

May 18, 2011

UNITED STATES NUCLEAR REGULATORY COMMISSION  
Region III, Materials Licensing Section  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

**Re: Amendment to License No. 21-26764-01, Grand River Cardiology, PLC**

Please amend our license to add Gregory G. Pellizzon as authorized user of 10 CFR 35.100 and 35.200 (limited to cardiovascular procedures). Documentation of his training and experience is enclosed for your review.

Thank you for your cooperation in this matter. If you have any questions, please contact our Nuclear Medicine Department, Holly or Kerri at 616-949-8554.

Sincerely,

A handwritten signature in black ink, appearing to read "Stan Mills".

Stan Mills  
(Administrator)

RECEIVED MAY 24 2011

**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

State or Territory Where Licensed

Gregory Gerhard Pellizzon, M.D.

Michigan

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			
<b>Total Hours of Training:</b>			

- 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 userSupervisor 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.

**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 Gregory G. Pellizzon, MD 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 Gregory G. Pellizzon, MD 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(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 <u>Gregory L. Miller</u>	Signature <u>[Signature]</u>	Telephone Number <u>616-449-8554</u>	Date <u>5/17/11</u>
License/Permit Number/Facility Name <u>21-26764-01    Grand River Cardiology PLC</u>			

**THE CERTIFICATION BOARD OF NUCLEAR CARDIOLOGY**  
Incorporated 1996  
CERTIFIES THAT

**Gregory Gerhard Pellizzon, M.D.**

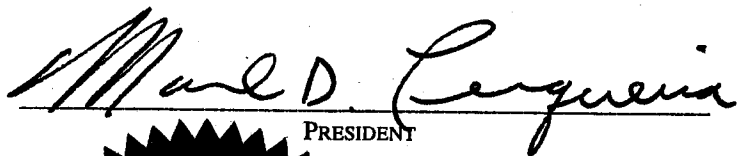
HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD FOR PHYSICIANS RESIDING  
IN THE UNITED STATES AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION,

IS HEREBY DESIGNATED

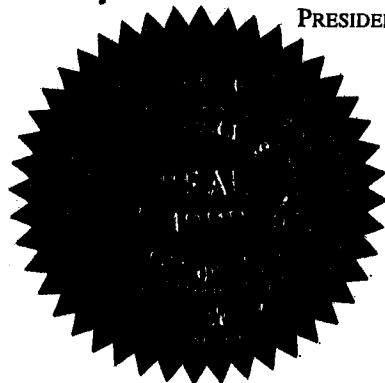
A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF

**NUCLEAR CARDIOLOGY**

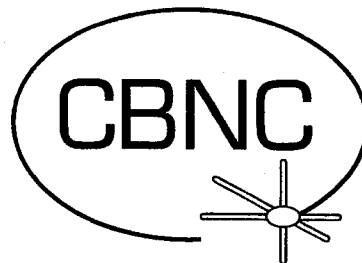
FOR THE PERIOD 2005 THROUGH 2015

  
PRESIDENT

  
SECRETARY



CERTIFICATE # 4146



OCTOBER 23, 2005

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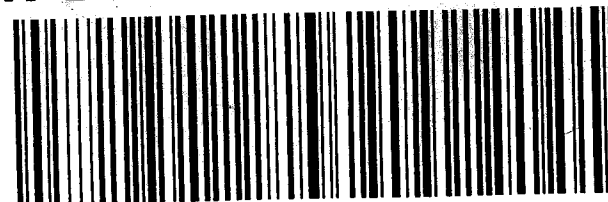
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8464 5126 5502

TUE - 24 MAY A1  
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FedEx USA Airbill

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FedEx  
Tracking  
Number

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1 From This portion can be removed for Recipient's records.

Date 5-23-11

FedEx Tracking Number

8464 5126 5502

Sender's  
Name

ANDREA RIBANDO

Phone 616 949-8554

Company

GRAND RIVER CARDIOLOGY XXXX

Address

1000 E PARIS AVE SE STE 118

City

GRAND RAPIDS

State

MI

ZIP

49546-3680

2 Your Internal Billing Reference

3 To

Recipient's  
Name

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Company

Region III, Materials Licensing Section

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2443 Warrenville Road, Suite 210

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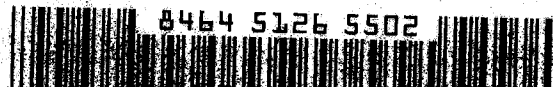
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4a Express Package Service

☒ FedEx Priority Overnight  
Next business morning☐ FedEx Standard Overnight  
Next business afternoon

Packages up to 150 lbs.

☐ FedEx First Overnight  
Earliest next business morning  
delivery to select locations☐ FedEx 2Day  
Second business day☐ FedEx Express Saver  
Third business day

FedEx Envelope rate not available. Minimum charge: One-pound rate

4b Express Freight Service

☒ FedEx 1Day Freight\*  
Next business day☐ FedEx 2Day Freight  
Second business day

Packages over 150 lbs.

☐ FedEx 3Day Freight  
Third business day

\*Declared value limit \$500

5 Packaging

☐ FedEx Envelope\*☐ FedEx Pak\*  
Includes FedEx Small Pak, FedEx  
Large Pak, and FedEx Sturdy Pak☐ Other

6 Special Handling

☐ SATURDAY DeliveryAvailable ONLY for FedEx Priority  
Overnight, FedEx 2Day, FedEx  
1Day Freight, and FedEx 2Day  
Freight select ZIP codes☐ HOLD WeekdayAt FedEx location  
Available only for  
FedEx Priority Overnight  
and FedEx 2Day Freight  
select locations☐ HOLD SaturdayAt FedEx location  
Available only for  
FedEx Priority Overnight  
and FedEx 2Day Freight  
select locations

Does this shipment contain dangerous goods?

One box must be checked.

☐ No☐ YesAs per  
Shipper's DeclarationDangerous Goods  
including Dry Ice cannot be shipped in FedEx packages☐ YesShipper's Declaration  
not required☐ Dry Ice

Dry Ice, S, UN 1845

☐ Cargo/Air Freight Only

Payment to:

Sender

Acct. No. in Section  
1 will be billed.☐ Recipient☐ Third Party☐ Credit Card☐ Cash/Check☐ Obtain Recipient's  
Acct. No.☐ Cash/Check

Total Packages

1

Total Weight

15

Total Charges

Credit Card Auth.

8 Release Signature

Sign to authorize delivery without obtaining signature.

NO POUCH NEEDED

See back for peel and stick application instructions.