

Roldan, Lizette

From: Fairbanks, Jeff PhD [fairbanj@slhs.org]
Sent: Tuesday, June 26, 2012 3:07 PM
To: Roldan, Lizette
Subject: RE: St. Luke's Amendment Request to add Radiologists
Attachments: Loren Camille Macey MD NRC Form 313A 06-26-12.pdf; Michael Alan Fuchs MD NRC Form 313A 06-26-12.pdf

Lizette, this email is related to a separate amendment than what we have been discussing today. On form 313A for both of the radiologists on this request, I had not properly filled in Section 3. I have attached the corrected copies to this email.

Thank you,

Jeff

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

From: Roldan, Lizette [mailto:Lizette.Roldan@nrc.gov]
Sent: Monday, June 11, 2012 5:19 AM
To: Fairbanks, Jeff PhD
Subject: RE: St. Luke's Amendment Request to add Radiologists

Remind me that I have already put this in the queue when you send the form.

Lizette Roldán-Otero, Ph.D.
Health Physicist
U.S. Nuclear Regulatory Commission
1600 E. Lamar Blvd.
Arlington, TX 76011-4511
Office: 817-200-1596
Fax: 817-200-1188

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

From: Fairbanks, Jeff PhD [mailto:fairbanj@slhs.org]
Sent: Friday, June 08, 2012 3:16 PM
To: Roldan, Lizette
Subject: RE: St. Luke's Amendment Request to add Radiologists

Thank you. I will re-do the form with Section 3 and get it to you early next week.

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

From: Roldan, Lizette [mailto:Lizette.Roldan@nrc.gov]
Sent: Friday, June 08, 2012 12:00 PM
To: Fairbanks, Jeff PhD
Subject: RE: St. Luke's Amendment Request to add Radiologists

Jeff,

Does her certificate say AU eligible above the seal? If not, you cannot qualify her using the certificate pathway (#1) and would have to complete the table in pathway #3. You would still use her training from wherever she got it many years ago.

**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

Loren Camille Macey, 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	University of Colorado Health Sciences Center	40	July 1998-June 2002
Radiation protection	University of Colorado Health Sciences Center	20	July 1998-June 2002
Mathematics pertaining to the use and measurement of radioactivity	University of Colorado Health Sciences Center	20	July 1998-June 2002
Chemistry of byproduct material for medical use (not required for 35.590)	University of Colorado Health Sciences Center	20	July 1998-June 2002
Radiation biology	University of Colorado Health Sciences Center	80	July 1998-June 2002
Total Hours of Training: 180			

- 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 St. Luke's Nuclear Med. Dept.		Total Hours of Experience: 392 hours	
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	11-27312-01 St. Luke's Regional Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	June 3,10,17,26, 2011
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	11-27312-01 St. Luke's Regional Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	July 1,8,15,22,29, 2011

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	11-27312-01 St. Luke's Regional Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	August 5,12,19,26, 2011
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	11-27312-01 St. Luke's Regional Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	September 2,9,16,23, 2011
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	11-27312-01 St. Luke's Regional Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	October 5,12,19,26, 2011
Administering dosages of radioactive drugs to patients or human research subjects	11-27312-01 St. Luke's Regional Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	November 2,9,16,23,30, 2011
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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Supervising Individual

Christopher J. Jennings, MD

License/Permit Number listing supervising individual as an
authorized user

11-27312-01 St. Luke's Regional Medical

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)

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	11-27312-01 St. Luke's Regional Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	August 4,11,18,25, 2011
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	11-27312-01 St. Luke's Regional Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	September 1,8,15,22, 2011
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	11-27312-01 St. Luke's Regional Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	October 4,11,18,25, 2011
Administering dosages of radioactive drugs to patients or human research subjects	11-27312-01 St. Luke's Regional Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	November 1,8,15,22, 2011
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
Christopher J. Jennings, MDLicense/Permit Number listing supervising individual as an
authorized user

11-27312-01 St. Luke's Regional Medical

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 Michael Alan Fuchs, MD 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 Michael Alan Fuchs, MD 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

Christopher J. Jennings, MD

Signature

Christopher Jennings

Telephone Number

(208) 381-2094

Date

6/7, 12

License/Permit Number/Facility Name

11-27312-01 St. Luke's Regional Medical Center

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 **Loren Camille Macey, MD** 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 **Loren Camille Macey, MD** 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

Christopher J. Jennings

Signature



Telephone Number

(208) 381-2094

Date

6/7/12

License/Permit Number/Facility Name

11-27312-01 St. Luke's Regional Medical