

Ted Bialy, MD, FACP, FACC
Andrey Espinoza, MD
Jonathan Horiuchi, MD, FACC
Austin H. Kutscher, Jr, MD, FACC
Robert S. Lind, MD, FACC
Andrew G. Rudnick, MD
Dubravka Starcevic, MD, FACC
Glen E. Tonnessen, MD, FACC, FSCAI

RECEIVED
REGION I

2008 SEP 25 AM 10:17

Br. 2

Dennis Lawyer
US NRC Region I
475 Allendale Rd.
King of Prussia, PA 19406-1415

September 23, 2008

Re : Amendment Request for Hunterdon Cardiovascular,
License #: 29-30542-01

03035260

Dear Mr Lawyer,

I am requesting an amendment to the above referenced license in order to:

1. Add the following authorized users to the license:

a) Dubravka Starcevic, M.D.

Dr. Starcevic's credentials are attached for your review.

We recently submitted an amendment request which included adding Dr. Starcevic to our license as an authorized user. You wanted evidence that Dr. Starcevic had been trained in the use of generators as well as the other qualifications submitted. Dr. Starcevic attended a training session at our radiopharmacy to address this need on 9/23/08. I have amended page three of her form 313A to reflect this additional training and have included that and other forms.

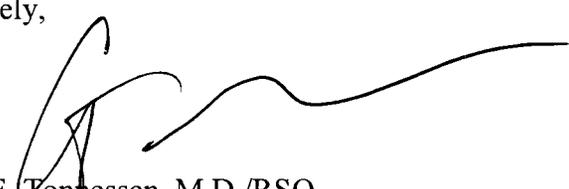
All other aspects of our program will remain the same. We have already submitted an amendment request to the New Jersey Department of Environmental Protection, radioactive materials section, in order to duplicate these changes on our State license, as well.

If you have any questions or need any additional information please contact me at your convenience at (908) 788-6460.

**Hunterdon Doctors
Office Building**
1100 Wescott Drive, Suite G3
Flemington, NJ 08822
908 788-6471 | FAX 908 788-6460
www.hunterdoncardiovascular.com

**Hunterdon Health and
Wellness Center**
Third Floor
537 Route 22 East
Whitehouse Station, NJ 08889
908 823-9200 | FAX 908 823-9211
www.hunterdoncvhealth.com

Sincerely,


Glen E. Tonnessen, M.D./RSO

Attachments: Physicians Credentials

REC'D IN LAT

9/24/08

Ref. 142525

142830
NMSS/RGN! MATERIALS-002

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Licensing Specialist
US NRC- Region I
475 Allendale Rd.
King of Prussia, PA 19406-1415

June 16, 2008

Re: **Nuclear Cardiology Qualifications for Dubravka Starcevic, M.D.**

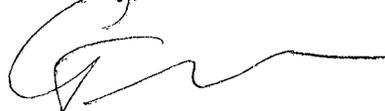
Dear Licensing Specialist,

I have worked closely with Dubravka Starcevic, M.D. for the past 8 years, since she joined our practice on 8/1/01. She has been fully integrated into our nuclear cardiology diagnostic lab operating under the authority granted in license **NRC-29-30542-01** and **NJSL-20666** under my supervision.

During that time period, Dr Starcevic has completed more than the 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of by-product material, as outlined in 10 CFR 35.290, paragraph (c). In addition, Dr Starcevic has successfully completed the radiation physics courses offered by the Institute for Nuclear Medicine Education.

I believe that Dr. Starcevic has achieved a level of competence sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200 and the authority granted by the above referenced radioactive materials license.

Sincerely,



Glen E. Tonnessen, M.D.
RSO/Authorized User

Radioactive Materials License # **NRC-29-30542-01**, and **NJSL-20666**



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NUCLEAR MEDICAL EDUCATION PROGRAM

Affidavit of Academic Completion & Competency

This document is to attest that

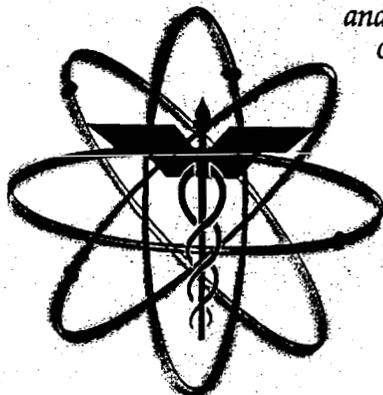
Dubravka Imsirovic, MD

has successfully completed the didactic program

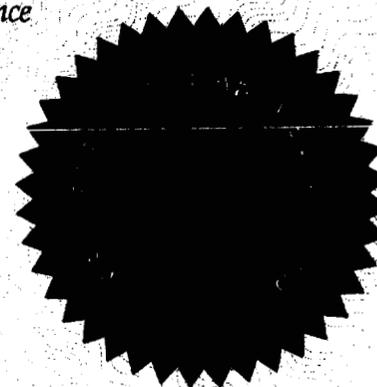
PRINCIPLES OF RADIATION PHYSICS

and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.

This program provides the following levels of accomplishment:



- 5.0 Continuing Education Units (CEU)
- 50 Didactic Instructional Hours (DIH)
In compliance with 10CFR35/AEA 73-689
- 50 Board Accepted Hours NUSPEX, NMTCB III b,
ABMRSO, CBNC, MRLB
- 3.0 Semester Hours American Council on
Education (ACE), American Association for
Collegiate Registrars



Charles H. Rose

Certifying Official

18 October 2000

Date Completed

198696

Certification

Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.

INME1132-Class I-Compl&Comp 1/00

NUCLEAR MEDICAL EDUCATION PROGRAM

Affidavit of Academic Completion & Competency

This document is to attest that

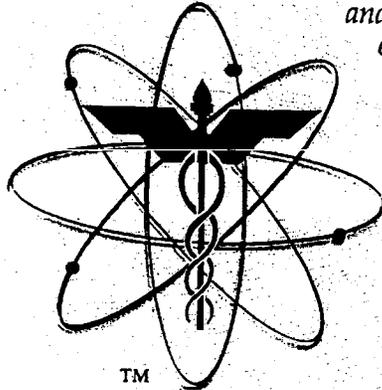
Dubravka Imsirovic, MD

has successfully completed the didactic program

MEDICAL RADIATION INSTRUMENTATION

and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.

This program provides the following levels of accomplishment:



TM

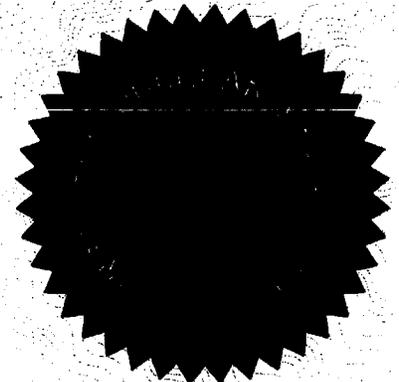
5.0 Continuing Education Units (CEU)

50 Didactic Instructional Hours (DIH)

In compliance with 10CFR35/AEA 73-689

50 Board Accepted Hours NUSPEX, NMTCB III b,
ABMRSO, CBNC, MRLB

3.0 Semester Hours American Council on
Education (ACE), American Association for
Collegiate Registrars



Charles H. Rose

Certifying Official

22 October 2000

Date Completed

198754

Certification

Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.

NIME1132-Class II-Comp&Corp 1/00

NUCLEAR MEDICAL EDUCATION PROGRAM

Affidavit of Academic Completion & Competency

This document is to attest that

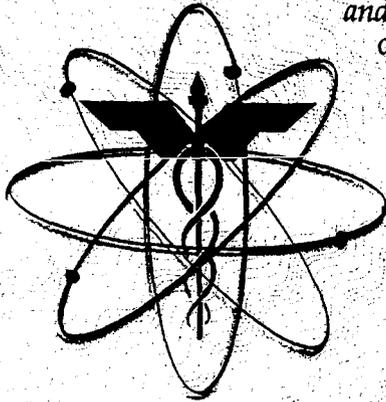
Dubravua Imsirouc, MD

has successfully completed the didactic program

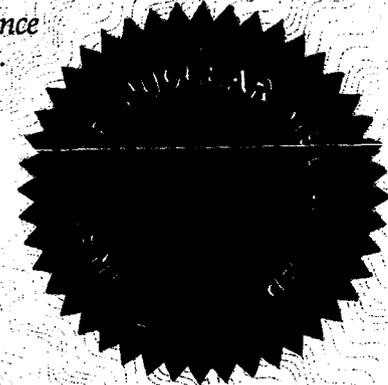
MEDICAL RADIATION PROTECTION

and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.

This program provides the following levels of accomplishment:



- 5.0 Continuing Education Units (CEU)
- 50 Didactic Instructional Hours (DIH)
In compliance with 10CFR35/AEA 73-689
- 50 Board Accepted Hours NUSPEX, NMTCB III b,
ABMRSO, CBNC, MRLB
- 3.0 Semester Hours American Council on
Education (ACE), American Association for
Collegiate Registrars



Charles H. Rose
Certifying Official

14 March 2001

Date Completed

199054

Certification

Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.

INME 1132 Class III-Comp & Comp. 1/00

NUCLEAR MEDICAL EDUCATION PROGRAM

Affidavit of Academic Completion & Competency

This document is to attest that

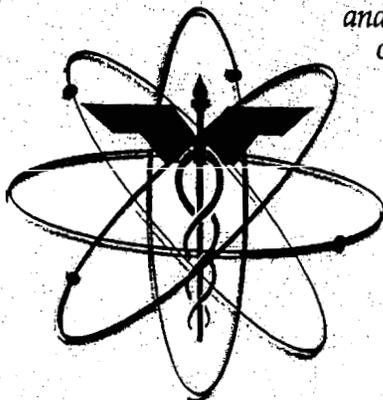
Dubravua Imsirouc, MD

has successfully completed the didactic program

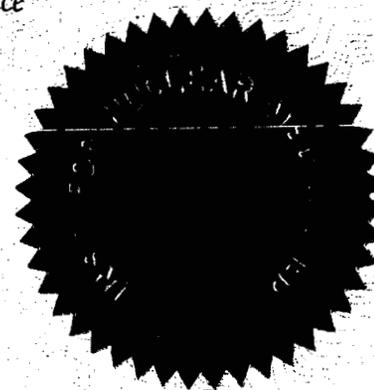
RADIOPHARMACEUTICALS AND CHEMISTRY

and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.

This program provides the following levels of accomplishment:



- 5.0 Continuing Education Units (CEU)
- 50 Didactic Instructional Hours (DIH)
In compliance with 10CFR35/AEA 73-689
- 50 Board Accepted Hours NUSPEX, NMTCB III b,
ABMRSO, CBNC, MRLB
- 3.0 Semester Hours American Council on
Education (ACE), American Association for
Collegiate Registrars



Charles H. Rose

Certifying Official

18 March 2001

Date Completed

199125

Certification

Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.

INME1132-Class IV-Comp&Comp 1/00

**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

Dubravka Starcevic, M.D.

State or Territory Where Licensed

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 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	Institute for Nuclear Medical Education	200	Completed
Radiation protection			October 2000
Mathematics pertaining to the use and measurement of radioactivity			to March 2001
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.)**

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	Hunterdon Cardiovascular Associates	<input type="checkbox"/> Yes <input type="checkbox"/> No	2002-2008
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	Includes participation in: > 2000 Tc ^{99m} Stress Tests > 30 Tl ²⁰¹ Studies > 640 Pharmacokinetic Stress Tests	<input type="checkbox"/> Yes	2007 - 2008
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes	↓
Administering dosages of radioactive drugs to patients or human research subjects		<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 Glen E. Tonnessen, M.D.		License/Permit Number listing supervising individual as an authorized user 29-30542-01	
Supervisor meets the requirements below, or equivalent Agreement State requirements (check one). <input type="checkbox"/> 35.190 <input checked="" 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.

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 _____ 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 Dubravka Starovic, M.A. has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

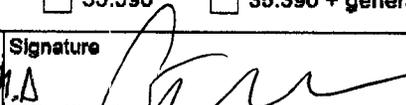
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

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>Glen E. Tannessen, M.D.</u>	Signature 	Telephone Number	Date <u>7/29/08</u>
License/Permit Number/Facility Name	<u>29-30542-01</u>		<u>9/23/08</u>

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

9/23/08, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (29-30542-01) 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** 142830.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.