



**Charleston Area
Medical Center**

NUCLEAR PHARMACY

3200 MacCorkle Ave. SE
Charleston, WV 25304
(304) 388-9295
Pharmacy (304) 388-9701
Fax: (304) 388-8922

5/11/2011

J-9

U.S. NRC Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Re: Amendment request License #47-15473-01
Docket No. 030-09164
Control No. 574915

Dear Sirs,

Please amend the above referenced license as follows:

1. Please add Sangeeta Mandapaka, M.D. as authorized users to the above referenced license. Please find enclosed:
 - NRC Form 313A.
 - Training document dated 6/9/2009
 - Certificate of Completion dated 10/13/2009
 - Letter dated 10/22/2010 - Attestation of Training and Experience.

If there are any questions regarding this amendment please feel free to contact me at the telephone numbers provided below or you may e-mail your questions to me at kim.lowe@camc.org.

Sincerely,

Kim Lowe, Pharm.D., BCNP, Assistant RSO
Charleston Area Medical Center
3200 MacCorkle Avenue, SE
Charleston, WV 25304
(304) 388-9295 office
(304) 549-0147 mobile

George A. Farris, Associate Administrator
Charleston Area Medical Center
3200 MacCorkle Avenue, SE
Charleston, WV 25304
(304) 388-4367

574915

NMSS/RGN1 MATERIALS-002

NRC FORM 313A (AUD) (3-2009)	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 3/31/2012
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]		

Name of Proposed Authorized User Sangeeta Mandapaka, MD	State or Territory Where Licensed West Virginia
---	---

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)

NRC FORM 313A (AUD)
(3-2009)

J.S. NUCLEAR REGULATORY COMMISSION

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	see attached signed certificate Corscan- 80 hour classroom and laboratory training program		
Radiation protection	Program director- Steven Walter, MD RSO NC #092-1457-1 919-561-2111		
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: 80			

**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.)**

(PLEASE SEE LETTER)

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	

NRC FORM 313A (AUD)
(3-2009)

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		<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.

NRC FORM 313A (AUD)
(3-2008)

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 _____ 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 _____ 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
-------------------	-----------	------------------	------

License/Permit Number/Facility Name

Corscan™

The Nuclear Imaging Company
www.corscanimg.com
(910) 528-6251

Quality Control Procedures Worksheet

Name SANGEETA MANDAPAKA, MD

§ 35.290 Training for imaging and localization studies

Please complete the following activities and have them attested by the nuclear medicine technologist in the laboratory and fax to 703-895-4433.

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

Date Completed 6/9/09 Attestation Signature [Signature] CNMT III

(2) Calibrating instruments and performing quality control procedures used to determine the activity of dosages and performing checks for proper operation of survey meters;

Date Completed 6/9/09 Attestation Signature [Signature] CNMT III

(3) Calculating, measuring, and safely preparing patient or human research subject dosages;

Date Completed 6/9/09 Attestation Signature [Signature] CNMT III

(4) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

Date Completed 6/9/09 Attestation Signature [Signature] CNMT III

(5) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

Date Completed 6/9/09 Attestation Signature [Signature] CNMT III

(6) Administering dosages of radioactive drugs to patients or human research subjects;

Date Completed 6/9/09 Attestation Signature [Signature] CNMT III

Attester: (must be certified nuclear medicine technologist, authorized user, Radiation Safety Officer, or certified medical physicist)

Name: HEATHER GRILLO

Title: CNMT III, LEAD TECH

Telephone Number: 252-847-4770

Certificate of Completion
Authorized User
Classroom and Laboratory Training Program

Sangeeta Mandapaka, MD

has successfully completed 80 hours of classroom and laboratory training that included:

Radiation physics and instrumentation;

Radiation protection;

Mathematics pertaining to the use and measurement of radioactivity;

Chemistry of byproduct material for medical use;

Radiation biology; Generator elution for 10CFR35.290(ii) (G) and

Review of regulations regarding the medical use of radionuclides.

Corscan

The Nuclear Imaging Company

www.corscanplus.com

Steven W. Walter, MD

Steven W. Walter, MD

Program Director

910 528 6251

Radiation Safety Officer NC 092-1457-1

October 13, 2009

Date

January 19, 2009

Start Date

ECU PHYSICIANS

Smart medicine

East Carolina Heart Institute at East Carolina University
Department of Cardiovascular Sciences
Brody School of Medicine
115 Heart Drive
East Carolina University
Greenville, NC 27834-4354

252-744-4400 information
1-866-401-3244 toll free

Cardiothoracic Surgery
252-744-4400 office
252-744-5539 Fax

Vascular Surgery
252-744-4400 office
252-744-3794 fax

Cardiology Medicine
252-744-4400 office
252-744-3987 fax

October 22, 2010

To Whom It May Concern:

Dr. Sangeeta Mandapaka has completed a nuclear cardiology training program that meets the requirements for Level 2 as outlined in the *ACCF/ASNC COCATS Guidelines for Training in Nuclear Cardiology, revised 2006* within an accredited program.

Dr. Sangeeta Mandapaka completed Level 2 nuclear cardiology training between the dates of July 1, 2006 through June 30, 2009.

I attest that Dr. Sangeeta Mandapaka is competent to independently function as an authorized user under NRC 10 CFR 35.200 uses.

The above-named applicant completed a minimum of 80 hours of classroom and laboratory training that meets the NRC requirements external to his/her fellowship program.

Sincerely,



Assad Movahed, MD, FACP, FACC
Director of Cardiovascular Imaging
Professor of Medicine, Radiology and Cardiovascular Sciences
East Carolina University Brody School of Medicine
Nuclear License Number of Facility: 074-0296-3