



In alliance with
The University of Vermont

MCHV CAMPUS 111 Colchester Avenue
Burlington, VT 05401

*faxed ok
11/16/07*

FAX COVER SHEET

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K-3*

DEPARTMENT OF RADIATION ONCOLOGY
SHEPARDSON 2S MCHV - FAHC
111 COLCHESTER AVENUE
BURLINGTON, VT 05401

FAX: (802) 847-2386

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*44-10187-03
03003289*



Date of Transmittal:

11/16/07

FAX Number:

610 337 6921

TO:

NRC

Attn Michelle

Company Name:

Simmons

5269

FROM:

Maureen Moore

Radiation Oncology

Total number of pages:
(including cover sheet)

6

Comments:

*In response to your request for
additional information*



141246

License No.: 44-10187-03
Docket No: 03003289
Mail Control No: 141246

In your letter dated October 25, 2007 you requested to add Dr. Higgins as an authorized user. Please be advised, all proposed authorized users, including authorized user's qualifying under the board certification pathway, need preceptor attestations. Therefore, please provide the following additional information.

In support of your request to authorize Dr. Higgins for materials permitted under 10 CFR 35.100 and 35.200, please provide a written attestation, signed by a preceptor authorized user who meets the requirements in 10 CFR 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section 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.

Thank you for your help. If you have any questions, you may send an e-mail or call me at 610-337-6921. Please provide this information within 30 days of receipt of this letter. Please fax your signed response to 610-337-5269, referencing mail control number 141246. When you send the fax, you may wish to leave a voicemail or e-mail message to alert me to look for it.

Please send an e-mail to confirm receipt of this message

NRC FORM 313A (AUD) (3-2007)	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3160-0120 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 Timothy J. Higgins, M.D.		State or Territory Where Licensed Vermont				
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 checked="" type="checkbox"/> 35.500 Sealed sources for diagnosis (specify device as given in 6F License #44-10187-03)						
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.						
<input checked="" 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*	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:40%; height: 100px; vertical-align: top;"> 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 </td> <td style="width:30%;"></td> <td style="width:10%;"></td> <td style="width:10%;"></td> </tr> </table>		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			
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(e)(1)(ii)(G)						

NRC FORM 313A (AUD) (3-2007) **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			
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	

NRC FORM 313A (AUD) (3-2007) **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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
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 _____

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.

NRC FORM 313A (AUD) (3-2007) 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 [Name of Proposed Authorized User] has satisfactorily completed the requirements in

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 [Name of Proposed Authorized User] has satisfactorily completed the 60 hours of training and

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 Timothy J Higgins, M.D. has satisfactorily completed the requirements in

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 [Name of Proposed Authorized User] has satisfactorily completed the 700 hours of training

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: Janusz K Kikut, M.D. Signature: [Handwritten Signature] Telephone Number: 802 847-2526 Date: 11/16/2007 License/Permit Number/Facility Name: Fletcher Allen Health Care, Burlington, Vermont NRC License #44-10187-03