



CARDIOVASCULAR
CLINICAL ASSOCIATES, P.C.

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F.A.C.O.I.

Daniel R. Harber, D.O.
F.A.C.C., F.A.C.O.I.

Mark A. Rasak, D.O.
F.A.C.C., F.A.C.O.I., F.S.C.A.I.

David P. Gowman, D.O.
F.A.C.C., F.A.C.O.I., F.A.S.E., F.A.S.N.C.

M. Imran Qureshi, M.D.
F.A.C.C., F.S.C.A.I.

Mukarram A. Siddiqui, M.D.

Mohamad H. Kabbani, M.D.
F.A.C.C.

Majid Qazi, D.O.

Mark Sierra, M.D.

Nenad Serafimovski, M.D.

January 21, 2010

United States Nuclear Regulatory Commission
Region III, Materials Licensing
2443 Warrenville Road Ste 210
Lisle, IL 60532-4352

RE: Amendment to add authorized user
NRC License No. 21-26391-01

Dear Sir or Madam:

Please add the following individuals as authorized user physicians
to our NRC license for 10 CFR 35.200.

Nenad Serafimovski, M.D.
Mark Sierra, M.D.

Copies of the the physician's board certification (CBNC) and
preceptor forms (313A) AUD are enclosed.

If you have any questions or require additional information, please
contact our medical physics consultant, Cari Dzanbazoff, at 734-
662-3197 or fax 734-662-3197. E-mail correspondence can be
sent to Cdz@mpcphysics.com.

Sincerely,

Executive Management
Cardiovascular Clinical Associates, P.C.



FARBROOK CENTER

29877 Telegraph Road
Suite 400
Southfield, MI 48034
(248) 799-2600
Fax: (248) 799-2604
www.heartdrs.com

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Certification Board of Nuclear Cardiology

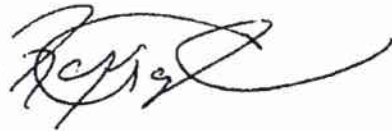
Incorporated 1996

Certifies that

Mark Sierra, 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 2007 - 2017



President



Secretary



CERTIFICATE NUMBER: 5780

**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

Mark Sierra, M.D.

State or Territory Where Licensed

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 (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 (*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)

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)

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(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 Mark Sierra 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

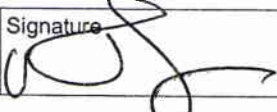
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

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>David Gowman, DO</u> | Signature  | Telephone Number <u>298-799-2600</u> | Date <u>1-20-2010</u> |
| License/Permit Number/Facility Name <u>21-2391-01 Cardiovascular Clinical Associates, PC</u> | | | |

Certification Board of Nuclear Cardiology

Incorporated 1996

Certifies that

Nenad Serafimovski, 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 2007 - 2017



President



Secretary



CERTIFICATE NUMBER: 5779

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
Nenad Serafimovski M.D.

State or Territory Where Licensed
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 | | | |
| 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 (*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 _____ 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 Nenad Serafimovski 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

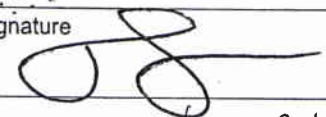
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

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>David Gouman, D.O.</u> | Signature  | Telephone Number <u>248-799-2000</u> | Date <u>1-20-10</u> |
| License/Permit Number/Facility Name <u>21-26391-01 Cardiovascular Clinical Associates, P.C.</u> | | | |

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City FARMINGTON HILLS State MI ZIP 48336

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Company US ...

Recipient's Address ...

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City _____ State MI ZIP ...



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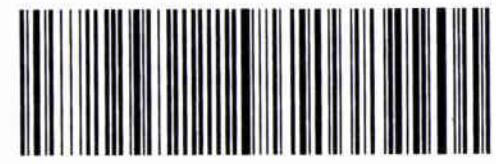
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 FedEx 3Day Freight

5 Packaging

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 FedEx Pak*
 FedEx Box
 FedEx Tube
 Other

6 Special Handling

SATURDAY Delivery
 HOLD Weekday at FedEx Location
 HOLD Saturday at FedEx Location

Does this shipment contain dangerous goods?
 No Yes
 Dry Ice Cargo Aircraft Only

7 Payment Bill to:

Sender
 Recipient
 Third Party
 Credit Card
 Cash/Check

Total Packages _____ Total Weight _____

Your liability is limited to \$100 unless you declare a higher value. See the current FedEx Service Guide for details.

8 Residential Delivery Signature Options

No Signature Required
 Direct Signature
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