Hill, Carol

From: Daniel Dugan <dan@hpnw.com>
Sent: Thursday, December 20, 2018 4:45 PM
To: Hill, Carol
Cc: 'Ryan-O'Hara, Kimberly'
Subject: [External_Sender] Amendment Request
Attachments: Amendment Request Add AU.pdf

Carol:

Please find attached an amendment request to add authorized users to our license. If you have any questions, or would like to discuss this, please don't hesitate to contact me.

Dan Dugan, MS, DABR
Medical Physicist
HEALTH PHYSICS NORTHWEST
503-620-6617 Office
503-684-5548 Fax
http://www.hpnw.com/

HPNW
HEALTH PHYSICS NORTHWEST

PUBLIC
☐ Immediate Release
☒ Normal Release

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

Reviewer: Date: 1-4-19

№ 610947

HPNW
HEALTH PHYSICS NORTHWEST

December 20, 2018

Carol Hill
Licensing Assistant
U.S. Nuclear Regulatory Commission, Region IV
1600 East Lamar Boulevard
Arlington, Texas 76011-4511

RE: 25-18361-01 License amendment to add AU's

Carol:

This letter serves as a written request to add Dr. Turlington to our license as an authorized user under 10 CFR 35.100 and 10 CFR 35.200. In addition, we would like to add Dr. Bauer and Dr. Turlington as authorized users under 10 CFR 35.1000 to perform radioactive seed localizations using Pd-103 and I-125. Please find attached Form 313A for Dr. Turlington and letters of attestation from Dr. Stewart regarding training and competency to perform radioactive seed localization procedures.

If you have any questions, please contact me.

Sincerely,

Dan Dugan, MS, DABR
Radiation Safety Officer
Community Medical Center

Encl.

7525 SE Lake Road, Milwaukie, Oregon 97267
Phone: 503-620-6617 Fax: 503-684-5548
www.hpnw.com

NRC FORM 313A (AUD)
(06-2016)

U.S. NUCLEAR REGULATORY COMMISSION

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: 06/30/2019

Name of Proposed Authorized User	State or Territory Where Licensed
Bruce Stuart Turlington, MD	Montana

Requested Authorization(s) *(check all that apply)*

- [x] 35.100 Uptake, dilution, and excretion studies
- [x] 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.

[x] **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	

№ 610947

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		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		☐ Yes ☐ No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		☐ Yes ☐ No	
Administering dosages of radioactive drugs to patients or human research subjects		☐ Yes ☐ 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		☐ Yes ☐ 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 Bruce Turlington, 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 Bruce Turlington, 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	Signature	Telephone Number	Date
Mark W Elliott MD	MWElliott MD	406-327-4334	12-19-18

License/Permit Number/Facility Name
25-18361-01

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 Therapeutic Radiology and Oncology,
and the Association of University Radiologists
Hereby certifies that

Bruce Stuart Turlington, M.D.

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology

On this seventh day of June, 1990

Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Diagnostic Radiology

Robert G Parner
President

Secretary

THE AMERICAN BOARD OF RADIOLOGY
INCORPORATED IN THE DISTRICT OF COLUMBIA
1934

AMERICAN BOARD OF MEDICAL SPECIALTIES
EXPERIENCE
OPTIMUS QUE

Ph 6 1 0 9 4 7

PRECEPTOR ATTESTATION:

I attest that Dr. David Bauer has performed three (3) cases for Radioactive Seed Localization (RSL) under my supervision as an authorized user with the following supervised work experience:

1. Performed radiation surveys as needed using proper instrumentation.
2. Implanted sealed sources safely, including the use of handling tools to manipulate seeds and the proper use of shields, if needed.
3. Monitored the routine use of sealed sources before, during and after the procedure.

Additional training included instruction on the following topics:

1. Applicable regulations
2. RSL program policies and procedures
3. Radiation safety (source handling) issues
4. Inventory and security of radioactive seeds
5. Implanting and removing RSL sources safely
6. Performing surveys with a survey meter
7. Emergency procedures, including how to respond to a lost or leaking source.

David Bauer, M.D. is already on NRC RAM license #25-18361-01 as an Authorized User for35.100; 35.200 and oral administration of sodium iodide I-131 and is therefore well experienced in radiation safety and now has achieved a level of competency sufficient to function independently as an authorized user for RSL procedures covered in 10 CFR 35.1000.

Name of Proctor: Michael Stewart, M.D.

Signature: Michael Stewart MD

Date: 12/5/18

PRECEPTOR ATTESTATION:

I attest that Bruce Turlington, M.D. has performed _3 (three) cases for Radioactive Seed Localization (RSL) under my supervision as an authorized user with the following supervised work experience:

1. Performed radiation surveys as needed using proper instrumentation.
2. Implanted sealed sources safely, including the use of handling tools to manipulate seeds and the proper use of shields, if needed.
3. Monitored the routine use of sealed sources before, during and after the procedure.

Additional training included instruction on the following topics:

1. Applicable regulations
2. RSL program policies and procedures
3. Radiation safety (source handling) issues
4. Inventory and security of radioactive seeds
5. Implanting and removing RSL sources safely
6. Performing surveys with a survey meter
7. Emergency procedures, including how to respond to a lost or leaking source.

Name of Proctor: Michael Stewart, M.D.

Signature: Michael Stewart MD

Date: 12/5/18

№ 610947

NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee	Date
	01/03/2019
Mr. Daniel C. Dugan, M.S. Radiation Safety Officer RCHP Billings – Missoula LLC dba Community Medical Center 2827 Fort Missoula Road Missoula, MT 59804	**License Number(s)** 25-18361-01
	Mail Control Number(s) 610947
	Licensing and/or Technical Reviewer or Branch C. Hill

This is to acknowledge receipt of your: ☑ **Letter and/or** ☐ **Application** **Dated:** 12/20/2018

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 complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link:** http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf

Follow the instructions on the form for submission.

☐ **The following administrative omissions have been identified:**

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) 200-1103 or (817) 200-1140

V 1/3/19

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM WBL

Program Code: 02230
Status Code: Pending Amendment
Fee Category: 7C
Exp. Date: 10/31/2023
Fee Comments: CODE 23
Decom Fin Assur Reqd: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: RCHP Billings - Missoula LLC
Received Date: 12/20/2018
Docket Number: 3014921
Mail Control Number: 610947
License Number: 25-18361-01
Action Type: Amendment

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: Carol L Hill

Date: 1/3/19

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: _____