

Hill, Carol

From: Fairbanks, Jeff PhD <fairbanj@slhs.org>
Sent: Thursday, March 24, 2016 12:58 PM
To: Hill, Carol
Subject: [External_Sender] #11-27312-01 St. Luke's (Boise) Amendment Request/Notification
Attachments: 11-27312-01 StLukes 24March2016 - Notification - Bergset and Address.pdf; Board Certification - Jon Bergset.pdf; 313A (AUD) - Jon Bergset.pdf; Letter that Preceptor is AU for Univ of Louisville.pdf; Nuclear Training Certificate - Jon Bergset.pdf

Hi Carol, attached is an amendment request with supporting documentation. Below I have copied the content of the letter as well.

Thank you,

Jeff

I am providing notification of the addition of Jon M. Bergset, M.D. as an authorized user for 35.100 and 35.200 to our license, according to 35.14. The following documents are attached:

- Board Certification – Nuclear Cardiology
- NRC Form 313A (AUD) – 35.100, 35.200
- Letter from the University of Louisville RSO indicating that the preceptor who signed Form 313A is an AU for their broad-scope license

I am also requesting an address change due to an error in a suite number listed on our license. There is no physical address change, so this also falls under 35.14 as a notification. Condition 10.K. lists St. Luke's Saltzer Medical Imaging, 3277 East Louise, Suite 102, Meridian, Idaho. All of this is correct except that the suite number should read "Suite 100" instead of "Suite 102".

Thank you for making these additions and changes to our license.

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PUBLIC

- ☐ Immediate Release
☒ Normal Release

NON-PUBLIC

- ☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other: _____

Reviewer: MT Date: 4/6/16



March 24, 2016

Carol L. Hill, Licensing Assistant
US Nuclear Regulatory Commission Region IV
Nuclear Materials Licensing Branch
1600 E. Lamar Blvd, Arlington, Texas 76011-4511
817-200-1140, 800-952-9677, Carol.Hill@nrc.gov

RE: Amendment/Notification of License #11-27312-01

Dear Carol Hill:

I am providing notification of the addition of Jon M. Bergset, M.D. as an authorized user for 35.100 and 35.200 to our license, according to 35.14. The following documents are attached:

- Board Certification – Nuclear Cardiology
- NRC Form 313A (AUD) – 35.100, 35.200
- Letter from the University of Louisville RSO indicating that the preceptor who signed Form 313A is an AU for their broad-scope license

I am also requesting an address change due to an error in a suite number listed on our license. There is no physical address change, so this also falls under 35.14 as a notification. Condition 10.K. lists St. Luke's Saltzer Medical Imaging, 3277 East Louise, Suite 102, Meridian, Idaho. All of this is correct except that the suite number should read "Suite 100" instead of "Suite 102".

Thank you for making these additions and changes to our license.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeff Fairbanks", is written over a horizontal line.

Jefferson Fairbanks, PhD
Radiation Safety Officer
208-381-3192, fairbanj@slhs.org

100 E. Idaho Street
Boise, Idaho 83712
P (208) 381-2711 F (208) 381-4675
(800) 845-4624

1118 NW 16th Street, Suite D
Fruitland, Idaho 83619 P (208) 452-7677 F (208) 452-8681
(800) 473-9618

520 S. Eagle Road
Meridian, Idaho 83642
P (208) 706-5651 F (208) 706-5344
(800) 473-0331

308 E. Hawaii Avenue
Nampa, Idaho 83686
P (208) 467-6700 F (208) 463-6001
(800) 553-6415

725 Pole Line Road W.
Twin Falls, Idaho 83301
P (208) 814-1600 F (208) 814-1910
(800) 947-4852



Certification Board of Nuclear Cardiology

Incorporated 1996

A Division of the Council for Certification in Cardiovascular Imaging

Certifies That

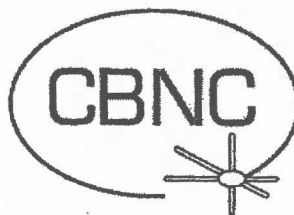
Jon M. Bergset, MD

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD FOR PHYSICIANS
TRAINED IN THE UNITED STATES AND HAVING SATISFACTORILY PASSED
THE REQUIRED EXAMINATION, IS HEREBY DESIGNATED
A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF
NUCLEAR CARDIOLOGY

VALID: JANUARY 1, 2015 — MARCH 1, 2025

Thomas Kelly

President



Manuel Zorad

Secretary



CERTIFICATE NUMBER: 9742

**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: (05/31/2015)

Name of Proposed Authorized User

Jon M. Bergset M.D.

