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1 June 2009

US Nuclear Regulatory Commission
Region 1
475 Allendale Rd.
King of Prussia, PA 19403-1415

License 06-30933-02

03036825

To whom it may concern:

I am submitting a request to add Gabriella Bedarida, M.D. to our license as a part 35.100 authorized user (AU) and assistant RSO for the Pfizer New Haven Clinical Research Unit.

Enclosed you will find NRC form 313A which has been signed by Subhashis Banerjee, M.D., the present RSO ad AU (part 35.100) for our facility.

Respectfully,

A handwritten signature in cursive script that reads "Howard Uderman".

Howard Uderman, M.D.
Medical Director
Pfizer New Haven CRU
Howard.D.Uderman@Pfizer.com
Fax # 860-715-6932

CC: Subhashis Banerjee, MD; Pfizer New Haven CRU

143779

NMSS/RGN1 MATERIALS-002

www.NewHavenCRU.com

**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

Gabriella Bedarida, MD

State or Territory Where Licensed

Connecticut

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)

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	Radiation Safety Associates, Inc, Hebron, CT	4.5	June 2-6, 2008
Radiation protection	Radiation Safety Associates, Inc, Hebron, CT & Pfizer Clinical Research Unit (CRU) , New Haven, CT	2	June 2-6, 2008 February 2009
Mathematics pertaining to the use and measurement of radioactivity	Radiation Safety Associates, Inc, Hebron, CT	5	June 2-6, 2008
Chemistry of byproduct material for medical use <i>(not required for 35.590)</i>	Radiation Safety Associates, Inc, Hebron, CT	2	June 2-6, 2008
Radiation biology	Radiation Safety Associates, Inc, Hebron, CT	3.5	June 2-6, 2008
Total Hours of Training: 17			

- 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:	
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	Radiation Safety Associates, Inc, Hebron, CT & Pfizer CRU, New Haven, CT	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	June 2-6, 2008 Feb-Mar 2009
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Radiation Safety Associates, Inc, Hebron, CT & Pfizer CRU, New Haven, CT	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	June 2-6, 2008 Feb-Mar 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	Radiation Safety Associates, Inc, Hebron, CT & Pfizer CRU, New Haven, CT	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	June 2-6, 2008 Feb-Mar 2009
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Radiation Safety Associates, Inc, Hebron, CT & Pfizer CRU, New Haven, CT	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	June 2-6, 2008 Feb-Mar 2009
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Radiation Safety Associates, Inc, Hebron, CT & Pfizer CRU, New Haven, CT	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	June 2-6, 2008 Feb-Mar 2009
Administering dosages of radioactive drugs to patients or human research subjects	Yale New Haven Hospital/ Yale School of Medicine, New Haven, CT	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Jul 1-Oct 28, 2008
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	N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Supervising Individual Subhashis Banerjee, MD		License/Permit Number listing supervising individual as an authorized user NRC License no. 06-30933-02	
Supervisor meets the requirements below, or equivalent Agreement State requirements (<i>check one</i>). <input checked="" type="checkbox"/> 35.190 <input type="checkbox"/> 35.290 <input type="checkbox"/> 35.390 <input type="checkbox"/> 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.

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 Gabriella Bedarida, 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 _____ has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

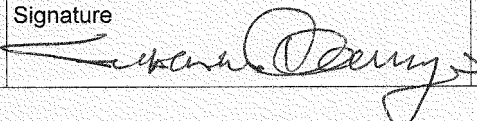
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

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 Subhashis Banerjee, MD	Signature 	Telephone Number (203) 401-0231	Date May 29, 2009
License/Permit Number/Facility Name NRC License no. 06-30933-02; Pfizer New Haven Clinical Research Unit, New Haven, CT			

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

6/11/2008, and to inform you that the initial processing which includes an administrative review has been performed.

☒ AMEND. 06-30933-02
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** 143779.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader