Community Healthcare System

COMMUNITY Hospital

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,

Jacqueline Katz, RT, MBA

Jacqueline Katz, RT, MBA
Director of Medical Physics
Community Healthcare System

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

U.S. NUCLEAR REGULATORY COMMISSION

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
RAMANA V. YEDAVALLI	INDIANA

Requested Authorization(s) *(check all that apply)*

- [X] 35.100 Uptake, dilution, and excretion studies
- [X] 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.

[X] **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 *(not required for 35.590)*			
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		☐ 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	

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		☐ Yes ☐ 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/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)
(05-2012)

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 DR. YEDAVALLI 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 DR. YEDAVALLI 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	Signature	Telephone Number	Date
JONATHAN LEE MD		219-836-4569	1-22-14

License/Permit Number/Facility Name

13-15882-01 The Community Hospital 901 Mac Arthur Munster, IN 46321

NRC FORM 313A (AUD) (05-2012) | U.S. NUCLEAR REGULATORY COMMISSION

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: Thomas Shin

State or Territory Where Licensed: IN

Requested Authorization(s) *(check all that apply)*

- [X] 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.

[X] **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 *(not required for 35.590)*			
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		☐ 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	

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		☐ Yes ☐ 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/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) (05-2012) 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 Thomas Shin (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 Thomas Shin (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 _____ (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 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	Signature	Telephone Number	Date
JONATHON LEE MD	[redacted]	[redacted] 219-836-4569	1-30-14

License/Permit Number/Facility Name

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 Therapeutic Radiology and Oncology, the Association of University Radiologists, and American Association of Physicists in Medicine

Hereby 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 sixth day of June, 2007

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

Diagnostic Radiology

All Eligible

THE AMERICAN BOARD OF RADIOLOGY INCORPORATED IN THE DISTRICT OF COLUMBIA 1934

Certificate No. 56047

Peggy O Hickman, MD
President

Beth Erickson
Secretary-Treasurer

R.P. Hartey, MD
Executive Director

Valid through 2017

NRC FORM 313A (AUD) (05-2012) U.S. NUCLEAR REGULATORY COMMISSION

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
JUSTIN SPACKEY	INDIANA

Requested Authorization(s) *(check all that apply)*

- [X] 35.100 Uptake, dilution, and excretion studies
- [X] 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.

[X] **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 *(not required for 35.590)*			
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		☐ 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	

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		☐ Yes ☐ 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/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) (05-2012) 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 JUSTIN SPACKEY (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 JUSTIN SPACKEY (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 _____ (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 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	Signature	Telephone Number	Date
JONATHON LEE MD		(ZIP)836-4569	1-30-14
License/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, Toye
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