

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

Br. 1 03007565

PEC RG 1 V2 17*15 PM0251

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:
 - o Zi Rong Xu, M.D. (see attached Form 313A and Board Certification)
 - o 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

NRC FORM 313A (AUD)	U.S. NUCLEA	AR REGULATORY COMMISSION	I	
(05-2012) AUTHORIZED USER TF AND PRECEPT (for uses defined under [10 CFR 35.190,	OR ATTESTA 35.100, 35.200	ΓΙΟΝ), and 35.500)	APPROVED BY EXPIRES: (05/3	OMB: NO. 3150-0120 1/2015)
Name of Proposed Authorized User	:	State or Territory Where License	ed	
Zikong XU, M.D.		Delavare		
Requested Authorization(s) (check all that	apply)			
35.100 Uptake, dilution, and excretion	studies			
35.200 Imaging and localization studie	S			
35.500 Sealed sources for diagnosis (specify device)			
(S	elect one of the th	AND EXPERIENCE hree methods below)		
* Training and Experience, including boa the date of application or the individual the required training and experience wa education and experience related to the	must have obtained as completed. Prov	d related continuing education vide dates, duration, and des	on and experie	nce since
1. Board Certification				
a. Provide a copy of the board certific	ation.			
 b. If using only 35.500 materials, stop Preceptor Attestation. 	here. If using 35.	100 and 35.200 materials, sl	kip to and com	plete Part II
2. Current 35.390 Authorized User	Seeking Addition	al 35.290 Authorization		
a. Authorized user on Materials Lice	nse	meeting 10 CFR 35.	390 or equival	ent Agreement
State requirements seeking autho	rization for 35.290.			
 b. Supervised Work Experience. (If more than one supervising individual copies of this section.) 	vidual is necessary	to document supervised wo	rk experience,	provide multiple
Description of Experience		Experience/License or 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	of Experience:		
Supervising Individual		License/Permit Number listing authorized user	supervising ind	ividual as an
Supervisor meets the requirements b	-	Agreement State requireme in 32.290(c)(1)(ii)(G)	ents (check all	that apply).

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²⁾ AUTHORIZED USER TRAINING A	ND EXPERIENCE AND PRECEPTOR AT	TESTATION (co	ontinued)	
3. Training and Experience for Propo	sed 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:		1	
	eletion of this table is not required for 35.590 dual is necessary to document supervised w			
Supervised Work Experience Total Hours of Experience:				
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experienc	
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		☐ Yes ☐ No		
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		Yes No		

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Training and Experience for Pr	oposed Authorized Use	<u>er</u> (continued)		
b. Supervised Work Experience.	(continued)			
Description of Experience Must Include:		Experience/License or lumber of Facility	Confirm	Dates of Experience
Calculating, measuring, and safe preparing patient or human resea subject dosages			☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving use of unsealed byproduct mater			Yes No	
Using procedures to contain spill byproduct material safely and usi proper decontamination procedu	ng		Yes No	
Administering dosages of radioad drugs to patients or human resea subjects	tive rch		☐ Yes ☐ No	
Eluting generator systems approp for the preparation of radioactive drugs for imaging and localizatior studies, measuring and testing th eluate for radionuclidic purity, and processing the eluate with reager kits to prepare labeled radioactive drugs	e I		☐ Yes ☐ No	
Supervising Individual		icense/Permit Number listir uthorized user	ng supervising indiv	/idual as an
Supervisor meets the requiremer	•	•		
35.190 35.290	35.390 35	5.390 + generator experie	ence in 35.290(c)(1)(ii)(G)
c. For 35.590 only, provide docur				
Device	Type of Training] L	ocation and Da	tes

