



Terence M. Murphy, FACHE  
President and Chief Executive Officer  
640 S. State Street ~ Dover, DE 19901  
302.744.7000 ~ 302.744.7181 fax

February 9, 2015

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REC'D 02/17/15 AM 08:51

U.S. Nuclear Regulatory Commission  
Region 1  
2100 Renaissance Blvd., Suite 100  
King of Prussia, PA 19406-2713

RE: License No. 07-14850-01

To Whom It May Concern:

Bayhealth Medical Center wishes to amend our radioactive materials license, captioned above, to reflect the following:

- Please add the following Authorized Users for 35.100 and 35.200 materials use:
  - Zi Rong Xu, M.D. (see attached Form 313A and Board Certification)
  - Daniel Wood, M.D. (see attached Form 313A and Board Certification)

Please direct any questions about this amendment to our radiation safety officer, Adam M. Henry, at 866-755-2756 x 703.

Respectfully,

Terence M. Murphy, FACHE  
President and Chief Executive Officer

Enclosures:  
Form 313A  
Board Certification

586103  
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: (05/31/2015)

Name of Proposed Authorized User

Zi Rong XU, M.D.

State or Territory Where Licensed

Delaware

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			
<b>Total Hours of Training:</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 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		<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.**

**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 Zi Rong XU 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 Zi Rong XU 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 Zi Rong XU 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 <u>Vijay Viswanathan</u>	Signature <u>[Signature]</u>	Telephone Number <u>302-744-7062</u>	Date <u>11-25-14</u>
License/Permit Number/Facility Name <u>Bayhealth Medical Center 07-14850-01</u>			

# The American Board of Radiology

*Organized through the cooperation of the  
American College of Radiology, the American Roentgen Ray Society,  
the American Radium Society, the Radiological Society of North America,  
the Section on Radiology of the American Medical Association,  
the American Society for Radiation Oncology, the Association of  
University Radiologists, and the American Association of Physicists in Medicine*

*Hereby certifies that*

**Zi Rong Xu, MD**

*Has pursued an accepted course of graduate study  
and clinical work, has met certain standards and qualifications, including  
passing the examinations conducted under the authority of  
The American Board of Radiology,  
demonstrating to the satisfaction of the Board that he is qualified to practice,  
and is therefore awarded the Board's certification in the specialty of*

**AB Eligible**

**Diagnostic Radiology**

*Effective June 30, 2010*

*Frederic J. Harp*  
President

*Richard T. Morin*  
Secretary-Treasurer

*Hayden R. ...*  
Executive Director



Certificate No. 59374

Valid through 2020

**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: (05/31/2015)

Name of Proposed Authorized User

State or Territory Where Licensed

*Daniel Wood*

*De*

Requested Authorization(s) (check all that apply)

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**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).

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**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

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Radiation biology			
<b>Total Hours of Training:</b>			

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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		<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*).

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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 Daniel Wood 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 Daniel Wood 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 <u>Tom Vaerhagen</u>	Signature <u>[Signature]</u>	Telephone Number <u>302-744-7062</u>	Date <u>10/14/14</u>
License/Permit Number/Facility Name <u>Bayhealth Medical Center</u>		<u>07-14850-01</u>	

# The American Board of Radiology

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American College of Radiology, the American Roentgen Ray Society,  
the American Radium Society, the Radiological Society of North America,  
the Section on Radiology of the American Medical Association,  
the American Society for Radiation Oncology, the Association of University Radiologists,  
the American Association of Physicists in Medicine, and the Society of Interventional Radiology,  
the American Board of Radiology hereby certifies that*

**Daniel Joseph Wood, MD**

*Has pursued an accepted course of graduate study and clinical work; has met certain standards  
and qualifications, including passing the examinations conducted under the authority of  
the American Board of Radiology, demonstrating to the satisfaction of the Board qualification  
to practice; and is therefore awarded the Board's certification in*

## Diagnostic Radiology

All Eligible



Certificate No. 63213

*Ongoing validity of this certificate is contingent upon  
meeting the requirements of Maintenance of Certification.*

*This diplomate of the American Board of Radiology  
is permitted to use the **ABR** mark to signify this certification.*

*James P. Boyette, MD*  
President

*[Signature]*  
Secretary-Treasurer

*[Signature]*  
Executive Director

ABR



Effective: June 12, 2013

This is to acknowledge the receipt of your letter application dated

2-09-15, and to inform you that the initial processing which includes an administrative review has been performed.

Amend : 07-14850-01  
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** 586103.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)  
(6-96)

Sincerely,  
Licensing Assistance Team Leader