

May 24, 2007

NRL

United States
Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406

03001276

RE: NRC License No. 06-09522-01

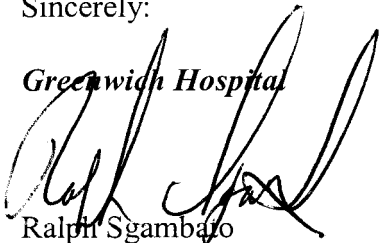
Dear Sir or Madam:

Please accept this letter as an application to amend our license to add Dr. Sarah Stewart as an Authorized User for Materials in 35.100 and 35.200. I have enclosed a preceptor attestation form.

If you have any additional questions regarding our request, please contact me at 203-863-3742.

Sincerely:

Greenwich Hospital



Ralph Sgambato
Administrative Director of Radiology

: Enclosures (1)

2007 MAY 29 PM 1:35

RECEIVED
REGION 1

140570

NMSS/RGN1 MATERIALS-002

5 Perryridge Road
Greenwich, CT 06830-4697
(203) 863-3000

NRC FORM 313A (AUD) (10-2006)		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 <i>Dr. Sarah Travis Stewart</i>			State or Territory Where Licensed <i>CT</i>		
Requested Authorization(s) (check all that apply)					
<input checked="" 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) <i>(please see next page)</i>					
* 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)
(10-2006)

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	Yale-New Haven Hospital Radiology Residency Program New Haven, CT 06510	25	7/2001 - 6/2005
Radiation protection	↓	25	↓
Mathematics pertaining to the use and measurement of radioactivity		25	
Chemistry of byproduct material for medical use (not required for 35.590)		25	
Radiation biology		25	
Total Hours of Training:		(125) 125	hours.

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	Yale-New Haven Hospital Radiology Residency Program New Haven, CT 06510	85	7/2001 - 6/2005
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	↓	85	↓
Calculating, measuring, and safely preparing patient or human research subject dosages	↓	90	↓

NRC FORM 313A (AUD)
(10-2006)

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	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	Yale-New Haven Hospital Radiology Residency Program New Haven, CT 06510	85	7/2001 - 6/2005
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	↓	85	↓
Administering dosages of radioactive drugs to patients or human research subjects		85	
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		85	

Total Hours of Experience:

600

Supervising Individual

License/Permit Number listing supervising individual as an authorized user

DAVID W. CHENG, MD, PhD

06-00819-03

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
N/A ↓	N/A ↓	N/A ↓

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

NRC FORM 313A (AUD)
(10-2006)

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 Sarah Travis Stewart 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 Sarah Travis Stewart has satisfactorily completed the ⁶⁰⁰~~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

DAVID W. CHENG

Signature

David W. Cheng

Telephone Number

203-785-2384

Date

5/14/07

License/Permit Number/Facility Name

06-00819-03

Yale-New Haven Hospital

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

5/24/2007, and to inform you that the initial processing which includes an administrative review has been performed.

☒ AMEND. 06-09522-01
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 140570.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.