

Kanawha Valley Heart Specialists, Inc.
dba West Virginia Heart & Vascular Institute
Scott P. Duffy, M.D. – Elie G. Gharib, M.D. – Mitchell N. Rashid, M.D.
Thomas Medical Office Pavilion
4607 MacCorkle Avenue, SW – Suite 300
South Charleston, West Virginia 25309
Office (304) 767-7780 Fax (304) 767-7789

NH62

March 14, 2008

US Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

03037413

Re: License # 47-31223-01

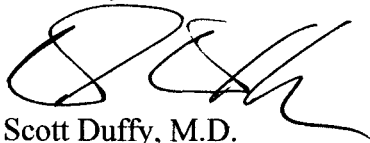
To Whom It May Concern:

Please amend our radioactive materials license as follows:

1. Add the following two (2) physicians to our license as authorized users for materials identified in 10 CFR 25.200:
Elie Gharib, M.D.
Mitchell Rashid, M.D.

Verification of physician training and experience is attached. Thank you in advance for your assistance.

Sincerely,


Scott Duffy, M.D.

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REGION I
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NMSS/RCN1 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

Elie Gharib, M.D.

State or Territory Where Licensed

West Virginia

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	Corscan See Certificate		
Radiation protection	See Certificate		
Mathematics pertaining to the use and measurement of radioactivity	See Certificate		
Chemistry of byproduct material for medical use (not required for 35.590)	See Certificate		
Radiation biology	See Certificate		
Total Hours of Training: 80			

- 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	Marshall University	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/98- 6/01
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Marshall University	<input checked="" 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	Marshall University	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/99 6/01
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Marshall University	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	↓
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Marshall University	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	↓
Administering dosages of radioactive drugs to patients or human research subjects	Marshall University	<input checked="" 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	CorScan	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Certificate

Supervising Individual

Tina M. Sias, MD

License/Permit Number listing supervising individual as an
authorized user

472562001

470957601

470040402

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 Elie Gharib, M.D. 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 Elie Gharib, M.D. 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 Tina M. Sias, MD	Signature <i>Tina M. Sias, MD</i>	Telephone Number 304-691-8500	Date 2/25/08
License/Permit Number/Facility Name 47-25620-01 47-09576-01 47-00404-02			

Certificate of Completion
Authorized User Classroom and Laboratory
Training Program

Elie G. Gharib, M.D.

has successfully completed 80 hours of classroom and laboratory training that included:

Radiation physics and instrumentation;

Radiation protection;

Mathematics pertaining to the use and measurement of radioactivity;

Chemistry of byproduct material for medical use;

Radiation biology; Generator elution for 10CFR35.290(ii)(G) and

Review of regulations regarding the medical use of radioisotopes.

Corscan

The Nuclear Imaging Company
www.corscanplus.com

Steven W. Walter, MD

Steven W. Walter, MD
Program Director
General Manager and CEO
CORS
910-528-6251
Authorized user and PG for CORS No. 07528351-01

October 4, 2007

Date



MARSHALL UNIVERSITY
Joan C. Edwards School of Medicine

www.marshall.edu

Department of Cardiovascular Services

May 23, 2006

RE: Mitchell Rashid, MD

TO WHOM IT MAY CONCERN:

I am an Authorized User listed on the Radioactive Materials License of the Huntington--WV, VA Medical Center, license number 47-03630. This communication is to confirm that Mitchell Rashid, M.D. has successfully completed all training requirements set forth by the Nuclear Regulatory Commission section §35.290, paragraph c (1) from July 1, 2003 to June 30, 2006. I attest he has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under the NRC guidelines 35.200.

Dr. Rashid has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. This training and experience included a minimum of the following:

A. 1) 80 hours of classroom and laboratory training in the following areas:

- a) Radiation physics and instrumentation,
- b) Radiation protection,
- c) Mathematics pertaining to the use and measurement of radioactivity;
- d) Chemistry of byproduct material for medical use;
- e) Radiation biology
- f) Generator Elution


2) Work experience, under the supervision of authorized user(s) Tina Sias, MD, Silvestre Cansino, MD and Imran Arif, MD, which meet the requirements in §§ 35.290, involving:

- a) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- b) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- c) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- d) Calculating, measuring, and safely preparing patient or human research subject dosages;

- e) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
- f) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
- g) Administering dosages of radioactive drugs to patients or human research subjects, and
- h) Eluting generator systems appropriate for 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

I am pleased to attest that Dr. Rashid has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under the NRC regulations CFR 35.290.

Sincerely,



Imran Arif, MD, FACC
Assistant Professor of Medicine

NRC or State Agreement Authorized User Numbers:

License # 47-25620-01
University Cardiovascular Services

License # 47-09576-01
St. Mary's Medical Center

License # 47-00404-02
Cabell Huntington Hospital

License # 47-03630
VA Medical Center

Certificate of Completion
Authorized User Classroom and Laboratory
Training Program

Mitchell Rashid, M.D.

has successfully completed 80 hours of classroom and laboratory training that included:

Corscan™
The Nuclear Imaging Company
www.corscanplus.com

Radiation physics and instrumentation; Radiation protection; Mathematics pertaining to the use and measurement of radioactivity; Chemistry of byproduct material for medical use; Radiation biology; Generator elution; Review of regulations regarding the medical use of radioisotopes and performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters.

Steven W. Walter, MD

May 18, 2006

Steven W. Walter, MD
Program Director
General Manager and CEO
CorScan Plus
910-246-0434
Authorized User NRC License No. 32-31038-01

Date

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

3/14/2008, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amend. 47-31223-a
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** 142280.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.