COMMUNITY Cospital

February 3, 2014

Materials Licensing Branch USNRC Region III 2443 Warrenville Road Lisle, IL 60532-4351

Re: 13-15882-01 License Amendment for Community Hospital Re: 13-01148-01 License Amendment for St. Mary Medical Center Re: 13-03459-03 License Amendment for St. Catherine Hospital

Dear Madam/Sir:

In reference to our November 6, 2013 request to amend the above mentioned licenses, attached are the required 313A AUD preceptor forms signed by Dr. Jonathan Lee.

Dr. Lee is an authorized under 35.100 and 35.200 on our license for Community Hospital, 13-15882-01, St. Mary Medical Center 13-01148-01 and St. Catherine Hospital 13-03459-03.

1. Thomas Shin, MD

Attachment: 313A AUD form

2. Ramana Yedavalli, MD

Attachment: Attachment: 313A AUD form

3. Justin Spackey, MD

Attachment: Attachment: 313A AUD form

If you have any further questions, please contact me at 219-836-7351 or jpkatz@comhs.org.

Sincerely, Jorqueline Laz IRT, MB+

Jacqueline Katz, RT, MBA

Director of Medical Physics

Community Healthcare System

NRC FORM 313A (AUD)

U.S. NUCLEAR REGULATORY COMMISSION

(05-2012)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION

APPROVED BY OMB: NO. 3150-0120 EXPIRES: (05/31/2015)

(for uses defined under [10 CFR 35.190,			Ì	
Name of Proposed Authorized User RAMANA V. YEDAVAC	11	State or Territory Where License	ed	
Requested Authorization(s) (check all that a				
35.100 Uptake, dilution, and excretion s				
35.200 Imaging and localization studies				
35.500 Sealed sources for diagnosis (s	pecify device)		No. de contracto de la contrac	
		NG AND EXPERIENCE three methods below)		
* Training and Experience, including board the date of application or the individual me the required training and experience was education and experience related to the	must have obtain s completed. Pr	ned related continuing education rovide dates, duration, and des	on and experie	ence since
1. Board Certification				
a. Provide a copy of the board certifica	ation.			
 b. If using only 35.500 materials, stop in Preceptor Attestation. 	here. If using 3!	5.100 and 35.200 materials, sk	cip to and com	plete Part II
2. Current 35.390 Authorized User S	Seeking Additio	onal 35.290 Authorization		
a. Authorized user on Materials Licens		meeting 10 CFR 35.3	390 or equival	ent Agreement
State requirements seeking authorize		0.		
b. Supervised Work Experience. (If more than one supervising individual copies of this section.)	idual is necessa	ry to document supervised wo	rk experience,	provide multiple
Description of Experience		of Experience/License or hit 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:	the state of the s	
Supervising Individual		License/Permit Number listing authorized user	supervising indi	vidual as an
Supervisor meets the requirements below 35.290 35.390 + gene		nt Agreement State requirement e in 32.290(c)(1)(ii)(G)	nts (check all t	that apply).

3. Training and Experience for Prop	AND EXPERIENCE AND PRECEPTOR AT		
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 (not required for 35.590)			
Radiation biology			
	Total Hours of Training:		
	npletion of this table is not required for 35.590 vidual is necessary to document supervised vition.)		
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 operation of survey meters		☐ Yes	

FORM 313A (AUD) D12) AUTHORIZED USER TRAI	INING AND	EXPERIENC	E AND PREC		CLEAR REGULA STATION (CO		
Training and Experience for F	Proposed A	uthorized Us	ser (continue	d)			
b. Supervised Work Experienc	e. (continue	inued)					
Description of Experience Must Include:	Э		Experience/Li Number of Fa		Confirm	Dates of Experience	
Calculating, measuring, and sar preparing patient or human reso subject dosages			Marie Marie		☐ Yes		
Using administrative controls to prevent a medical event involvir use of unsealed byproduct mater	ing the				Yes No		
Using procedures to contain spi byproduct material safely and u proper decontamination proced	using				Yes No		
Administering dosages of radioa drugs to patients or human rese subjects					☐ Yes		
Eluting generator systems approfor the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, approcessing the eluate with reage kits to prepare labeled radioactive drugs	e on the nd ent				☐ Yes		
Supervising Individual			License/Permit I authorized user	Number listing so	upervising indiv	idual as an	
Supervisor meets the requireme	∍nts below, c	or equivalent /	Agreement Sta	ate requiremen	its (check one).	
35.190 35.290	35.3	90 _ 3	5.390 + gener	rator experience	e in 35.290(c))(1)(ii)(G)	
c. For 35.590 only, provide docu		of training on u		Charles and the second of the	ation and Dat	tes	
d. For 35.500 uses only, stop he							

NRC	FORM	313A	(AUD)

