

S E N T A R A

Sentara Williamsburg Regional Medical Center
100 Sentara Circle
Williamsburg, VA 23188
www.sentara.com

June 25, 2007

NMS01

U.S. Nuclear Regulatory Commission
Region I Office, Division of NMSS
Attn: Materials Licensing
475 Allendale Road
King of Prussia, PA 19406

Re: License No.: 45-16209-02

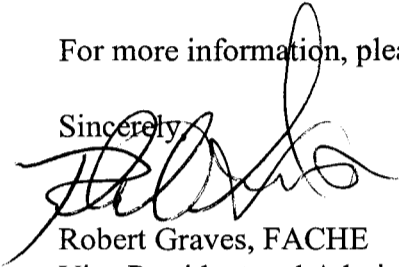
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To Whom It May Concern:

We would like to add Mozhdeh Salour, MD as an authorized user for 35.100 and 200: uptake, dilution, excretion, imaging and localization under our license. Enclosed is her residency verification letter and Form 313AUD.

For more information, please do not hesitate to contact Sandy Wolff, RSO, at (757) 388-3030.

Sincerely,



Robert Graves, FACHE
Vice President and Administrator

Enclosures

cc: Ms. Maureen Green, Manager, Imaging
Ms. Sandy Wolff, RSO

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REGION 1

140755

NMSS/RGN1 MATERIALS-002

**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

Mozhdeh Salour, MD

State or Territory Where Licensed

VA

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	VCU MCV See attached		1996- 2000
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:		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.)

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	VCU MCV 45-00048-17		1996- 2000
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	"		"

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	VCU MCV		196-2000
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
Paul R. Jolles MD	45-000 48-17

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)

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

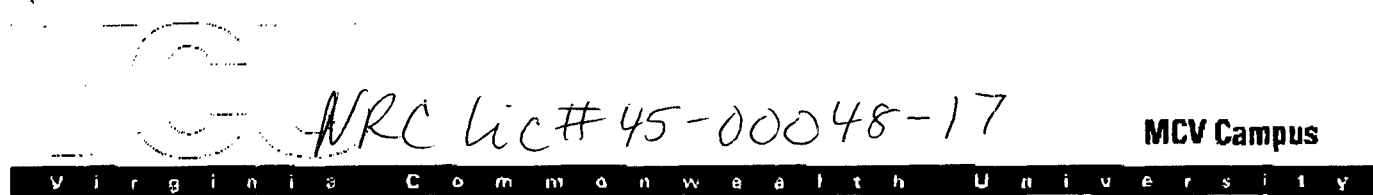
☒ I attest that Dr. Mozhdeh Salour has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function 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	Signature	Telephone Number	Date
Thomas Jamison MD		757-984 7910	06/25/07
License/Permit Number/Facility Name			
SWRMC # 45-16209-02			



Health System

MCV Hospitals and Physicians

MCV Campus

Department of Radiology Division of Nuclear Medicine

1300 East Marshall Street
P.O. Box 980001
Richmond, Virginia 23298-0001

804 828-6828
Fax: 804 628-0275 Scheduling
Fax: 804 828-4181
TDD: 1-800-828-1120

PRECEPTOR STATEMENT

June 19, 2007

Ms. Sandy Wolff
Radiation Safety Officer
Sentara Norfolk General Hospital
600 Gresham Drive
Norfolk, VA 23507

RE: Mozhddeh Salour, MD

Dr. Mozhddeh Salour has satisfied the requirements for imaging and localization studies (10 CFR 35.290) by successful completion of the Diagnostic Radiology Residency Training Program at Virginia Commonwealth University's Medical College of Virginia Hospitals from July 1, 1996, through June 30, 2000 and by receiving Board Certification in Diagnostic Radiology by the American Board of Radiology.

During her residency training, Dr. Salour has received the required training in the following areas:

200 hours of classroom and laboratory training
500 hours of supervised work experience
500 hours of supervised clinical experience

Should you need any further information, please do not hesitate to contact me.

Sincerely,

Paul R. Jolles, MD
Associate Professor of Radiology
Program Director, Nuclear Medicine

Melvin J. Fratkin, M.D.
Chairman

Paul R. Jolles, M.D.
804 828-7975

Karen Kurdziel, M.D.
804 827-4984

Jerry I. Hirsch, Pharm.D.
804 828-8267

Joseph D. Kalen, Ph.D., MSHA
804 828-1443

Sharon R. Gibbs, BS, CNMT
Manager
804 828-4175

This is to acknowledge the receipt of your letter/application dated 6/25/2007, and to inform you that the initial processing which includes an administrative review has been performed.

☒ AMEND. 45-16209-02 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** 140755.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.