Kukafka, M D., FACC
Subhashini A Gowda M.D., FACC
Pratik B. Patel, M.D., ACC, FSCAI
Ross J. Goodfellow. D). , FACC

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Medical Licensing Assistant
Nuclear Regulator Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406

February 20,2009

03032376

To Whom It May Concern:

Attached you will find the NRC Form 313A. This request is for New Brunswick Cardiology Group, license #29-28656-01. Please amend the radioactive materials license to add Anthony J. Passannante, Jr., M.D., FACC and John L. Dorazio, M.D., FACC as authorized users for 10 CFR 35.200.

Sincerely,

Anthony Passannante, Sr., M.D.

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NMSS/RGN1 MATERIALS-002

Main Office: 75 Veronica Ave., Suite 101
Somerset, NJ 08873 - **732-247-7444**

East Brunswick Office: 15H Brier Hill Ct.
East Brunswick, NJ 08816 - **732-613-9313**

Cranbury/Monroe Office: 111 Union Valley Road
Monroe Township, NJ 08831 - **609-409-6856**

NRC FORM 313A (AUD) U.S. NUCLEAR REGULATORY COMMISSION
(10-2006)

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: 10/31/2008

Name of Proposed Authorized User	State or Territory Where Licensed
ANTHONY J. PASSANNANTE, JR., M.D., FACC	NEW JERSEY

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 end 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)

NRC FORM 313A (AUD) U.S. NUCLEAR REGULATORY COMMISSION
(10-2006)

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 *(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.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys			
Performing quality control procedures on 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			

NRC FORM 313A (AUD) U.S. NUCLEAR REGULATORY COMMISSION
(10-2006)

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	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material			
Using procedures to contain spilled byproduct material safely and using proper decantamination procedures			
Administenng dosages of radioactrve drugs to patients or human research subjects			
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* 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.

NRC FORM 313A (AUD) U.S. NUCLEAR REGULATORY COMMISSION
(10-2006)

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 expenence, obtain a separate preceptor statement from each. (Not required to meet training requirements in 35.590)

First Section
Check one of the following for each use requested:

For 35.190

Board Certification

☐ I attest that _____ has satisfactorily completed the requrrernents 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 authonzed 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 authonzed under 10 CFR 35.100.

For 35.290

Board Certification

☒ I attest that Anthony L. Passannante Jr MD FACC 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 authonzed under 10 CFR 35.100 and 35.200.

OR

Trainina and Experience

☐ I attest that _____ has satisfactorily completed the 7130 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 20 CFR 35 100 and 35.200.

Second Section
Compfete the following for preceptor attestation and signature:

☒ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for

☐ 35.1913 ☒ 35.290 ☐ 35.390 ☐ 35.390 + generator experience

Name of Preceptor	Signature	Telephone Number	Date
ANTHONY PASSANNANTE, SR, MD			3/3/09

License/Permit Number/Facility Name
29-28656-01 NEW BRUNSWICK CARDIOLOGY GROUP

NRC FORM 313A (AUD) U.S. NUCLEAR REGULATORY COMMISSION
(10-2006)

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 35.5901

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2008

Name of Proposed Authorized User	State or Territory Where Licensed
JOHN L. DORAZIO, M.D., FACC	NEW JERSEY

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 Port 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 We 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, ar equivalent Agreement State requirements *(check all that* **apply).**

☐ 35.290 ☐ 35.390 + generatar experiance in 32.290(c)(1)(ii)(G)

NRC FORM 313A (AUD) U.S. NUCLEAR REGULATORY COMMISSION
(10-2006)
AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

☐ 3. **Training and Experience for Proposed Authorized User**

a. Classnoom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiotion 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 thin 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.)*

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys			
Performing quality control procedures on instruments used to determine the activity of dosages and perfoming checks for proper operation of survey meters			
Calculating! measuring, and safely preparing patient or human research subject dosages			

NRC FORM 313A (AUD) U.S. NUCLEAR REGULATORY COMMISSION
(10-2006)
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	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material			
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures			
Administering dosages of radioactive drugs to patients or human research subjects			
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** *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.

NRC FORM 313A (AUD) U.S. NUCLEAR REGULATORY COMMISSION
(10-2006)
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)

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 John L. Dorazio, MD, FACC 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 niedical 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 on 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
ANTHONY PASSANANTE, SR, M.D.			3/3/09

License/Permit Number/Facility Name
29-28456-01 NEW BRUNSWICK CARDIOLOGY GROUP

Certification Board of Nuclear Cardiology

Incorporated 1996

Certifies that

John L. Dorazio, 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 2008 - 2018

President

CBNC

Secretary

CERTIFICATE NUMBER: 6100

Certification Board of Nuclear Cardiology

Incorporated 1996

Certifies that

Anthony J. Passannante Jr., 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 2008 - 2018

President

CBNC

Secretary

CERTIFICATE NUMBER: 6504

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

2/20/2009, and to inform you that the initial processing which includes an administrative review has been performed.

☑ AMEND. 29-28656-01 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** 143514.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader