

## Simmons, Michelle

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**From:** Cann,Kari <KCann@bozemanhealth.org>  
**Sent:** Thursday, October 20, 2016 2:08 PM  
**To:** Simmons, Michelle  
**Subject:** [External\_Sender] FW: NRC License 25-10994-04: Deficiency Letter  
**Attachments:** Kirwan AUD 9 2016.pdf

One more try

*Kari*

Kari Cann MS DABR  
Medical Physicist/ Radiation Safety Officer

BOZEMAN HEALTH DEACONESS HOSPITAL  
915 Highland Boulevard  
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Tel: 406.788-7887

[kcann@bozemanhealth.org](mailto:kcann@bozemanhealth.org)  
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**From:** Cann,Kari  
**Sent:** Thursday, October 20, 2016 12:31 PM  
**To:** Simmons, Michelle (Michelle.Simmons@nrc.gov)  
**Subject:** FW: NRC License 25-10994-04: Deficiency Letter

Hi Michelle  
Here is the information again  
Please let me know when you receive it  
Thanks for checking up on this

*Kari*

Kari Cann MS DABR  
Medical Physicist/ Radiation Safety Officer

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**PUBLIC**

- ☐ Immediate Release  
☒ Normal Release

**NON-PUBLIC**

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

Reviewer: MS Date: 10/21/16

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**From:** Cann,Kari  
**Sent:** Thursday, September 29, 2016 3:01 PM  
**To:** 'Simmons, Michelle'  
**Cc:** Cann,Kari  
**Subject:** RE: NRC License 25-10994-04: Deficiency Letter

Hello Michelle

I have attached the NRC Form 313(aud) for Dr. Kirwan as requested. We (members of the Radiation Safety Committee) decided to add Dr Kirwan to our license for parts 100 and 200 only at this time. I believe you are already in possession of his board certification stating that he is AU eligible. I have attached another copy to help with the documentation.

Thank you for your quick attention to this matter. Please do not hesitate to let me know if there are additional documents that are needed

*Kari*

Kari Cann MS DABR  
Medical Physicist/ Radiation Safety Officer

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**From:** Simmons, Michelle [<mailto:Michelle.Simmons@nrc.gov>]  
**Sent:** Wednesday, September 21, 2016 9:06 AM  
**To:** Cann,Kari  
**Subject:** NRC License 25-10994-04: Deficiency Letter

Ms. Cann,  
I apologize. Part of the original deficiency letter must have been deleted inadvertently. Please see below. Additional information is needed for Dr. Kirwan.

Docket No.: 030-33305  
License No.: 25-10994-04  
Control No.: 591542

This email is in reference to your letter dated July 21, 2016, requesting to add Dr. Kirwan to your license and to increase Dr. Kalagher's authorized uses. Please note, the NRC has issued new guidance concerning the use of Y-90 microspheres. For your convenience, I have attached a copy of the guidance to this email. In order to continue our review of your request, we need the following additional information.

1. Please make the following commitments:

We commit to following the "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance" dated February 2016 in its entirety.

For Dr. Kirwan

Please complete the attached NRC Form 313(aud) and (aut). Please remember to include documentation of the three cases for each authorization you wish Dr. Kirwan to have under any byproduct material permitted by 10 CFR 35.300.

Please provide this information by **October 21, 2016**. You may fax your signed response to 817-200-1263, referencing mail control 591542. When you send the fax, you may wish to leave a voicemail or e-mail message to alert me to look for it. If you are submitting your response by email, the response must be submitted in pdf format. Please send me an e-mail or call me at 817-200-1590 if you have any questions.

Michelle Simmons  
Health Physicist  
US NRC  
1600 East Lamar Blvd.  
Arlington, Texas 76011  
817-200-1590

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**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

Ryan C Kirwan, MD

State or Territory Where Licensed

Montana

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			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use <i>(not required for 35.590)</i>			
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.**



**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 Ryan C Kirwan, 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 Ryan C Kirwan, 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

Ronald Tharp, MD

Signature



Telephone Number

406 587 8631

Date

09/22/2016

License/Permit Number/Facility Name

Bozeman Health Deaconess Hospital License #25-10994-04

## Simmons, Michelle

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**From:** Cann,Kari <KCann@bozemanhealth.org>  
**Sent:** Thursday, September 08, 2016 5:25 PM  
**To:** Simmons, Michelle  
**Cc:** Cann,Kari  
**Subject:** [External\_Sender] Re: NRC License 25-10994-04: Deficiency Letter  
**Attachments:** deficiency response for Kirwan and Kalagher.pdf

Resending to include my correct email address  
KC

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**From:** Cann,Kari  
**Sent:** Thursday, September 8, 2016 4:23 PM  
**To:** Simmons, Michelle  
**Cc:** kcann@bozemanhealth.com  
**Subject:** Re: NRC License 25-10994-04: Deficiency Letter

Hello Michelle  
Please find the requested statement attached to this email  
Thank you

*Kari*

Kari Cann MS DABR  
Medical Physicist/ Radiation Safety Officer  
BOZEMAN HEALTH DEACONESS HOSPITAL  
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Bozeman, MT 59715  
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[www.bozemanhealth.org](http://www.bozemanhealth.org)

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**From:** Simmons, Michelle <Michelle.Simmons@nrc.gov>  
**Sent:** Thursday, August 25, 2016 3:18 PM  
**To:** kcann@bozemanhealth.com  
**Cc:** Cann,Kari; Cann,Kari  
**Subject:** NRC License 25-10994-04: Deficiency Letter

This email was sent to your old bdh-boz.com address. Please let the sender know that your new address is  
[@bozemanhealth.org](mailto:@bozemanhealth.org)  
Docket No.: 030-33305  
License No.: 25-10994-04  
Control No.: 591542



This email is in reference to your letter dated July 21, 2016, requesting to add Dr. Kirwan to your license and to increase Dr. Kalagher's authorized uses. Please note, the NRC has issued new guidance concerning the use of Y-90 microspheres. For your convenience, I have attached a copy of the guidance to this email. In order to continue our review of your request, we need the following additional information.

1. Please make the following commitments:

We commit to following the "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance" dated February 2016 in its entirety.

Please provide this information by **September 15, 2016**. You may fax your signed response to 817-200-1263, referencing mail control 591542. When you send the fax, you may wish to leave a voicemail or e-mail message to alert me to look for it. If you are submitting your response by email, the response must be submitted in pdf format. Please send me an e-mail or call me at 817-200-1590 if you have any questions.

Michelle Simmons  
Health Physicist  
US NRC  
1600 East Lamar Blvd.  
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Michelle Simmons  
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817-200-1590

BOZEMAN HEALTH DEACONESS HOSPITAL  
Docket No.: 030-33305  
License No.: 25-10994-04  
Control No.: 591542

Sept 6, 2016

This letter is in reference to your Deficiency Letter notification pertaining to our amendment requesting to add Dr. Kirwan to our license and to increase Dr. Kalagher's authorized uses.

"We commit to following the "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance" dated February 2016 in its entirety"

I hope this satisfies the requirements. Please contact me if you need additional information.

Sincerely

A handwritten signature in black ink that reads "Kari Cann". The signature is fluid and cursive, with the first name "Kari" and last name "Cann" clearly distinguishable.

Kari Cann MS DABR  
Medical Physicist/ Radiation Safety Officer  
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