

# 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

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

NMSS

August 30, 2007

United States Nuclear Regulatory Commission  
Region 1  
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 William Didie, MD and Felix Kravets, MD as authorized users under 10 CFR 35.200.

Please find copies of Dr. Didie's and Dr. Kravets' 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

SEP - 4 2007 AM 10:52

RECEIVED  
REGION 1

140996

NMSS/RGN1 MATERIALS-002



NRC FORM 313A (AUD) (10-2006)	U.S. NUCLEAR REGULATORY COMMISSION
<b>AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION</b> (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: 10/31/2008

Name of Proposed Authorized User <b>Felix Kravetz, MD</b>	State or Territory Where Licensed <b>HJ</b>
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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 <b>Cora CABANOG, MD</b> <b>Terry Button Ph.D.</b>	License/Permit Number listing supervising individual as an authorized user <b># 455</b>
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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)  
(10-2005)

U.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	Stony Brook University	100	7/2000 - 6/30/2001 7/2002 - 6/30/2005
Radiation protection	Stony Brook University	50	↓
Mathematics pertaining to the use and measurement of radioactivity	Stony Brook University	20	
Chemistry of byproduct material for medical use (not required for 35.590)	Stony Brook University	20	
Radiation biology	Stony Brook University	10	
<b>Total Hours of Training:</b>		<b>200</b>	

**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.)**

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys			
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters			
Calculating, measuring, and safely preparing patient or human research subject dosages			

**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)

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 Felix Kravitz 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
CABANUE, CORAZON	<i>ycabue</i>	(631) 444-1298	3/12/07
License/Permit Number/Facility Name			
# <del>454</del> # 455 Stony Brook Univ			

**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	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material			
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures			
Administering dosages of radioactive drugs to patients or human research subjects			
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 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.**

March 12, 2007

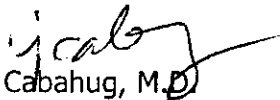
**Re: Felix Kravets, M.D.**

To Whom It May Concern:

This is to certify that Felix Kravets, M.D. read 465 nuclear medicine studies during his Radiology residency from 7/1/00 to 6/30/05.

List is enclosed.

Very truly yours,

  
Cora Cabahug, M.D.  
Section Chief of Nuclear Medicine

CC:dd

NRC FORM 313A (AUD) <small>(10-2008)</small>	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008
<b>AUTHORIZED USER TRAINING AND EXPERIENCE                  AND PRECEPTOR ATTESTATION</b> (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 <b>WILLIAM DIDIE MD</b>	State or Territory Where Licensed <b>NEW JERSEY</b>
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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
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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) (10-2005) U.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	RADIOLOGICAL PHYSICS, INSTRUMENTATION, AND RADIATION BIOLOGY	112 h	9-10-02 THRU 8-9-03
Radiation protection	COURSE FOR RADIOLOGY RESIDENTS -		
Mathematics pertaining to the use and measurement of radioactivity	MEDICAL COLLEGE OF PENNSYLVANIA PHILADELPHIA PA		
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.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*	
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	ROTATIONS IN NUCLEAR MEDICINE -- INVOLVED WITH ALL ASPECTS OF PROCEDURES IN FULL -	NOT RECORDED DURING THIS RESIDENTS TRAINING	4/9/01 - 5/6/01	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	SERVICE NUCLEAR MEDICINE DEPT. CHRISTIANA CARE HEALTH SYSTEM			11/19/01 - 12/16/01
Calculating, measuring, and safely preparing patient or human research subject dosages	R.M.L.# 07-12153-02			4/7/03 - 5/4/03



NRC FORM 313A (AUD)  
 (10-2002)

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	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	SEE ABOVE		6/2/03 - 6/30/03
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures			7/26/04 - 9/19/04
Administering dosages of radioactive drugs to patients or human research subjects			9/20/04 - 11/14/04
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			3/7/05 - 5/1/05

**Total Hours of Experience:**

Supervising Individual

*[Signature]*

MANZONI

License/Permit Number listing supervising individual as an authorized user

07-12153-02

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.**

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)

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 William Didie MD 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 William Didie 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
TIMOTHY A. MARONE		302-733-1530	4-16-07

License/Permit Number/Facility Name  
 CHRISTIANA CARE HEALTH SYSTEM # 07-12153-02