

**Cook, Jackie**

License: 40-00238-04  
Docket: 130-03231  
Control: 589928

**From:** Cook, Jackie  
**Sent:** Tuesday, May 03, 2016 2:14 PM  
**To:** 'JMckee1@regionalhealth.com'  
**Cc:** LHusman@regionalhealth.com  
**Subject:** RE: Re: Re: REQUEST FOR ADDITIONAL INFORMATION FOR RAPID CITY REGIONAL HOSPITAL, INC. LICENSE # 40-00238-04  
**Attachments:** NRC FORM 313A AUT Rapid City Reg Hosp Inc.pdf

Good Afternoon Mr. Mckee: I confirm receipt of your email below and the 2 attestations.

1. Please expand Dr. Brinks experience to include documentation of the following in accordance with 10 CFR 35.396(d)(2): Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in § 35.390 must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(4). The work experience must involve—

(vi) Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required;

OR complete the attached NRC Form 313A(AUT) accordingly with those asterisks sections.

2. In addition, please update the Preceptor Attestation (Part II, Third Section of NRC Form 313A[AUT]) to include the following statement: "I attest that \_\_\_\_\_ has satisfactorily achieved a level of competency to function independently as an authorized user for: Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive".

Please do not hesitate to contact me if you would like to discuss further.

Sincerely,

Ms. Jacqueline "Jackie" D. Cook  
Senior Health Physicist  
US Nuclear Regulatory Commission Region IV Division of Nuclear Materials Safety Nuclear Materials Safety Branch B  
1600 East Lamar Blvd., Arlington, TX 76011  
817-200-1132 (office)/817-200-1263 (fax) Email address: Jackie.Cook@nrc.gov -----Original Message-----  
From: JMckee1@regionalhealth.com [mailto:JMckee1@regionalhealth.com]  
Sent: Tuesday, May 03, 2016 12:17 PM  
To: Cook, Jackie <Jackie.Cook@nrc.gov>  
Cc: LHusman@regionalhealth.com  
Subject: [External\_Sender] Re: Re: Re: REQUEST FOR ADDITIONAL INFORMATION FOR RAPID CITY REGIONAL HOSPITAL, INC. LICENSE # 40-00238-04

~~PUBLIC~~  
☒ Immediate Release  
☐ Normal Release

Ms. Cook,

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

I have attached 2 attestations. Please let me know if you need any more information.

Thank you,

Jim Mckee  
Medical Physicist  
Radiation Safety Officer  
John T. Vucurevich Regional Cancer Care Institute  
353 Fairmont Blvd  
Rapid City, SD 57701  
(605) 755-2339  
jmckee1@regionalhealth.com

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License: 40-00238-4  
Docket: 030-02231  
Control: 589928

**Cook, Jackie**

**To:** JMckee1@regionalhealth.com  
**Cc:** LHusman@regionalhealth.com  
**Subject:** RE: Re: REQUEST FOR ADDITIONAL INFORMATION FOR RAPID CITY REGIONAL HOSPITAL, INC. LICENSE # 40-00238-04  
**Attachments:** FSME 13-002 Ra-223 Dichloride Licensing ML13008A149.pdf

Good Morning Mr. McKee: I received your voice mail message and email below. I apologize for the short notice in requesting you to respond. Please give me a date on which you can submit your response and I will grant your extension accordingly.

Please see the attached Agreement State letter regarding the licensing decision the NRC has made regarding Xofigo. Although Xofigo is an alpha emitter, it also contains some beta emitters also; therefore, Dr. Brink will be authorized for parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV. Therefore the 3 cases Dr. Brink participated in from Dr. White and Dr. Flynn is sufficient case work and all that is needed at this time in response to Item 3 of my email.

Please let me know if you still want me to call you. In addition, please do not hesitate to contact me if you have any questions regarding the above.

Sincerely,

Ms. Jacqueline "Jackie" D. Cook  
Senior Health Physicist  
US Nuclear Regulatory Commission Region IV Division of Nuclear Materials Safety Nuclear Materials Safety Branch B  
1600 East Lamar Blvd., Arlington, TX 76011  
817-200-1132 (office)/817-200-1263 (fax) Email address: Jackie.Cook@nrc.gov

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

From: JMckee1@regionalhealth.com [mailto:JMckee1@regionalhealth.com]  
Sent: Friday, April 15, 2016 10:31 AM  
To: Cook, Jackie <Jackie.Cook@nrc.gov>  
Cc: LHusman@regionalhealth.com  
Subject: [External\_Sender] Re: REQUEST FOR ADDITIONAL INFORMATION FOR RAPID CITY REGIONAL HOSPITAL, INC. LICENSE # 40-00238-04

Ms. Cook,

Dr. Brink is not in today. Therefore, having a written attestation from him by noon on Monday is not practical. Dr. Brink has been involved with the injection of xofigo, which is an alpha emitter. Xofigo does require a written directive. Does he need to be involved in a parenteral case involving a beta emitter? Not being able to meet the time constraints, is an extension possible, or should I resubmit the amendment?

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☐ A.7 Sensitive Internal  
☐ Other:

Thank you

Jim McKee

Reviewer: [Signature] Date: 5/6/16

April 27, 2016

United States Nuclear Regulatory Commission Region IV

License Branch

612 E. Lamar Blvd.

Suite 400

Arlington, TX

Subject: Attestation Letter from Dr. Joel Brink, MD

I attest that I have experience in administering doses of beta / alpha emitter (Xofigo) requiring a written directive. I meet the requirements as an authorized user for 35.392 and 35.394.

I am an authorized user under NRC license 40-00238-04.

  
Joel M. Brink, MD

4/28/2016

**PUBLIC**

- ☐ Immediate Release  
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**NON-PUBLIC**

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

Reviewer:  Date: 5/3/16

May 3, 2016

United States Nuclear Regulatory Commission Region IV

License Division

612 E. Lamar Blvd.

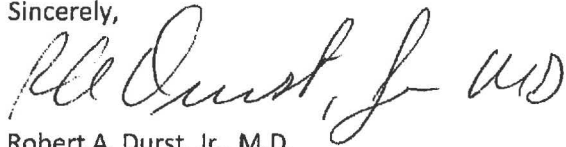
Suite 400

Arlington, TX

Subject: Attestation Letter for Joel M. Brink, M.D.

I attest that Joel M. Brink, M.D. has participated in 3 separate Parenteral IV therapies of byproduct materials requiring a written directive. He has achieved competency in Beta/Alpha(Xiofigo) emitting radiopharmaceuticals requiring a written directive.

Sincerely,



Robert A. Durst, Jr., M.D.

**PUBLIC**

☐ Immediate Release  
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**NON-PUBLIC**

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

Reviewer: JDL

Date: 5/3/16