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May 2, 2016

DNMS

United States Nuclear Regulatory Commission  
Attn: Radioactive Materials Licensing  
Region IV  
1600 E. Lamar Blvd.  
Arlington, TX 76011-4511

Re: License #25-16906-01

PUBLIC

☐ Immediate Release  
☒ Normal Release

NON-PUBLIC

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

Reviewer: JK

Date: 6/1/16

Dear Sir or Madam:

I am writing to request an amendment to the Frances Mahon Deaconess Hospital radioactive materials license (License) #25-16906-01. Please note the following:

1. Please add Louis D. Bailey, D.O. as an Authorized User Physician.
2. Please authorize Dr. Bailey as follows:
  - a. Any byproduct material permitted by 10 CFR 35.100.
  - b. Any byproduct material permitted by 10 CFR 35.200.
3. Attached please find a copy of Dr. Bailey's American Osteopathic Board of Radiology board certification diploma noting 'AU Eligible.' (See Attachment A – Board Certificate)
4. Attached please find a copy of the NRC Form 313A *Authorized User Training and Experience and Preceptor Attestation*. (See Attachment B – Form 313A)
5. Dr. Bailey is licensed to practice medicine in the State of Montana.

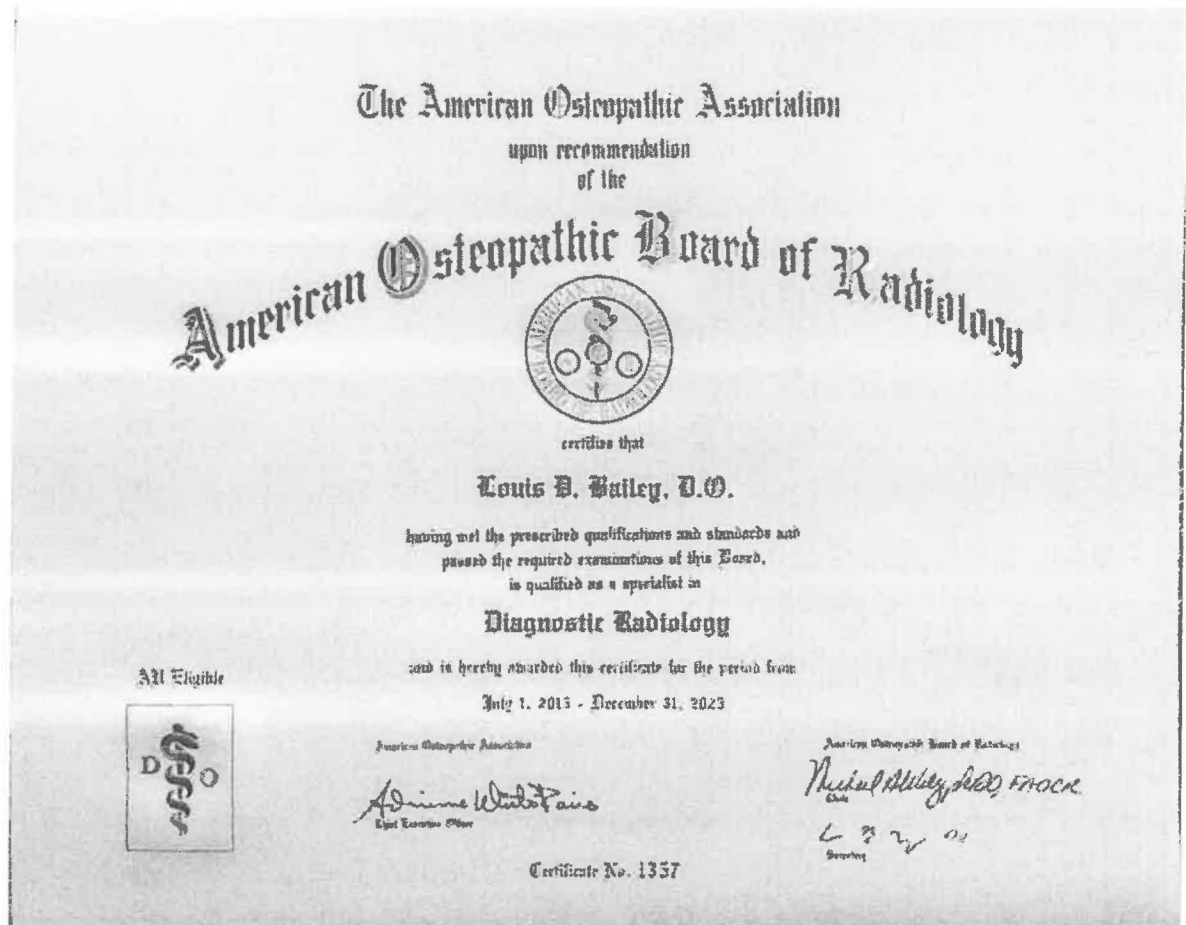
Please contact me with any questions. I can be reached at 406-262-4127. Additionally, you may reach Ms. Lindsey Zoanni, Nuclear Medicine Technologist, at 406-228-3630 or [lindsey.zoanni@fmdh.org](mailto:lindsey.zoanni@fmdh.org) with any questions. Thank you for your continued assistance.