U.S. NUCLEAR REGULATORY COMMISSION

(05-2012)

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 individual as long as the preceptor provides, directs, or verifies training and experies one preceptor is necessary to document experience, obtain a separate preceptor st required to meet training requirements in 35.590)	nce required. If more than
	By checking the boxes below, the preceptor is attesting that the individual has know of the position sought and not attesting to the individual's "general clinical competer	
	t Section ck one of the following for each use requested:	
For:	For 35.190	
	Board Certification	
	I attest that DR. YCDA VALL 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 authorized user for the medical uses authorized under 10 CFR 35.100.	on independently as an
	OR	
	Training and Experience	
	I attest that has satisfactorily completed the	60 hours of training and
	Name of Proposed Authorized User	required by 10 CEP
	experience, including a minimum of 8 hours of classroom and laboratory training 35.190(c)(1), and has achieved a level of competency sufficient to function indepartments dustrial user for the medical uses authorized under 10 CFR 35.100.	endently as an
For 3	or 35.290	
	Board Certification	
	I attest that Name of Proposed Authorized User has satisfactorily completed the	requirements in
	10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function authorized user for the medical uses authorized under 10 CFR 35.100 and 35.20	on independently as an 10.
	OR	
	Training and Experience I attest that has satisfactorily completed the	700 hours of training
	I attest that Name of Proposed Authorized User Name of Proposed Authorized User	700 floars of training
	and experience, including a minimum of 80 hours of classroom and laboratory tra CFR 35.290(c)(1), and has achieved a level of competency sufficient to function authorized user for the medical uses authorized under 10 CFR 35.100 and 35.20	independently as an
	ond Section plete 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 experien	
Name of	of Preceptor Signature / Telephone N	lumber Date
JON4-	147400 LEE 110 Jan 29-836-	4568 1-22-14
	se/Permit Number/Facility Name	Gol Hac Arthur
13	se/Permit Number/Facility Name 13-15882-01 The Community Hospital	Munskr, 1221

NRC FORM 313A (AUD) (05-2012)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION

APPROVED BY OMB: NO. 3150-0120

	35.100, 35.200, and 35.500)	EXPIRES: (0	5/31/2015)
	35.290, and 35.590]		
ame of Proposed Authorized User	State or Territory Where Lice	ensed	
Thomas Sin	IN		
equested Authorization(s) (check all that a	apply)		
₹35.100 Uptake, dilution, and excretion si	tudies		
35.200 Imaging and localization studies			
35.500 Sealed sources for diagnosis (sp	pecify device)		
	RT I TRAINING AND EXPERIENCE lect one of the three methods below)		
the date of application or the individual mi	certification, must have been obtained with ust have obtained related continuing educa completed. Provide dates, duration, and du uses checked above.	ition and experi	ence since
1. Board Certification			
a. Provide a copy of the board certificati	ion.		
 b. If using only 35.500 materials, stop he Preceptor Attestation. 	ere. If using 35.100 and 35.200 materials,	skip to and con	nplete Part II
2. Current 35.390 Authorized User Se	eking Additional 35,290 Authorization		
Authorized user on Materials License State requirements seeking authorize		5.390 or equiva	lent Agreement
 b. Supervised Work Experience. (If more than one supervising individual copies of this section.) 	lual is necessary to document supervised w	ork experience,	, provide multiple
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 authorized user	g supervising indi	ividual as an
Supervisor meets the requirements below	w, or equivalent Agreement State requireme	ents (check all t	hat apply).
35.290 35.390 + genera	ator experience in 32.290(c)(1)(ii)(G)		

Authorized User		
July 1 v 1 v v v v v v v v v v v v v v v v		
** **	Clock	Dates of
Location of Training	Clock Hours	Dates of Training*
sando e e e conserva donte entre escripción e entre de la conserva	a processor and the second sec	
The state and a first contract of		income to highway and a list of
		11. 11.00
l Hours of Training		
l Hours of Training:		
		to seem whose me no .
of this table is not required for 35.590) necessary to document supervised wo	rk experience,	To the control of the
of this table is not required for 35.590) necessary to document supervised wo	ı. ork experience,	1 pro-10
of this table is not required for 35.590). necessary to document supervised wo	Confirm	Dates of Experience
of this table is not required for 35.590) necessary to document supervised wo Total Hours of Experience: ocation of Experience/License or	Confirm Yes	
of this table is not required for 35.590) necessary to document supervised wo Total Hours of Experience: ocation of Experience/License or	Confirm	
of this table is not required for 35.590) necessary to document supervised wo Total Hours of Experience: ocation of Experience/License or	Confirm Yes No	
of this table is not required for 35.590) necessary to document supervised wo Total Hours of Experience: ocation of Experience/License or	Confirm Yes	
		Hours

