

Roldan, Lizette

From: Fairbanks, Jeff PhD [fairbanj@slhs.org]
Sent: Tuesday, July 03, 2012 9:37 AM
To: Roldan, Lizette
Subject: RE: REQUEST FOR ADDITIONAL INFORMATION REGARDING AMENDMENT CONTROL 577631
Attachments: Einav Shochat md NRC Form 313A 07-03-12.pdf

Lizette, attached is the original form that I sent on January 13. The form I sent you in the previous email is the incorrect form that I had sent in October, 2011.

Jeff

From: Roldan, Lizette [mailto:Lizette.Roldan@nrc.gov]
Sent: Tuesday, July 03, 2012 7:27 AM
To: Fairbanks, Jeff PhD
Subject: REQUEST FOR ADDITIONAL INFORMATION REGARDING AMENDMENT CONTROL 577631

License No.: 11-27312-01
Docket No.: 030-32196
Control No.: 577631

Dear Dr. Fairbanks:

This is in reference to your letters dated January 13, 2012, June 8, 2012 and email received June 26, 2012 requesting to amend Nuclear Regulatory Commission License No. 11-27312-01. In order to continue our review, we need the following additional information:

1. In support of your request to add Dr. Einav Shochat as an authorized user for 10 CFR 35.100 and 35.200 please complete the attached NRC Form 313A(AUD). Dr. Shochat can follow Pathway 1 "Board Certification". The form you provided is not adequate for the modalities requested.
2. You have requested to add Dr. Loren Camille Macey as an authorized user for 10 CFR 35.100 and 35.200. In letter dated June 8, 2012 you submitted the NRC Form 313(A)(AUD) and followed Pathway 1 "Board Certification". This pathway was not adequate for Dr. Macey because the Board Certificate provided is not recognized by the NRC. In email dated June 26, 2012 you submitted a revised NRC Form 313A(AUD) following Pathway 3 "Training and Experience". We cannot add Dr. Macey with the information provided for 10 CFR 35.200 for the following reasons:
 - a. You have documented 572 hours of training and experience. In accordance with 35.290, the individual must complete a minimum of 700 hours of training and experience.
 - b. Please provide a location/license or permit number of facility, and date for when Dr. Macey received training and experience on eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide purity, and processing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs.
 - c. Please have the preceptor check off the "Training and Experience" boxes on the "Preceptor Attestation" page.

**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

Einav Shochat, MD

State or Territory Where Licensed

Idaho

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 protection			
Mathematics pertaining to the use and measurement of radioactivity			
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.)**

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		Yes No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		Yes No	

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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Administering dosages of radioactive drugs to patients or human research subjects		<input type="checkbox"/> Yes <input type="checkbox"/> No	
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		<input type="checkbox"/> Yes <input type="checkbox"/> No	

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.

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 Einav Shochat 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 Einav Shochat 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

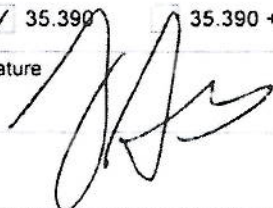
☒ 35.390

☐ 35.390 + generator experience

Name of Preceptor

Jeffrey Stevens, MD

Signature



Telephone Number

(503) 494-2204

Date

01/13/2012

License/Permit Number/Facility Name

ORE-90013

The American Board of Radiology

Organized through the cooperation of the
 American College of Radiology, the American Roentgen Ray Society,
 the American Radium Society, the Radiological Society of North America,
 the Section on Radiology of the American Medical Association,
 the American Society for Radiation Oncology, the Association of
 University Radiologists, and the American Association of Physicians in Medicine
 Hereby certifies that

Feiman Schuchat, PhD

Has pursued an accepted course of graduate study
 and clinical work, has met certain standards and qualifications, including
 passing the examinations conducted under the authority of
 The American Board of Radiology,
 demonstrating to the satisfaction of the Board that she is qualified to practice,
 and is therefore awarded the Board's certification in the specialty of

Diagnostic Radiology

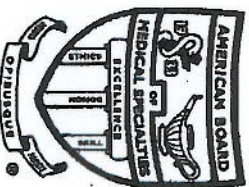
Effective August 27, 2010



Eric J. Harris
 President

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 Secretary-Treasurer

Walter E. Bland
 Executive Director



Certificate No. 59047

Valid through 2020

No. 577631