



**Charleston Area
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NUCLEAR PHARMACY

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J-2

12/7/2010

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

Re: Amendment request License #47-15473-01
Docket Number: 03009164
Mail Control: 573837

Robin,

Per your request please find attached a completed NRC Form 313A (AUD).

Per our telephone conversation the previously enclosed certificate from Health & Radiological Seminars, Inc. outlining the hours of classroom and laboratory training will be accepted in place of a completed Section 3a.

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,

A handwritten signature in black ink, appearing to read 'Kim Lowe', written over a printed name.

Kim Lowe, Pharm.D., BCNP, Assistant RSO
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573837

NMSS/RGN1 MATERIALS-002

NRC FORM 313A (AUD)
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

**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. 3160-0120
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)

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 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 (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	Scott & 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	''	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	10/23/09 - 6/3/10

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 (3-2008)

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 <i>John White MD</i>	License/Permit Number listing supervising individual as an authorized user 100331 Texas
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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.

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(3-2009)

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)

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 <u>Mike Middleton</u>	Signature <u>[Signature]</u>	Telephone Number <u>254-724-7395</u>	Date <u>10-6-10</u>
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License/Permit Number/Facility Name
L00331 Texas ; Scott & White Memorial Hospital, Temple TX