	Training and Experience for Prop	osed Authorized L	iser (continued)		
	b. Supervised Work Experience. (d	ontinued)			
:	Description of Experience Must Include:		of Experience/License of Number of Facility	Confirm	Dates of Experience
	Calculating, measuring, and safely preparing patient or human research			Yes	
	subject dosages			☐ No	
	Using administrative controls to prevent a medical event involving the	e ·		Yes	
	use of unsealed byproduct material			☐ No	
	Using procedures to contain spilled byproduct material safely and using			Yes	
	proper decontamination procedures			No	· · · · · · · · · · · · · · · · · · ·
/	Administering dosages of radioactive drugs to patients or human research	•		Yes	
S	subjects			☐ No	
f	Eluting generator systems appropriat or the preparation of radioactive	e		Yes	
s e p k	trugs for imaging and localization tudies, measuring and testing the cluate for radionuclidic purity, and processing the eluate with reagent its to prepare labeled radioactive trugs			∏ No	
S	upervising Individual		License/Permit Number lis authorized user	sting supervising indiv	idual as an
s	Supervisor meets the requirements b		Agreement State requir 35.390 + generator expe		
	For 35.590 only, provide document	ation of training on	use of the device.		
	t Mais owner or mentals .				
-	Device	Type of Trainir	1 g	Location and Date	2 5
	11 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	1 No 1 a 100			11 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
		and the same specialism			

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	AUTHURIZED	JSER I KAINI			PTOR ATTESTATION	(continuea)
			PART II - PREC	EPTOR ATTESTATI	ON	
Note:	individual as long one preceptor is	g as the prece necessary to	ptor provides, direc	cts, or verifies training nce, obtain a separat	ptor does not have to be g and experience requir e preceptor statement fr	ed. If more than
				testing that the individual's "general clin	dual has knowledge to fi ical competency."	ulfill the duties
	Section one of the follow	ing for each	use requested:			
For	35.190					
	Board Certification	<u>in</u>				
	I attest that	Thomas Name of Prop	Shing	has satisfactorily of	completed the requireme	ents in
				l of competency sufficed under 10 CFR 35.1	cient to function indeper 100.	ndently as an
				OR		
	Training and Expe	<u>erience</u>				
	l attest that	Thomas Name of Propo	Shing osed Authorized User	has satisfactorily c	completed the 60 hours	of training and
	35.190(c)(1), a	and has achiev	ved a level of comp		ratory training, required function independently a 100.	
For:	<u>35.290</u>					
	Board Certification	<u>1</u>				
	l attest that	Name of Propo	sed Authorized User	has satisfactorily co	ompleted the requireme	ents in
				of competency suffic d under 10 CFR 35.1	tient to function indepen 00 and 35.200.	dently as an
	Terinian and Fran	Manaa		OR		
	Training and Expe	nence		hae eatisfactorily o	ompleted the 700 hours	of training
	attest that	Name of Propos	sed Authorized User	nas sausiacioniy ce	impleted the 700 flours	Or training
	CFR 35.290(c)	e, including a r (1), and has a	minimum of 80 hou chieved a level of o		laboratory training, requ t to function independer 00 and 35.200.	
	Section		-ttestation and si			,
ompie	<i></i>		attestation and sig	- .		and want fast
{	I meet the requ	irements belo	w, or equivalent Ag	greement State requi	rements, as an authoriz	ed user for:
	35.190	35.290	35.390	35.390 + genera	ator experience	
ame of F	Preceptor		Signature	- 1	Telephone Number	
	Arteon Lea Permit Number/Facility	y Name		U-	219-836-4569	1-30-14
					, 0 21	

The American Board of Radiology American College of Radichay, the American Runtgen Ray Secrety the American Radium Locaty, the Badulegical Levely of North America. the Section on Rudichagy of the American Medical Association

the American Society for Therapoula Budishayy and Onchagy, the Association of University Radiologists, and American Association of Physicists in Medicine Hereky certifies that

Thomas Arnold Shin, MD

Has pursued an accepted course of graduate study and clinical work, has met certain standards and qualifications and has passed the examinations conducted under the authority of The American Board of Radiology

On this arth day of June 2017

Thereby demonstrating to the satisfaction of the Board that he is qualified to practice the specialty of

Diagnostic Radiology

PP Hatter of



Certificate No. 55047

AN Eligible

Malid through 2017

NRC FORM 313A (AUD) (05-2012)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE