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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AUTHORIZED USER TRAINING AND EXPERIEN	CE AND PRECEPTOR ATTESTATION (continued)
	PTOR ATTESTATION
individual as long as the preceptor provides, directs	ceptor. The preceptor does not have to be the supervising s, or verifies training and experience required. If more than e, obtain a separate preceptor statement from each. (Not
By checking the boxes below, the preceptor is attes of the position sought and not attesting to the indivi	sting that the individual has knowledge to fulfill the duties dual's "general clinical competency."
First Section	
Check one of the following for each use requested:	
<u>For 35.190</u>	
Board Certification	
I attest that Zi Kow XU Name of Proposed Authorized User	has satisfactorily completed the requirements in
10 CFR 35.190(a)(1) and has achieved a level of authorized user for the medical uses authorized	of competency sufficient to function independently as an under 10 CFR 35.100.
	OR
Training and Experience	
Name of Proposed Authorized User	has satisfactorily completed the 60 hours of training and
	classroom and laboratory training, required by 10 CFR
	etency sufficient to function independently as an
For 35.290	
Board Certification	
I attest that Z: Rong XU Name of Proposed Authorized User	has satisfactorily completed the requirements in
10 CFR 35.290(a)(1) and has achieved a level of authorized user for the medical uses authorized	of competency sufficient to function independently as an under 10 CFR 35.100 and 35.200.
	DR
Training and Experience	
I attest that	has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User	
	rs of classroom and laboratory training, required by 10 competency sufficient to function independently as an under 10 CFR 35.100 and 35.200.
Second Section Complete the following for preceptor attestation and sig	gnature:
meet the requirements below, or equivalent Ag	greement State requirements, as an authorized user for:
35.190 35.290 35.390	35.390 + generator experience
Name of Preceptor Signature	Telephone Number Date
Vijay Viswanathan Syl	302-744-7062 11-25-14
License/Permit Number/Facility Name	
Bayhealth Medical	Center 07-14850-01
NRC FORM 313A (AUD) (05-2012)	Center VI 19830 VI PAGE 4

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The American Radiclogy of the American Medical Association of the American Society for Radiclogy, the American Medical Association, the American Society for Radiclogy, the Association of Minersity 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,

AU Fligible

Diagnostic Radiology Effective June 30, 2010

and is therefore awarded the Board's certification in the specialty of

barre H Happer

Richard I. Morin Berretary-December

Hay Pelayin

Malid through 2020

Certificate No. 59374

NRC FORM 313A (AUD) (05-2012)	U.S. NUCLEAR REGULATORY COMMISSIO	N	
AND PRECEPT (for uses defined under	RAINING AND EXPERIENCE FOR ATTESTATION r 35.100, 35.200, and 35.500) , 35.290, and 35.590]	APPROVED BY EXPIRES: (05/3	OMB: NO. 3150-01 1/2015)
Name of Proposed Authorized User	State or Territory Where Lice	nsed	
Requested Authorization(s) (check all that	t apply)		
X 35.100 Uptake, dilution, and excretion			
35.200 Imaging and localization studie			
35.500 Sealed sources for diagnosis (
P/	ART I TRAINING AND EXPERIENCE		
•	Select one of the three methods below)		
the date of application or the individual	ard certification, must have been obtained with must have obtained related continuing educa as completed. Provide dates, duration, and c e uses checked above.	ation and experie	nce since
1. Board Certification			
a. Provide a copy of the board certific	cation		
	p here. If using 35.100 and 35.200 materials	skip to and com	nloto Port II
Preceptor Attestation.	phere. In using 55,100 and 55,200 materials	, skip to and com	piele Fait ii
2 Current 35 390 Authorized User	Seeking Additional 35.290 Authorization		
a. Authorized user on Materials Lice		35 390 or equival	ent Agreement
State requirements seeking author			•
b. Supervised Work Experience. (If more than one supervising indicopies of this section.)	ividual is necessary to document supervised	work experience,	provide multip
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			
purity, and processing the eluate with reagent kits to prepare labeled	Total Hours of Experience:		
purity, and processing the eluate with reagent kits to prepare labeled	Total Hours of Experience: License/Permit Number list authorized user	ing supervising ind	ividual as an

