

Mercy Jeannette Hospital
600 Jefferson Avenue
Jeannette, PA 15644

724 527 3551 telephone

L-6

March 13, 2006

Attention: Christopher Hott
Mail Control Number: 138191
U.S.N.R.C. Region 1
Division of Nuclear Materials Safety
475 Allendale Road
King of Prussia, PA 19406-1415

03009165

RE: License # 37-15471-01



To Whom It May Concern,

Please amend the above referenced license for our facility to reflect the following changes:

Add the following physician as an authorized user for oral administration of I-131 for Hyperthyroid and Thyroid Cancer treatment under Part 35.300:

Mani Bashyam, MD

For training and experience please refer to the enclosed document of training from the American Association of Clinical Endocrinologists, preceptor form 313A, and supporting documentation.

Also, please update information for authorized user **Stephen Kowalyk, MD** to use of oral administration of I-131 for Hyperthyroid and Thyroid Cancer treatment.

Please reference Westmoreland Regional Hospital NRC material license **030-09731** which lists him as a user for Hyperthyroid and cancer treatment.

Also, please add **35.500** to our material license for maximum amount of **500 mCi's**. Please update authorized user **Shyam Vijay Gohel, MD** to include **Use of sealed source for medical diagnosis Part 35.500**. This usage would be for **2 Gd-153 Profile** attenuation correction sources installed in a Siemens E-cam system.

Manufacturer: **Isotope Products Laboratories**
Model No: **NES-8726**
Activity: **100-125 mCi/each (Total max:250 mCi)**

After installation, training will be given by application specialist to all users in the correct handling and usage of sources. Please refer to the enclosed document entitled Siemens NM Clinical Applications Training Checklist, which details training that will take place.

138191

NMSS/RGN MATERIALS-002

Mercy Jeannette Hospital
600 Jefferson Avenue
Jeannette, PA 15644

724.527.3551 telephone

Delete the following authorized users:

**Usha V. Kanakamedala
Lawrence A Denino
Daniel M O'Roark**

Please feel free to contact the facilities RSO at (724)527-9252 with any questions.

Sincerely,

Edwin Miller, RSO

Edwin Miller, RSO
RSO, Mercy Jeannette Hospital



Enclosures

Siemens NM Clinical Applications Training Checklist - 2 -

General Guidelines for Applications Training

(Also see Pre-Application Checklist)

- During the turnover, a maximum of 2 technologists should be dedicated for the training period.
- Training for profile is 12 hours.
- Applications training should commence during normal business hours. Personnel from the 2nd or 3rd shift that are to be trained should be brought in at this time.
- Technologists scheduled for training must be removed from all responsibilities such as phone calls, scheduling of patients, coverage for other areas of department
- NRC and State inspections are to be completed no later than the week prior to the arrival of the applications specialist.
- Applications on OEM equipment (i.e.: laser imager) should be done prior to the arrival of the Siemens applications specialist.

Siemens NM Clinical Applications Training Checklist - 4 -

Overview of NM Applications Training Schedule

Day 1:

Please schedule two Patients for the afternoon

Arrival of application specialist

Safety Issues

System Quality Control Procedures

Camera and Gantry Explanation

Acquisition Protocols

Review of Recommended scanning Protocols

Last Day:

Schedule a routine patient schedule

Review checklist with customer

Scanning Procedures, Processing and Options

Image Evaluation and Film Technique

Post Installation Meeting

Address application issues from post installation meeting

Siemens NM Clinical Applications Training Checklist - 5 -**Siemens Application Training Checklist****Course title: e.cam profile 4.0 turnover*****Important: Please print clearly and complete each box.***

Applications Specialist:	
Training Date(s):	
Technologist name:	
Facility/ Site name:	
Dept.:	
Address: <input type="checkbox"/> Home <input type="checkbox"/> Work	
City, State Zip code:	
Tech. phone: <input type="checkbox"/> Home <input type="checkbox"/> Work	
Tech. email:	
Last four of Soc. Sec. #:	

ASRT Ref. # NCZ0195016 Possible credits: 11.5 Credits awarded: _____

Technologist Signature: _____**Date:** _____**Apps Spec. Signature:** _____**Date:** _____**Instructions:** Upon completion of training, forward this sheet *only* to MIC in **one** of the following ways. Please call 866-535-4528 with any questions.