APPROVED BY OMB: NO. 3150-0120

AND PRECEPTOR ATTESTATION (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590]			EXPIRES: (0	5/31/2015)
ame of Proposed Authorized User		ate or Territory Where Lic	ansad	
JUSTIN SPACKEY	3.6	NDIANA	61136 u	
equested Authorization(s) (check all that a	арріу)			
\S 35.100 Uptake, dilution, and excretion s	tudies			
35.200 Imaging and localization studies				
35.500 Sealed sources for diagnosis (sp	pecify device)	and agreement to the second state of the secon		
	RT I TRAINING A	ND EXPERIENCE		
Training and Experience, including board the date of application or the individual m the required training and experience was education and experience related to the u	certification, must liust have obtained r completed. Provide	have been obtained wit related continuing educ e dates, duration, and o	ation and experi	ence since
1. Board Certification				
a. Provide a copy of the board certificat	tion.			
 b. If using only 35.500 materials, stop h Preceptor Attestation. 	iere. If using 35.100	0 and 35.200 materials	, skip to and con	nplete Part II
2. Current 35.390 Authorized User Se	eking Additional	35.290 Authorization		
a. Authorized user on Materials Licens	e	meeting 10 CFR 3	35.390 or equiva	lent Agreement
State requirements seeking authoriz	ation for 35.290.	and the state of t		
 b. Supervised Work Experience. (If more than one supervising individed copies of this section.) 	lual is necessary to	document supervised v	work experience	, provide multip
Description of Experience		perience/License or mber 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 E	xperience:	and the second s	almong various security security
Supervising Individual		ense/Permit Number listin	ng supervising ind	ividual as an
and the state of t	au	thorized user		

3. Training and Experience for Propos	sed Authorized User		
a. Classroom and Laboratory Training.		and a second section of the second se	the first and a day the planes and a red and
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			3
Chemistry of byproduct material for medical use (not required for 35.590)			
Radiation biology			
7	Total Hours of Training:	Andrew Control of the	
b. Supervised Work Experience (complet (If more than one supervising individual provide multiple copies of this section.)	ial is necessary to document supervised w)). vork experience,	
Supervised Work Experience	Total Hours of Experience:		AND STATEMENT COMMON
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	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper		Yes No	

Training and Experience for Propose	d Authorized User (continued)		
b. Supervised Work Experience. (conti	inued)		
Description of Experience Must Include:	Location of Experience/License of Permit Number of Facility	or Confirm	Dates of Experience
Calculating, measuring, and safely preparing patient or human research subject dosages		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		☐ Yes	
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	
Supervising Individual	License/Permit Number i authorized user	listing supervising indivi	dual as an
Supervisor meets the requirements below	w. or equivalent Agreement State requ	irements (check one)	J.
	35.390 35.390 + generator exp		
c. For 35.590 only, provide documentation	on of training on use of the device. Type of Training	Location and Date	Ð\$

NRC FORM 313A (AUD)				U.S. NUCLEAR REGULATORY COMMISSION	
(05-2012)	AUTHORIZED USER TRAI	NING AND EXPERI	ENCE AND PRECEP	TOR 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 of the position sought and no	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."			
	Section cone of the following for eac	h use requested:			
For	35.190				
	Board Certification	-			
	The state of the s	TH SPACKEY roposed Authorized User	has satisfactorily o	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 P	STIN SPACKET	has satisfactorily c	ompleted 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				
	attest that		has satisfactorily co	ompleted the requirements in	
	Name of Pr	oposed 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.				
	Training and Experience		OR		
			han estinfactorily or	ompleted the 700 hours of training	
	attest that	oposed Authorized User	nas sausiacioniy co	ompleted 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.					
	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					
i	Preceptor	Signature		Telephone Number Date	
10h	ATTHON LEE MES	1 yh-	andre reprovision the physical property and the residence of the control of the c	(2A)836-4569 1-30-14	
icense/F	Permit Number/Facility Name				

Simmons, Toye

From:

Jacqueline P. Katz < Jacqueline.P.Katz@comhs.org>

Sent:

Monday, February 03, 2014 11:11 AM

To:

Simmons, Tove

Cc:

Santosh K. Kar

Subject:

Follow up paperwork Community Healthcare System

Attachments:

Dr. Ramana Yedavalli 313A AUD form.pdf; Dr. Thomas Shin 313A AUD form.pdf; Dr. Justin Spackey 313A AUD form.pdf; Feb 2014 313A forms Spackey Shin Yedavalli.pdf

Dear Ms. Simmons:

Attached are the 313A AUD forms for Dr. Shin, Dr. Yedavalli and Dr. Spackey that were needed to complete our amendment requests. A letter is attached summarizing our follow up.

Thank you,

Jackie Katz
Director Radiation Oncology and Medical Physics
Community Hospital
Munster, IN

Office: 219-836-7351 Fax: 219-852-6476

This message and attachment(s), if any, is intended for the sole use of the individual and/or entity of which it is addressed, and may contain information that is privileged, confidential and prohibited from disclosure under applicable law. If you are not the addressee, or authorized to receive this on behalf of the addressee, you are hereby notified that you may not use, copy, disclose or distribute to anyone this message or any part thereof. If you have received this in error, please immediately advise the sender by email and delete this information and all attachments from your computer and network. Thank you.