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 Louisville Hospital and Louisville VA Medical Center	40	7/1/2013-6/30/2014
Radiation protection	University of Louisville Hospital and Louisville VA Medical Center	12	7/1/2013-6/30/2014
Mathematics pertaining to the use and measurement of radioactivity	University of Louisville Hospital and Louisville VA Medical Center	8	7/1/2013-6/30/2014
Chemistry of byproduct material for medical use (not required for 35.590)	University of Louisville Hospital and Louisville VA Medical Center	12	7/1/2013-6/30/2014
Radiation biology	University of Louisville Hospital and Louisville VA Medical Center	8	7/1/2013-6/30/14
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	University of Louisville Hospital and Louisville VA Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/2012-6/30/2015
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	University of Louisville Hospital and Louisville VA Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/2012-6/30/2015

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	University of Louisville Hospital and Louisville VA Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/2012- 6/30/2015
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	University of Louisville Hospital and Louisville VA Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/2012- 6/30/2015
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	University of Louisville Hospital and Louisville VA Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/2012- 6/30/2015
Administering dosages of radioactive drugs to patients or human research subjects	University of Louisville Hospital and Louisville VA Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/2012- 6/30/2015
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	University of Louisville Hospital and Louisville VA Medical Center	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/2012- 6/30/2015

Supervising Individual

Stephen Wagner M.D.

License/Permit Number listing supervising individual as an authorized user

20202922

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 _____ 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 Jon M. Bergset M.D. 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 Jon M. Bergset M.D. 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

STEVEN WAGNER MD

Signature

Steven Wagner

Telephone Number

502-287-5675

Date

6/17/15

License/Permit Number/Facility Name

20202922

December 2, 2015

To Whom It May Concern:

The purpose of this letter is to document that Stephen Wagner, M.D., is an Authorized Radioactive Material User at the University of Louisville, broad scope license #202-029-22. He was authorized by the radiation safety committee originally in 1994 and has kept his authorization up to date since. We require a renewal every 5 years of each authorized user; his last authorization was approved in November 2015.

Dr. Wagner is authorized for the items listed below:

- 902 KAR 100:072 section 30 (10 CFR 35.100)
- 902 KAR 100:072 section 31 (10 CFR 35.200)

The University of Louisville operates under a Broad Scope Type "A" License issued by the State of Kentucky (202-029-22); therefore, users are not listed specifically on the license. The Radiation Safety Committee approves each authorized user based on training and education documentation that is given.

If there are any questions, please feel free to call me at (502) 852-5231.



Sarah Hughes, MS, DABR
Radiation Safety Officer

Department of Medicine
Division of Cardiovascular Medicine
Division of Radionuclide Studies

This is to certify that Jon Martin Bergset, M.D. has satisfactorily completed the training and experience criteria for diagnostic studies limited to Nuclear Cardiology, above the minimum as set by the Nuclear Regulatory Commission (NRC) standards. This training, from July 1, 2012 – June 30, 2015, totaled a minimum of 80 hours classroom and laboratory training dealing with radiation safety and physics for the use of radiopharmaceuticals and ionizing radiation including radiation biology, radiopharmacy and instrumentation as well as a minimum of 620 hours of work experience in Nuclear Cardiology, inclusive of radiation safety, encompassing didactic instruction, clinical study interpretation and supervised hands-on experience in clinical cases that satisfies the Core Cardiovascular Training Statement (COCATS) Level II requirements meeting eligibility for the Certification Board of Nuclear Cardiology (CBNC) examination.



Ibrahim B. Syed

Ibrahim B. Syed, Sc.D., Ph.D.
Clinical Professor of Medicine
Director, Basic Nuclear Medicine Sciences

Stephen Wagner

Stephen Wagner, M.D.
Associate Professor of Medicine
Director, Nuclear Cardiology



DATE
03/31/2016

NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE

E. Jefferson Fairbanks, Ph.D.
Radiation Safety Officer
St. Luke's Regional Medical Center
190 E. Bannock
Boise, ID 83712

LICENSE NUMBER

11-27312-01

MAIL CONTROL NUMBER

590525

LICENSING AND/OR TECHNICAL REVIEWER

CH

This is to acknowledge the receipt of your:

☒ LETTER and/or ☐ APPLICATION DATED: 03/24/2016

The initial processing, which included an administrative review, has been performed.

☒ AMENDMENT ☐ TERMINATION ☐ NEW LICENSE ☐ RENEWAL

- ☐ There were no administrative omissions identified during our initial review.
- ☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.
- ☐ Your application for a new NRC license did not include your taxpayer identification number. Please fill out NRC Form 531, located at the following link:

<http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>

Send the completed NRC Form 531, by facsimile, to the following number: (301) 415-5387

A copy of your action has been emailed to our License Fee and Accounts Receivable Branch, in our Headquarters office in Rockville, MD. You will be contacted separately if there is a fee issue involved.

Your application has been assigned the above listed **MAIL CONTROL NUMBER**. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region IV
U. S. Nuclear Regulatory Commission
DNMS/NMSB - B
1600 E. Lamar Boulevard
Arlington, TX 76011-4511
(817) 200-1140

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM WBL

Program Code: 02230
Status Code: Pending Amendment
Fee Category: 3E 7C
Exp. Date:
Fee Comments:
Decom Fin Assur Req: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: ST. LUKE'S REGIONAL MEDICAL CENTER
Received Date: 03/24/2016
Docket Number: 3032196
Mail Control Number: 590525
License Number: 11-27312-01
Action Type: Amendment

2. FEE ATTACHED

Amount: _____
Check No.: _____

3. COMMENTS

Signed: _____

Date: _____

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / /)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment: _____

Renewal: _____

License: _____

3. OTHER _____

Signed: _____

Date: _____