



Raritan Bay Medical Center

Advancing care every day

Perth Amboy Campus • 530 New Brunswick Avenue, Perth Amboy, New Jersey 08861 • (732) 442-3700
Old Bridge Campus • One Hospital Plaza, Old Bridge, New Jersey 08857 • (732) 360-1000

July 13, 2007

NMSB1

United States Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA. 19406-1415

Attention: Licensing Assistance Section

Re: License # 29-11935-01

03002539

To Whom It May Concern:


Raritan Bay Medical Center would like to request the addition of Mark Moshiyakhov, M.D. as an authorized user for materials listed in 10CFR 35.100 and 35.200 for cardiovascular clinical procedures. Documentation of Dr. Moshiyakhov's training and experience is attached.

At this time, we are also notifying you that William Zinn, M.D. is no longer performing duties as an authorized user under the above referenced Materials license.

If you have any questions, please contact myself or our consultant physicist at (732)324-5037.

Thank you for your time and cooperation in this matter.

Sincerely,


Michael R. D'Agnes
President and CEO

RECEIVED
REGION I

2007 JUL 19 PM 12:41

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NMSS/RGN1 MATERIALS-002

*Recipient of the Magnet Award for Nursing Excellence
A Major Clinical Affiliate of the University of Medicine and Dentistry of New Jersey - Robert Wood Johnson Medical School
Affiliated with The Cancer Institute of New Jersey
Member of the Robert Wood Johnson Health Network*

NRC FORM 313A (AUD) (3-2007)		U.S. NUCLEAR REGULATORY COMMISSION		APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008	
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]					
Name of Proposed Authorized User Mark Moshiyakhov			State or Territory Where Licensed New Jersey		
Requested Authorization(s) (check all that apply)					
<input type="checkbox"/> 35.100 Uptake, dilution, and excretion studies					
<input checked="" type="checkbox"/> 35.200 Imaging and localization studies					
<input type="checkbox"/> 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.					
<input type="checkbox"/> 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.					
<input type="checkbox"/> 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).					
<input type="checkbox"/> 35.290 <input type="checkbox"/> 35.390 + generator experience in 32.290(c)(1)(ii)(G)					


NRC FORM 313A (AUD)
(3-2007)

U.S. NUCLEAR REGULATORY COMMISSION

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	INME-Institute for Nuclear Medical Education	100	9/16/06 - 9/24/06; 10/14/06 - 10/22/06
Radiation protection	5660 Airport Blvd Suite 101 Boulder, CO 80301	30	9/16/06 - 9/24/06; 10/14/06 - 10/22/06
Mathematics pertaining to the use and measurement of radioactivity		20	9/16/06 - 9/24/06; 10/14/06 - 10/22/06
Chemistry of byproduct material for medical use (not required for 35.590)		30	9/16/06 - 9/24/06; 10/14/06 - 10/22/06
Radiation biology		20	9/16/06 - 9/24/06; 10/14/06 - 10/22/06
Total Hours of Training:		200	

- 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:	800 hours
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	Deborah Heart and Lung Center 200 Trenton Road Browns Mills, New Jersey 08015	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	July 2004 to June 2007
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Deborah Heart and Lung Center 200 Trenton Road Browns Mills, New Jersey 08015	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	July 2004 to June 2007

NRC FORM 313A (AUD)
(3-2007)

U.S. NUCLEAR REGULATORY COMMISSION

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	Deborah Heart and Lung Center 200 Trenton Road Browns Mills, New Jersey 08015	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	July 2004 to June 2007
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Deborah Heart and Lung Center 200 Trenton Road Browns Mills, New Jersey 08015	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	July 2004 to June 2007
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Deborah Heart and Lung Center 200 Trenton Road Browns Mills, New Jersey 08015	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	July 2004 to June 2007
Administering dosages of radioactive drugs to patients or human research subjects	Deborah Heart and Lung Center 200 Trenton Road Browns Mills, New Jersey 08015	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	July 2004 to June 2007
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	Cardinal Health- 200 Rittenhouse Circle - East Berthel, Pa 19007 License 34-29200-01(MD) <i>Kurt Z</i>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6/27/06

Supervising Individual

Harry J. Benigman, M.D., F.A.C.P.

License/Permit Number listing supervising individual as an authorized user

29-18190-01

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
Squibb Generator	Resident - ABIM Certified 1975	HARTEMANN UNIVERSITY Phila PA 1972-1975

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

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(3-2007)

U.S. NUCLEAR REGULATORY COMMISSION

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 _____ 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 Mark Moshiyakhov 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

Harry J. Lessig MD FACRP

Signature

Harry J. Lessig MD FACRP

Telephone Number

609-893-6611 Ext 20

Date

6/27/07

License/Permit Number/Facility Name

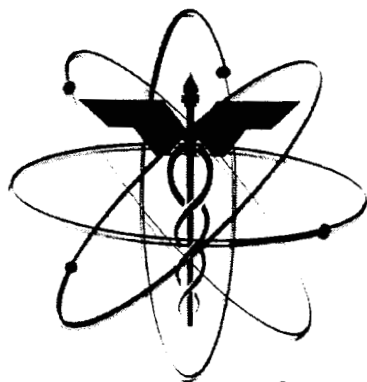
29-18190-01

FUNDAMENTALS
Radioisotope Handling
Attestation and Certification
Completion and Competency