Mail
MIC
CE Services – Siemens
1037 Route 46 East
Clifton, NJ 07013

Fax
973-574-8001

Email
Siemens@MICinfo.com

Siemens NM Clinical Applications Training Checklist - 6 -

To be initialed by both technologist and applications specialist:

Topic	Initials	Time
Profile Theory		120 min
Review Profile Lecture	_____	
Gantry		90 min
Hardware Orientation	_____	
Support Arm/Profile Wings	_____	
End Plate Removal	_____	
Loading Profile Sources	_____	
Display Panel / Persistence Scope (PPM)		45 min
Gantry Display	_____	
Detector Movement / Configuration	_____	
Patient Positioning Monitor (PPM) Display	_____	
PPM Display during Acquisition	_____	
c.cam Calibrations		90 min
Preparing Point Sources	_____	
Camera Preparation	_____	
Peaking & Tuning	_____	
Blank Scans	_____	
Daily QC / Initial QC	_____	
Monthly QC	_____	
Profile Source Replenishment	_____	
Ordering Profile Sources	_____	
Troubleshooting Techniques	_____	
e.soft		
Acquisition Workflows		90 min
Review & Modify Acquisition Workflows	_____	
Tomo & Gated-Tomo Acq.	_____	
Profile Acq. Workflows	_____	
Patient Setup & Positioning		30 min
Cardiac Tomo Imaging	_____	

Siemens NM Clinical Applications Training Checklist - 7 -**Processing Workflows**

60 min

Quality Control (Motion Correction)

AutoCardiac

3D Orientation

Flexible Display

30 min

Profile Review

Linking to additional programs

Dual Monitors

Saving JPEG, BMP, EMF & AVI

Third Party Packages

60 min

4D-MSPECT

Manuals Reviewed

15 min

Cleaning off System

10 min

Review with Physician

60 min

Hand Out Survey

1 min

- Introductory call to UPTIME Service Center Applications Hotline
Yes /No

Contact Phone

E-mail Address

Functional Location Number

System Model No. and Serial No.

Applications Specialist Name

Date

Trainee Signature

Date

NRC FORM 313A (10-2002)		U.S. NUCLEAR REGULATORY COMMISSION		APPROVED BY OMB: NO. 3180-0120 EOP REG: 10/31/2005	
TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT					
PART I - TRAINING AND EXPERIENCE					
Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulations.					
1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)					
<p style="text-align: center;"> AACE TRAINING MANI BASHYAM For 35.100 and 35.300 35:190 35:392 35:394 </p>					
2. For (Physicians, Podiatrists, Dentists, Pharmacists - State or Territory Where Licensed)					
<p style="text-align: center;">P.A</p>					
3. CERTIFICATION					
Specialty Board		Category		Month and Year Certified	
Stop here when using Board Certification to meet 10 CFR Part 35 training and experience requirements.					
4. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)					
Description of Training	Location	Clock Hours	Dates of Training		
Radiation Physics and Instrumentation	Kansas city, MO.	25	Sept 24 to OCT 1st 2005		
Radiation Protection	" "	25	"		
Mathematics Pertaining to the Use and Measurement of Radioactivity	" "	10	"		
Radiation Biology	" "	10	"		
Chemistry of Byproduct Material for Medical Use	" "	10	"		
OTHER					

NRC FORM 315A
(10-2002)U.S. NUCLEAR REGULATORY COMMISSION
TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

5a. WORK EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and Clock Hours of Experience
Ordering, receiving Radioactive Materials	PACE Instructor	Kansas City, MO	80 hrs
Calculating Doses	(Hands on Lab training)	9-24-05 Thru 10-1-05	↓
Spill containment			

5b. SUPERVISED CLINICAL CASE EXPERIENCE

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and Clock Hours of Experience
Na I ¹³¹	< 33 mCi	3	Dr. S. Kowalyk MD	Western Island Regional Hospital	3 hours
Na I ¹³¹	> 33 mCi	3	Dr. S. Kowalyk MD	# 37-02894- 02	3 hours

