

## Roldan, Lizette

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**From:** Roldan, Lizette  
**Sent:** Tuesday, July 03, 2012 8:27 AM  
**To:** 'Fairbanks, Jeff PhD'  
**Subject:** REQUEST FOR ADDITIONAL INFORMATION REGARDING AMENDMENT CONTROL 577631  
**Attachments:** nrc313a(aud).pdf

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.
  - d. You may resubmit a new NRC Form 313A(AUD) form when Dr. Macey has received a minimum of 700 hours of training.
  - e. Please note, Dr. Macey will be added on the license to perform uptake, dilution and excretion studies under 10 CFR 35.100 only.
3. You have requested to add Dr. Michael Alan Fuchs 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. Fuchs 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. Fuchs with the information provided for 10 CFR 35.200 for the following reasons:

- a. You have documented 564 hours of training and experience. In accordance with 35.290, the individual must complete a minimum of 700 hours of training and experience.
- b. Dr. Fuchs must receive 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.
- d. You may resubmit a new NRC Form 313A(AUD) form when Dr. Fuchs has received a minimum of 700 hours of training, and has received training and experience for the items described in 3b above.
- e. Please note, Dr. Fuchs will be added on the license to perform uptake, dilution and excretion studies under 10 CFR 35.100 only.

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region IV Office and refer to Mail Control No. 577631. You may respond by regular mail, fax at 817-200-1188 or email as a PDF attachment. If you have any technical questions regarding this deficiency letter, please call me at 817-200-1596.

If we do not receive a reply from you by August 3, 2012 we will assume that you do not wish to pursue your application for these individuals to be added on the license under 10 CFR 35.200.

Sincerely,

***Lizette Roldán-Otero, Ph.D.***

Health Physicist

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