Sincerely,

  
Earl R. Harrison, Jr., M.D.  
Radiation Safety Officer

No. 590982

Attachment A – Board Certificate



Attachment B – Form 313A

<p>NRC FORM 313A (AUD) (14-2016)</p>	<p>U.S. NUCLEAR REGULATORY COMMISSION</p>	<p>APPROVED BY OMF NO. 3150-2120 EXPIRES 04/30/2016</p>										
<p><b>AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION</b> (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.690]</p>												
<p>Name of Proposed Authorized User <u>James D. Bailey D.D.</u></p>		<p>State or Territory Where Licensed <u>Montana</u></p>										
<p>Requested Authorization(s) (check all that apply)</p> <p><input checked="" type="checkbox"/> 35.100 Uptake, dilution, and excretion studies</p> <p><input checked="" type="checkbox"/> 35.200 Imaging and localization studies</p> <p><input type="checkbox"/> 35.500 Sealed sources for diagnosis (specify device)</p>												
<p><b>PART I – TRAINING AND EXPERIENCE</b> (Select one of the three methods below)</p>												
<p>* 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.</p>												
<p><input checked="" type="checkbox"/> <b>1. Board Certification</b></p> <p>a. Provide a copy of the board certification.</p> <p>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.</p>												
<p><input type="checkbox"/> <b>2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization</b></p> <p>a. Authorized user on Materials License _____ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.</p> <p>b. Supervised Work Experience. (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 40%;">Description of Experience</th> <th style="width: 30%;">Location of Experience/License or Permit Number of Facility</th> <th style="width: 10%;">Clock Hours</th> <th style="width: 20%;">Dates of Experience*</th> </tr> </thead> <tbody> <tr> <td style="height: 60px; vertical-align: top;">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</td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p style="text-align: center;"><b>Total Hours of Experience:</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Supervising Individual</td> <td style="width: 50%;">License/Permit Number listing supervising individual as an authorized user</td> </tr> </table> <p>Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply).</p> <p><input type="checkbox"/> 35.290    <input type="checkbox"/> 35.390 + generator experience in 32.290(c)(1)(ii)(G)</p>			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				Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*									
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Supervising Individual	License/Permit Number listing supervising individual as an authorized user											

☐ 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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> 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.

**NBC FORM 314a (JAN 04-01)**  
**U.S. NUCLEAR REGULATORY COMMISSION**

Form 314a

**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 35.5820)

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not entering to the individual's general clinical competency.

**First Section**

Check one of the following for each user requested:

For 35.180

**Board Certification**

☐ I attest that

has satisfactorily completed the requirements in

10 CFR 35.180(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

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.180(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.

For 35.290

**Board Certification**

☒ I attest that

has satisfactorily completed the requirements in

10 CFR 35.280(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

and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.280(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.

**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:

☒ 35.180

☒ 35.290

☐ 35.390

☐ 35.390 + generator experience

Name of Preceptor

Signature

Telephone Number

Date

License or State Identification Number

21-04515101 Oakwood Hospital & Medical Center, DeBow, MD

U.S. NUCLEAR REGULATORY COMMISSION

Page 2

FMDH

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Coalinga, MT. 59230

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RECEIVED  
MAY 23 2016

DNMS

NRC Reg IV

1600 E Lamar Blvd

Arlington, TX 76011-4511

590982





ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Earl R. Harrison, Jr., M.D., Radiation Safety Officer  
Frances Mahon Deaconess Hospital  
621 Third Street South  
Glasgow, Montana 59230

Date

06/01/2016

License Number(s)

25-16906-01

Mail Control Number(s)

590982

Licensing and/or Technical Reviewer or Branch

CLH

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: 05/02/2016

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 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) 200-1140

✓ 6/1/16



BETWEEN:

Accounts Receivable/Payable  
and  
Regional Licensing Branches

[ FOR ARPB USE ]  
INFORMATION FROM WBL

Program Code: 02121  
Status Code: Pending Amendment  
Fee Category: 7C  
Exp. Date: 07/31/2013  
Fee Comments:  
Decom Fin Assur Req: N

## License Fee Worksheet - License Fee Transmittal

### A. REGION

#### 1. APPLICATION ATTACHED

Applicant/Licensee: FRANCES MAHON DEACONESS HOSPITAL  
Received Date: 05/23/2016  
Docket Number: 3011841  
Mail Control Number: 590982  
License Number: 25-16906-01  
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: \_\_\_\_\_