NRC FORM 313A (10-2002)		U.S. NUCLEAR REGULATORY COMMISSION	
TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)			
6. FORMAL TRAINING (applies to Medical Physicists and Therapy Physicists)			
Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Number	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)
NA			

7. RADIATION SAFETY OFFICER - ONE-YEAR FULL-TIME WORK EXPERIENCE

☐ YES Completed 1-year of full-time radiation safety experience (in areas identified in Item 5a) under supervision
☐ N/A of _____ the RSO for License No. _____

8. MEDICAL PHYSICIST - ONE-YEAR FULL-TIME TRAINING/WORK EXPERIENCE

☐ YES Completed 1-year of full-time training in therapeutic radiological physics under the supervision of
☐ N/A _____ who meets requirements for Authorized Medical Physicists; and

☐ YES Completed 1-year of full-time work experience (for areas identified in Item 5a) for _____
☐ N/A modality(ies) under the supervision of _____ who meets
requirements of Authorized Medical Physicists for _____ modality(ies).

9. SUPERVISING INDIVIDUAL - IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet requirements in 10 CFR 35, provide the following information for each):

A. Name of Supervisor Dr. S. Kowalyk, MD

B. Supervisor is:

☒ Authorized User ☐ Authorized Medical Physicist
☐ Radiation Safety Officer ☐ Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 190 392 394
for medical uses in Part 35, Section(s) 35.100 35.300 35.308

D. Address _____

E. Materials License Number 37-02894-02

NRC FORM 312A
(10-2002)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

PART II - PRECEPTOR STATEMENT

Note: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet the training requirements in 10 CFR 35.590.

Item 10 must be completed for Nuclear Pharmacists meeting the requirements of 10 CFR Part 35, Subpart J. Preceptors do not have to complete items 11a, 11b, or the certifying statements for other individuals meeting the requirements of 10 CFR Part 35, Subpart J.

- ☐ YES 10. The individual named in item 1 has satisfactorily completed the training requirements in 10 CFR 35.980 and is competent to independently operate a nuclear pharmacy.
- ☒ N/A

- ☒ YES 11a. The individual named in item 1 has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 19.0, 392, 394
- ☐ N/A

- ☒ YES 11b. The individual named in item 1 is competent to independently function as an authorized User for 35.100, 35.300 uses (or units).
- ☐ N/A

12. PRECEPTOR APPROVAL AND CERTIFICATION

- ☐ I certify the approval of item 10 and certify I am an Authorized Nuclear Pharmacist

OR

- ☐ I certify the approval of items 11a and 11b, and certify I am an Authorized Nuclear Pharmacist

OR

- ☒ I certify the approval of items 11a and 11b, and I certify that I meet the requirements of 19.0, 392, 394 or equivalent Agreement State requirements to be a preceptor authorized User for the following uses (or units) of byproduct material: 35.300, 35.100

A. Address

Mercy Jeanette Hospital
NUCLEAR MEDICINE DEPT
600 Jefferson Avenue
Jeanette, PA 15644

B. Materials License Number

37-15471-01

C. NAME OF PRECEPTOR (print clearly)

Dr. S. Kowalyk, MD

D. SIGNATURE - PRECEPTOR

[Signature]

E. DATE

10/12/15

PAGE 4

TOTAL P.04



American Association of Clinical Endocrinologists

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Editor in Chief, Endocrine Practice

EMERITUS 2006

Yank D. Corle, Jr., MD, MACP, MACP
Jacksonville, FL

October 5, 2005

Manu Bashyam, MD

Dear Dr. Bashyam:

The American Association of Clinical Endocrinologists (AACE) certifies that you successfully completed the following educational activity:

Program Title: AACE Nuclear Medicine Course

Date: September 24-October 1, 2005

Location: Kansas City, MO

Awarded: 80.25 category 1 credit(s) toward the AMA Physician's Recognition Award

The American Association of Clinical Endocrinologists (AACE) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The American Association of Clinical Endocrinologists designates this educational activity for a maximum of 80.25 category 1 credits toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

Please feel free to contact the AACE office if you have any questions.

Sincerely,

AACE CME Department

**PERSONAL INFORMATION WAS REMOVED
BY NRC. NO COPY OF THIS INFORMATION
WAS RETAINED BY THE NRC.**

The Voice of Clinical Endocrinology