



NM562

13 June 2007

US Nuclear Regulatory Commission  
Region 1  
475 Allendale Rd.  
King of Prussia, PA 19406-1415

03036825

Re: Amendment of License 06-30933-02

To whom it may concern:

I am now resubmitting my request to add our current RSO, Dr. Subhashis Banerjee to our license as the new ADME supervisor.

Dr. Banerjee has now completed his additional hours of training in the Department of Nuclear Medicine at Yale.

Enclosed, please find NRC form 313a which has been signed by James Frost, M.D., Chair of Nuclear Medicine at Yale as well as copies of prior correspondence for your convenience and reference.

Respectfully,

Howard Uderman, M.D.  
Medical Director  
Pfizer New Haven CRU  
[Howard.D.Uderman@pfizer.com](mailto:Howard.D.Uderman@pfizer.com)  
Fax # 860-715-9632

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REGION 1  
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NMSS/RGN1 MATERIALS-002

**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: 10/31/2008

Name of Proposed Authorized User

Subhashis Banerjee, 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	Rad. Safety Assoc, Inc., 19 Pendleton Drive, PO Box 107, Hebron, CT 06248 & Yale-New Haven Hospital, Dept. of Nuc. Med. 20 York St., New Haven, CT 06510	2	Sept. 2006 May 2007
Radiation protection	Rad. Safety Assoc, Inc., 19 Pendleton Drive, PO Box 107, Hebron, CT 06248 & Yale-New Haven Hospital, Dept. of Nuc. Med. 20 York St., New Haven, CT 06510	2	Sept. 2006 May 2007
Mathematics pertaining to the use and measurement of radioactivity	Rad. Safety Assoc, Inc., 19 Pendleton Drive, PO Box 107, Hebron, CT 06248 & Yale-New Haven Hospital, Dept. of Nuc. Med. 20 York St., New Haven, CT 06510	2	Sept. 2006 May 2007
Chemistry of byproduct material for medical use (not required for 35.590)	Rad. Safety Assoc, Inc., 19 Pendleton Drive, PO Box 107, Hebron, CT 06248 & Yale-New Haven Hospital, Dept. of Nuc. Med. 20 York St., New Haven, CT 06510	2	Sept. 2006 May 2007
Radiation biology	Rad. Safety Assoc, Inc., 19 Pendleton Drive, PO Box 107, Hebron, CT 06248 & Yale-New Haven Hospital, Dept. of Nuc. Med. 20 York St., New Haven, CT 06510	2	Sept. 2006 May 2007
<b>Total Hours of Training:</b> 10 hours			

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: 62.25	
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	Rad. Safety Assoc, Inc., 19 Pendleton Drive, PO Box 107, Hebron, CT 06248 & Yale-New Haven Hospital, Dept. of Nuc. Med. 20 York St., New Haven, CT 06510 (06-00819-03)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Sept. 2006 & May 2007
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Rad. Safety Assoc, Inc., 19 Pendleton Drive, PO Box 107, Hebron, CT 06248 & Yale-New Haven Hospital, Dept. of Nuc. Med. 20 York St., New Haven, CT 06510 (06-00819-03)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Sept. 2006 & May 2007

## 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	RSA, Inc., P.O. Box107, Hebron, CT 06248 & Yale-New Haven Hospital, 20 York St., New Haven, CT (06-00819-03)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Sept. 2006 & May 2007
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	RSA, Inc., P.O. Box107, Hebron, CT 06248 & Yale-New Haven Hospital, 20 York St., New Haven, CT (06-00819-03)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Sept. 2006 & May 2007
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	RSA, Inc., P.O. Box107, Hebron, CT 06248 & Yale-New Haven Hospital, 20 York St., New Haven, CT (06-00819-03)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Sept. 2006 & May 2007
Administering dosages of radioactive drugs to patients or human research subjects	RSA, Inc., P.O. Box107, Hebron, CT 06248 & Yale-New Haven Hospital, 20 York St., New Haven, CT (06-00819-03)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Sept. 2006 & May 2007
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	Rad. Safety Assoc. Inc., 19 Pendleton Drive, PO Box 107, Hebron, CT 06248 & Yale-New Haven Hospital, Dept. of Nuc. Med. 20 York St., New Haven, CT 06510 (06-00819-03)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Sept. 2006 & May 2007

Supervising Individual

James Frost, M.D.