This document is an affidavit that

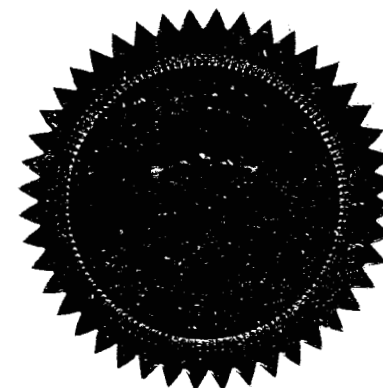
Mark Moshiyakhov, M.D.


*has successfully completed the prescribed didactic program of
education and has achieved the objectives of this program
as evidenced by written examination*



This Program provides the following levels of documented accomplishment

- 10.0 Continuing Education Units (CEU)
 - 100 Didactic Instructional Hours (DIH)
- In compliance with 10CFR35/ AEA 73-689
- 100 Board Accepted Hours NUSPEX, NMTCB III b,
ABMRSO, ABR, ABNM, CBNC




Certifying Official

24 September 2006
Date Completed

203925
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 American Council on Education (ACE), recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.

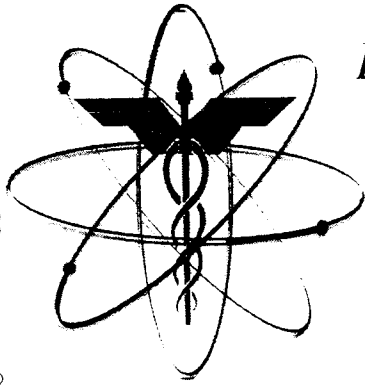
INME1132-Class I-Compl&Comp 1/00

CERTIFICATE OF COMPLETION

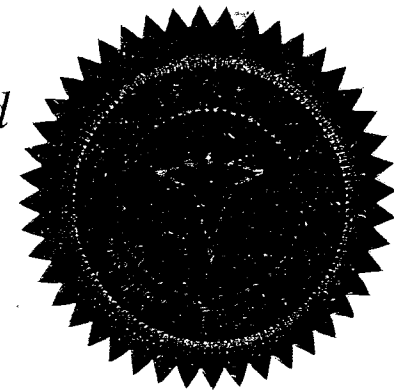
HAZMAT TRAINING - RADIOACTIVE MATERIALS

This document is to certify that

Mark Moshiyakhov, M.D.



*Has received training and has been tested
as required by 49CFR 172.704(d)*. This
training was limited to diagnostic
radioactive materials received or offered
for shipment in approved Type A
Packages, Class 7, UN2915, Yellow II.*




Certifying Official

22 October 2006

Date Completed

203943

Certification

Training Materials and Records are located at

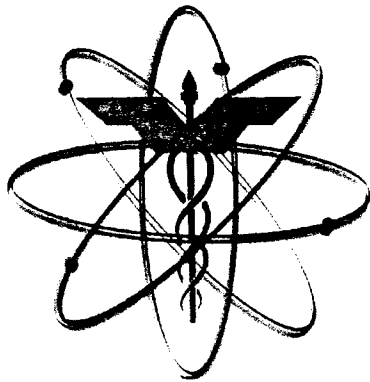
INME - Institute for Nuclear Medical Education • 5660 Airport Boulevard, Suite 101 • Boulder, Colorado 80301
(303) 541-0044 • (303) 541-0066 FAX • (800) 548-4024 • inme@nuclearcardiology.com • <http://www.nuclearcardiology.com/ncs>

EXTENDED COMPREHENSIVE *Radioisotope Handling* **Attestation and Certification Completion and Competency**

This document is an affidavit that

Mark Moshiyakhov, M.D.

*has successfully completed the prescribed didactic program of
education and has achieved the objectives of this program
as evidenced by written examination*

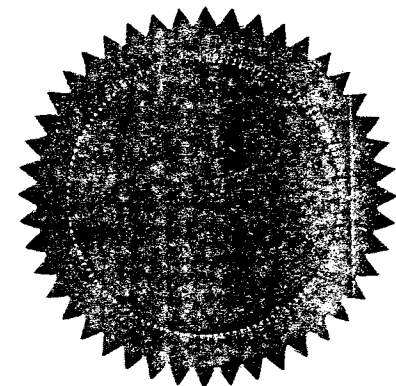


This Program provides the following levels of documented accomplishment

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


Certifying Official

22 October 2006
Date Completed



203962
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 American Council on Education (ACE), recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.

INME1132-Class I-Comp&Comp 1/00

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

7/13/2007, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amend. 29-11935-01
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** 140829.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.