



**Charleston Area
Medical Center**

NUCLEAR PHARMACY

3200 MacCorkle Ave. SE
Charleston, WV 25304
(304) 388-9295
Pharmacy (304) 388-9701
Fax: (304) 388-8922

Br L

3/15/2011

U.S. NRC Region I
475 Allendale Road
King of Prussia, PA 19406-1415

03009164

Re: Amendment request License #47-15473-01

Dear Sirs,

Please amend the above referenced license as follows:

RECEIVED
REGION I
2011 APR 15 AM 11:24

1. Please add Casey Shaun Hager, M.D. as authorized users to the above referenced license. Please find enclosed:
 - Completed Section 3 part II Preceptor Attestation of NRC Form 313A.
 - Letter dated 6/22/2010 - Attestation of Training and Experience.
 - Certificate dated 3/1/2009 – Documented Classroom and Laboratory Training.

If there are any questions regarding this amendment please feel free to contact me at the telephone numbers provided below or you may e-mail your questions to me at kim.lowe@camc.org.

Sincerely,

Kim Lowe, Pharm.D., BCNP, Assistant RSO
Charleston Area Medical Center
3200 MacCorkle Avenue, SE
Charleston, WV 25304
(304) 388-9295 office
[REDACTED] mobile

George A. Farris, Associate Administrator
Charleston Area Medical Center
3200 MacCorkle Avenue, SE
Charleston, WV 25304
(304) 388-4367

574915

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: 3/31/2012

Name of Proposed Authorized User

Casey Shaun Hager

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)

NRC FORM 313A (AUD)

U.S. NUCLEAR REGULATORY COMMISSION

(9-2009)

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	Steff & White Hospital Temple TX	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	10/23/09 - 6/3/10
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	ii	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	10/23/09 - 6/3/10

NRC FORM 313A (AUD)
(9-2009)

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	Scott & White Hospital	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/07 - 6/30/10
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	"
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	"	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	"
Administering dosages of radioactive drugs to patients or human research subjects	"	<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	"	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	"

Supervising Individual



License/Permit Number listing supervising individual as an authorized user

L00331 Texas

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 _____ 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 Casey Hager 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

Mike Middleton

Signature

[Signature]

Telephone Number

254-724-7395

Date

10-6-10

License/Permit Number/Facility Name

L00331 Texas

Scott & White Memorial Hospital, Temple TX

**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

Casey Shaun Hager

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			
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:			

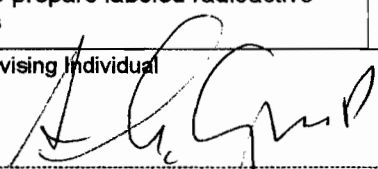
b. Supervised Work Experience (completion of this table is not required for 35.590).
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

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	Charleston Area Medical Ctr. Charleston, WV 47-15473-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	12/16/10			
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 47-15473-01					
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 _____ 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
Steven A. Artz, M.D.	[Signature]	304-388-7451	3/14/11

License/Permit Number/Facility Name
Charleston Area Medical Ctr. 47-15473-01



SCOTT & WHITE



TEXAS A&M
HEALTH SCIENCE CENTER
COLLEGE OF MEDICINE

June 22, 2010

TO WHOM IT MAY CONCERN

Re: Casey S. Hager, M.D.

This letter is to confirm that Dr. Hager has participated in the Level II Nuclear Cardiology training according to the American Society of Nuclear Cardiology Guidelines. He has completed >500 hours in clinical training as well as the required 200 hours of the Radiation Safety course, given by the Texas Heart Institute.

Dr. Hager has participated in >300 Myocardial Perfusion Studies as well as Angiographic correlation in >30 cases. The clinical training was at this institution, Scott & White Clinic, in the Division of Nuclear Radiology. His rotations were performed over 1 month intervals from July 2007 and completed in June 2010, as rotations during his Cardiology Fellowship Training.

If you should require further information, please do not hesitate to contact me.

Mike L. Middleton, M.D., FACNM, FASNC
Director, Division of Nuclear Medicine
Professor, Radiology

MLM:jcb

Health & Radiological Seminars, Inc.

Hereby certifies that

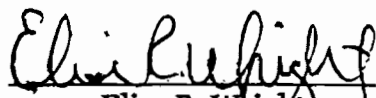
Casey S. Hagar M.D.

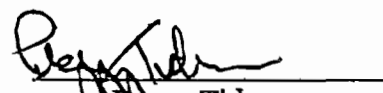
has successfully completed the 80 Hour Physician Training
Program in Basic Radioisotope Handling conducted
in accordance with the requirements of the
U.S. Nuclear Regulatory Commission (10 CFR 35).

COURSE OUTLINE

Radiation Physics and Instrumentation – 40 hours
Mathematics pertaining to the use and measurement of radioactivity - 15 hours
Radiation Protection – Radiopharmaceutical Chemistry - 15 hours
Radiation Biology – 10 hours

March 1, 2009


Elise R. Wright
Program Director


Peggy Tideman
Executive Director

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

3/15/2011 (^{RECEIVED} 4/15/2011), and to inform you that the initial processing which includes an administrative review has been performed.

☒ ATTEND. 47-15473-01 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** 574915.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.