



SENTARA

Sentara CarePlex Hospital  
3000 Coliseum Drive  
Hampton, Virginia 23666

May 28, 2008

Br. 1

U.S. Nuclear Regulatory Commission  
Region I Office, Division of NMSS  
Attn: Materials Licensing  
475 Allendale Road  
King of Prussia, PA 19406

03063331

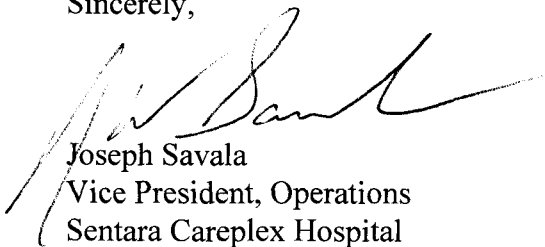
To Whom it may Concern, regarding NRC License No.: 45-09087-01

Attached are letters of attestation, board certificates and residency documents for Dr. Edward Trapani and Dr. Steven Pietruszynski to fulfill the training and experience documentation requirements of paragraph 10 CFR 35.290 (c) (1). We would like these physicians to be authorized for use of unsealed byproduct material under 10 CFR 35.100 and 35.200.

We would also like to add Delsin Khan as an authorized medical physicist for high dose rate brachytherapy. He is currently authorized on license 45-00131-02 as an AMP and has received vendor-specific training on this HDR unit.

For more information, please do not hesitate to contact our Radiation Safety Officer, Sandy Wolff, at (757) 388-3030.

Sincerely,

  
Joseph Savala  
Vice President, Operations  
Sentara Careplex Hospital

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NMSC/RONI MATERIALS-002

<b>NRC FORM 313A (AUD)</b> <small>(10-2007)</small>	<b>U.S. NUCLEAR REGULATORY COMMISSION</b>
<b>AUTHORIZED USER TRAINING AND EXPERIENCE                  AND PRECEPTOR ATTESTATION</b> (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 <b>Edward Trapani</b>	State or Territory Where Licensed <b>Virginia</b>
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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
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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**  
(10-2007) **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	University of Pittsburgh Medical Center	40	2001-2005
Radiation protection	University of Pittsburgh Medical Center	40	2001-2005
Mathematics pertaining to the use and measurement of radioactivity	University of Pittsburgh Medical Center	40	2001-2005
Chemistry of byproduct material for medical use <i>(not required for 35.590)</i>	University of Pittsburgh Medical Center	40	2001-2005
Radiation biology	University of Pittsburgh Medical Center	40	2001-2005
<b>Total Hours of Training: 200</b>			

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 600 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	University of Pittsburgh Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2001-2005
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	University of Pittsburgh Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2001-2005

**NRC FORM 313A (AUD)** (10-2007) **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	University of Pittsburgh Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2001-2005
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	University of Pittsburgh Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2001-2005
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	University of Pittsburgh Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2001-2005
Administering dosages of radioactive drugs to patients or human research subjects	University of Pittsburgh Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2001-2005
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	University of Pittsburgh Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2001-2005

Supervising Individual: **Barry McCook, MD**  
 License/Permit Number listing supervising individual as an authorized user: **37-00245-02**

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
	NA	

**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)  
(10-2007)

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)

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 **Edward Trapani** 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 **Edward Trapani** 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 <b>Stephen A. Fink, MD</b>	Signature 	Telephone Number <b>904.730.5405</b>	Date <b>5.20.08</b>
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License/Permit Number/Facility Name  
**Sentara Careplex Hospital, NRC License # 45-09087-01**

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Name of Proposed Authorized User <b>Steven Pietruszczynski</b>	State or Territory Where Licensed <input checked="" type="checkbox"/> <b>Virginia</b>
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Requested Authorization(s) (check all that apply)

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35.200 Imaging and localization studies

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Supervising Individual	License/Permit Number listing supervising individual as an authorized user
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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)** (10-2007) **U.S. NUCLEAR REGULATORY COMMISSION**  
**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

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**b. Supervised Work Experience (completion of this table is not required for 35.590).**  
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(10-2007)

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)**

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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	University of Pittsburgh Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2000-2004

Supervising Individual

License/Permit Number listing supervising individual as an authorized user

Barry McCook, MD

37-00245-02

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

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(10-2007) **AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

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**First Section**

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For 35.190

Board Certification

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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 **Steven Pietruszczynski** 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 **Steven Pietruszczynski** 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
Stephen A. Fink, MD		804-730-5405	5-20-08

License/Permit Number/Facility Name  
**Sentara Careplex Hospital, NRC License # 45-09087-01**

This is to acknowledge the receipt of your letter/application dated 6/19/08 <sup>received</sup>, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (45-09087-01) 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

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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** 142534.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.