

■ COMMUNITY ■ MEDICAL CENTER

An affiliate of the Saint Barnabas Health Care System

RONALD J. DEL MAURO
President and Chief Executive Officer
Saint Barnabas Health Care System

NMSSB1

MARK D. PILLA
Executive Vice President
Saint Barnabas Health Care System
and
Executive Director
Community Medical Center

August 28, 2007

United States Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

03012158

Re: Materials License 29-09806-03

Dear Sir or Madam,

At this time, Community Medical Center would like to amend its' Materials License, 29-09806-03, to reflect the addition of Kevin Willis, MD as an authorized user under 10 CFR 35.200.

Please find attached copies of Dr. Willis' documentation of training and experience.

If you have any questions or require additional information, please do not hesitate to contact me at 732-557-2036.

Sincerely,



William Caubet, MS, DABR
Radiation Safety Officer

2007 AUG 29 AM 10:08

RECEIVED
REGION 1

140996

NMSS/RGN1 MATERIALS-002



**MEDICAL USE TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**

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 regulation (10 CFR Part 35)

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

Kevin Willis Authorized User 10 CFR 35.290

2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed

New Jersey

3. CERTIFICATION

- a. Provide a copy of the board certification. (Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(a); continue if applying under other subparts.)
 - b. Provide documentation in appropriate items 4 through 10 of training or clinical case work required by 35.50(e); 35.51(c); 35.290(c)(1)(ii)(G) for AU seeking 35.200 authorization; 35.390(b)(1)(ii)(G); 35.396(d)(1) and 35.396(d)(2); 35.590(c); or 35.690(c).
 - c. Provide completed Part II Preceptor Attestation, Items 11a through 11d.
- Stop here after completing items 3a, 3b, and 3c when using board certification to meet 10 CFR Part 35 training and experience requirements.

4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO), AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICISTS (AMP), OR AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS

- a. Provide a copy of the license or broadscope permit listing the current authorization **and** (b) or (c)
- b. Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to meet requirements for: RSO in 35.50(c)(2) or 35.50(e); or AU in 35.290(c)(1)(ii)(G) or 35.390(b)(1)(ii)(G) or 35.590(c) or 35.690(c); or AMP under 35.51(c).
- c. Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).

5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	Rhode Island Hospital Providence, RI	80 hours Total	7/1/89 - 6/30/93
Radiation Protection			
Mathematics Pertaining to the Use and Measurement of Radioactivity			
Radiation Biology			
Chemistry of Byproduct Material for Medical Use			
OTHER			

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6a. WORK OR PRACTICAL EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
Training in Nuclear Medicine during Radiology Residency	R. Noto MD	Rhode Island 70-051-01	7/1/99 - 6/30/03 1000 hours

6b. SUPERVISED CLINICAL CASE EXPERIENCE (describe experience elements in 6a)

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
Tc-99m	Day work	700	R. Noto MD	Rhode Island 70-051-01	7/1/99 - 6/30/03
I-123	↓	80	↓	↓	↓
I-131		50			
Xe-133		50			
In-111		10			
Ga-67		10			
F-18		20			

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), or 35.690(c)

Training Element	Type of Training *	Location and Dates
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* Types of training may include supervised (complete item 10 for 35.50(e), 35.51(c), and 35.690(c)), didactic, or vendor training.

7. FORMAL TRAINING Physicians (for uses under 35.400 and 35.600) and Medical 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)
MD, Radiology Rhode Island Hospital	Rhode Island Hospital Radiology Residency, 78-051-01	7/1/99-6/30/03	ACGME

8. RADIATION SAFETY OFFICER (RSO) -- ONE-YEAR FULL-TIME EXPERIENCE

YES Completed 1 year of full-time radiation safety experience (in areas identified in item 6a) under supervision.
 N/A of _____ the RSO for License No. _____

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

YES Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics (35.961) or medical physics (35.51) under the supervision of _____
 N/A who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51);

and

YES Completed 1 year of full-time work experience (at location providing radiation therapy services described and for topics identified in item 6a) for (specify use or device) _____
 N/A under the supervision of _____ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device) _____

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

10. 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 Part 35, provide the following information for each) :

A. Name of Supervisor

Richard Noto, MD

B. Supervisor is:

Authorized User

Authorized Medical Physicist

Radiation Safety Officer

Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 35.290 & 35.390

for medical uses in Part 35, Section(s)

D. Address

Dept. of Diagnostic Imaging
Rhode Island Hospital
Providence, RI 02903

E. Materials License Number

70-051-01

PART II -- PRECEPTOR ATTESTATION

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 training requirements in 35.590 or Part 35, Subpart J (except 35.980).

I attest the individual named in Item 1:

11a.

has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 35.290 as documented in section(s) 5-7 of this form.

11b. Select one

meets the requirements in 35.50(e) 35.51(c) 35.390(b)(1)(ii)(G) 35.690(c) for types of use, as documented in section(s) of this form.

N/A

11c.

has achieved a level of competency sufficient to independently operate a nuclear pharmacy (for 35.980); **OR**

has achieved a level of competency sufficient to function independently as an authorized for uses (or units); **OR**

has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; **OR**

N/A

11d.

I am an Authorized Nuclear Pharmacist; **OR** I am a Radiation Safety Officer; **OR**

I meet the requirements of 35.290 & 35.390 section(s) of 10 CFR Part 35

or equivalent Agreement State requirements to be a preceptor AU or AMP

for the following byproduct material uses (or units):

A. Address

Dept of Diagnostic Imaging
Rhode Island Hospital
Providence RI 02903

B. Materials License Number

70-051-01

C. NAME OF PRECEPTOR (print clearly)

D. SIGNATURE -- PRECEPTOR

E. DATE

Richard Noto, MD

[Signature]

8/14/06

This is to acknowledge the receipt of your letter/application dated

8/28/2007, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 29-09206-03 There 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.

Your action has been assigned **Mail Control Number** 140996.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.