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. Training and Experience for Propos	sed 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</i> 35.590)			
Radiation biology			
	Total Hours of Training:		
b. Supervised Work Experience (comp (If more than one supervising individ provide multiple copies of this sectio	letion of this table is not required for 35.590 lual is necessary to document supervised v n.))). vork experience,	
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		Yes No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper		Yes No	

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Training and Experience for Propose	ed Authorized User (continue	ed)	
b. Supervised Work Experience. (con	tinued)		
Description of Experience Must Include:	Location of Experience/L Permit Number of Fa		Dates of Experience
Calculating, measuring, and safely preparing patient or human research subject dosages		Ves No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		☐ Yes ☐ No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		☐ Yes ☐ No	
Administering dosages of radioactive drugs to patients or human research subjects		☐ Yes ☐ 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		☐ Yes ☐ No	
Supervising Individual	License/Permi authorized use	it Number listing supervising indi er	vidual as an
Supervisor meets the requirements be		State requirements <i>(check one</i> erator experience in 35.290(c	
c. For 35.590 only, provide documenta	tion of training on use of the de	evice.	
Device	Type of Training	Location and Da	ates

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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	RM 313A (AUD)		•		U.S. NUCLEAR REGULATORY COMMISS
(05-2012)	AUTHORIZED US	SER TRAININ	NG AND EXPERI	ENCE AND PRECEP	TOR ATTESTATION (continued)
			PART II – PREC	EPTOR ATTESTATIO	ON
Note:	This part must be completed by the individual's preceptor. The preceptor does not have to be the supervi individual as long as the preceptor provides, directs, or verifies training and experience required. If more one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (N required to meet training requirements in 35.590)			and experience required. If more than	
				testing that the individ ividual's "general clini	lual has knowledge to fulfill the duties ical competency."
	ection one of the followir	ng for each i	use requested:		
For	35.190				
	Board Certification		0		
	-X + attest that	Name of Prop	Wood osed Authorized User	has satisfactorily c	completed the requirements in
				el of competency suffi ed under 10 CFR 35.	cient to function independently as an 100.
				OR	
	Training and Expe	rience			
	I attest that	Name of Prop	osed Authorized User	has satisfactorily o	completed the 60 hours of training and
	35.190(c)(1), a	nd has achie	ved a level of con		ratory training, required by 10 CFR function independently as an 100.
For	35.290				
	Board Certification				
	☑ I attest that _	Danie Name of Prop	1 Wood	has satisfactorily o	completed the requirements in
	10 CFR 35.290 authorized use)(a)(1) and ha r for the med	as achieved a leve lical uses authoriz	el of competency suffi ed under 10 CFR 35.	cient to function independently as an 100 and 35.200.
	The second s	•		OR	
	Training and Expe	nence			
	I attest that	Name of D		has satisfactorily o	completed the 700 hours of training
	and experience	•	osed Authorized User minimum of 80 h	ours of classroom and	d laboratory training, required by 10
	CFR 35.290(c)	(1), and has	achieved a level of	of competency sufficient ed under 10 CFR 35.	ent to function independently as an
	d Section				
Comp	lete the following f	or precepto	r attestation and	signature:	
	I meet the requ	uirements bel	low, or equivalent	Agreement State req	uirements, as an authorized user for:
	35.190	X 35.290	35.390	35.390 + gene	erator experience
l			Signature	Λ	Telephone Number Date
Name	of Preceptor		AM		305-744-7062 10/14/1

The American Board of Radiology 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 Bourd's certification in

Diagnostic Radiology

All Eligible

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 BABB mark to signify this certification.

James P. Bay tele U.O Iresident



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Effective: June 12, 2013

Certificate No. 63213

Secretary-Treasurer

This is to acknowledge the receipt of your letter application dated

2-09-15 2 - 09 - 15, and to inform you that the initial processing which includes an administrative review has been performed. -14850 OI OThere 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.

X 6 I Your action has been assigned Mail Control Number 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)

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Sincerely, Licensing Assistance Team Leader

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