

# West Shore Cardiology

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CLINICS • Grand Haven • Ludington • Shelby • Hart • 1-800-968-5483

August 26, 2010

U.S. Nuclear Regulatory Commission  
Region III  
Materials Licensing Section  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

RE: License # 21-24873-01

Dear Mr. Mullauer:

This letter is in response to your phone call regarding the "Supervised Work Hours" experience on Dr. David Bonnema's preceptor form that was submitted for review on 8/12/2010. The correct hours have been filled in on the attached form. Also attached is a letter from Glenn Goudy, RSO stating that Dr. Kenneth Spicer is an "authorized user" on the Medical University of South Carolina's Broadscope license. Dr. Spicer was the Supervising Individual for Dr. Bonnema.

Would you please change our license status to 35.200, imaging only and remove Gregory A. Bernath, MD as an authorized user also.

Our physicist, Ray A. Carlson, MS would be happy to help you with any further questions if needed at (734) 455-4730.

Sincerely,



Mark E. Meengs, MD. (RSO)

FROM RADIATION SAFETY 843 792 5099

(10E) AUG 26 2010 11:55/51

11:52/NO. 00201

P003/007

# MUSC

**MEDICAL UNIVERSITY  
OF SOUTH CAROLINA****University Risk  
Management****Radiation Safety**

19 Hagood Avenue • Suite 301

PO Box 250802

Charleston • SC 29425

Office (843) 792-4255

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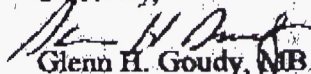
Shelly Pyman  
West Shore Cardiology

Dear Ms. Pyman,

The Medical University of South Carolina is a Broadscope Licensee (SC DHEC License # 081) within an NRC Agreement State. All licensees/ authorized users are approved to use Radioactive Materials by the Radiation Safety Committee. Dr. Kenneth Spicer is an "authorized user" at the Medical University of South Carolina. He is authorized to perform all Nuclear Medicine procedures including diagnostic and therapeutic procedures.

Should you need further information or if you have any questions please feel free to contact me.

Sincerely,



Glenn H. Goudy, MBA

-Radiation Safety Officer

Medical University of South Carolina



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

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: 3/31/2012

Name of Proposed Authorized User

David Dirk Bonneima

State or Territory Where Licensed

1) South Carolina  
2) Michigan

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)

U.S. NUCLEAR REGULATORY COMMISSION

(3-2009)

## AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

**X 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	MUSE Charleston, SC	25	01-2007 to 03-2007 10-2007 to 12-2007
Radiation protection	MUSE Charleston SC	25	01-2007 to 03-2007 10-2007 to 12-2007
Mathematics pertaining to the use and measurement of radioactivity	MUSE Charleston SC	10	01-2007 to 03-2007 10-2007 to 12-2007
Chemistry of byproduct material for medical use (not required for 35.590)	MUSE Charleston SC	10	01-2007 to 03-2007 10-2007 to 12-2007
Radiation biology	MUSE Charleston SC	10	01-2007 to 03-2007 10-2007 to 12-2007

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.)

Supervised Work Experience		Total Hours of Experience: 700	
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	MUSE Charleston, SC	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	01-2007 to 03-2007 10-2007 to 12-2007
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	MUSE Charleston, SC	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	01-2007 to 03-2007 10-2007 to 12-2007



NRC FORM 313A (AUD)

U.S. NUCLEAR REGULATORY COMMISSION

(3-2009)

## 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	MUSE Charleston SC	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	01-2007 to 03-2007 10-2007 to 12-2007
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	ll ll	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	ll ll
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	ll ll	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	ll ll
Administering dosages of radioactive drugs to patients or human research subjects	ll ll	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	ll ll
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	ll ll	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	ll ll

Supervising Individual

License/Permit Number listing supervising individual as an  
authorized user

Kenneth M Spore, MD

081-01

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)  
(3-2009)

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 David Dick Bonarino 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

X Kenneth M. Spree [Signature] 843-876-7146 7-30-200

081-01

MUSC Charleston, SC



## FACSIMILE TRANSMITTAL

## WEST SHORE CARDIOLOGY

1212 E. Sherman Blvd., Muskegon, MI 49444  
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Ralph G. Ryan, M.D.  
Daniel L. West, M.D.  
Ionut A. Oravitan, M.D.

Mark E. Meengs, M.D.  
Thomas J. Hill, M.D.

John F. Skallerup, M.D.  
Eric B. Stuart, M.D.  
D. Dirk Bonnema, M.D.



To: MR. Mullauer (NRC)

Fax: 630-515-1078

From: SHELLY

Date: 8/26/10

RE: D. Bonnema's Preceptor  
FORM

Pages 6 including cover

CC: \_\_\_\_\_

Contact:

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

Notes: PLEASE SEE ATTACHED PRECEPTOR FORM +  
LETTERS.

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