License/Permit Number listing supervising individual as an  
authorized user

YNHHospital, NRC Lic. No. 06-00819-03

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.

**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)

**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 Subhashis Banerjee, 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  
James Frost, M.D.

Signature

*James Frost*

Telephone Number

203-737-9738

Date

11 June '07

License/Permit Number/Facility Name

Yale-New Haven Hospital, 20 York St., New Haven, CT 06510, NRC Lic. No. 06-00819-03



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

March 6, 2007

Docket No. 03036825  
Control No. 139929

License No. 06-30933-02

Howard Uderman, M.D.  
Medical Director  
Pfizer New Haven Clinical Research Unit  
One Howe Street  
New Haven, CT 06510

SUBJECT: PFIZER NEW HAVEN CLINICAL RESEARCH UNIT, VOIDANCE OF  
APPLICATION FOR LICENSE AMENDMENT, CONTROL NO. 139929

Dear Dr. Uderman:

This concerns the subject application for an Amendment to your material license. Because you informed us that you will not be able to supply the additional information required to complete the requested action for some time, we have voided your application. This action is taken without prejudice to the resubmission of your request.

Sincerely,

A handwritten signature in black ink, appearing to read "Thomas K. Thompson".

Thomas K. Thompson  
Senior Health Physicist  
Commercial and R&D Branch  
Division of Nuclear Materials Safety

cc:  
Subhashis Banerjee, M.D., Radiation Safety Officer



March 5, 2007

Mr. Thomas Thompson  
US Nuclear Regulatory Commission  
Region 1  
475 Allendale Rd.  
King of Prussia, PA 19406-1415  
Fax 610-337-5269

Re: Amendment to License # 06-30933-02  
Mail Control No. 139929

Dear Mr. Thompson:

This note is written in follow up of your e-mail to me on March 1, 2007.

We had to spend some time sorting out the requirements of NRC form 313A. We have arranged for additional hours of training for Dr. Banerjee in the Department of Nuclear Medicine at Yale University Medical School – which is located across the street from our Research Unit. The Department routinely trains residents and research fellows in the use of radioactive material. Once satisfied with Dr. Banerjee's additional training, they are prepared to sign off on NRC form 313a on his behalf.

Dr. Banerjee has other clinical obligations in our Clinical Research Unit; so we expect his additional training to be complete by the end of May 2007.

Respectfully,

A handwritten signature in black ink that reads "Howard Uderman". The signature is fluid and cursive, with the first name "Howard" and last name "Uderman" clearly legible.

Howard Uderman, M.D.  
Medical Director  
Pfizer New Haven CRU  
One Howe Street  
New Haven, CT 06511

[www.NewHavenCRU.com](http://www.NewHavenCRU.com)

**Uderman, Howard D**

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**From:** Uderman, Howard D  
**Sent:** Monday, March 05, 2007 12:43 PM  
**To:** 'Thomas Thompson'  
**Subject:** RE: Your Amendment request to the NRC license.

We have just recently faxed a letter to you.

Questions are welcome.

Howard Uderman

-----Original Message-----

**From:** Thomas Thompson [mailto:TKT@nrc.gov]  
**Sent:** Thursday, March 01, 2007 9:16 AM  
**To:** Uderman, Howard D  
**Subject:** Your Amendment request to the NRC license.

Your request to have NRC authorize Dr. Banerjee for 10 CFR 35.100 uses of byproduct materials requires that you provide the information necessary to show that the candidate can meet the requirements in 10 CFR 35.190. Please provide this information. There are currently NRC form 313A (AUD)'s available on our website that may help you to provide the necessary information. Please reply by fax to 610 337-5269 and refer to Mail Control No.139929.

Thank you.





Re: License # 06-30933-02

US Nuclear Regulatory Commission  
Region 1  
475 Allendale Road  
King of Prussia, Pennsylvania 19406-1415

Dr. Thomas Murtaugh, our present ADME study supervisor, will be leaving Pfizer on 11 January 2007. In his place, I would like to add the current RSO, Dr. Subhashis Banerjee to our license as the new ADME study supervisor.

Respectfully,

Howard Uderman, M.D.  
Medical Director

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

6/13/2007, 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

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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** 140662.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.