

Hammond, Michelle

From: Hammond, Michelle
Sent: Tuesday, November 19, 2013 8:13 AM
To: 'sebastiano.anzalone@cardinalhealth.com'
Subject: Re: REQUEST FOR ADDITIONAL INFORMATION

License No.: 40-16775-01
Docket No.: 030-11624
Control No.: 581048

Dear Mr. Anzalone:

This is in reference to your renewal application dated June 3, 2013 regarding Nuclear Regulatory Commission License No. 40-16775-01. In order to continue our review, we need the following additional information:

- 1) Please provide contact information for the proposed RSO, William N. Salk, M.S. (phone and e-mail address).
- 2) Please confirm that you possess Co-57 (25mCi) as sealed source for calibration of Gamma Camera, in accordance with 35.65(a) and that it does not need to be listed on the license, as in previous license.
- 3) Please confirm and acknowledge that this license will not authorize "Notice of Claimed Investigational Exemption of New Drug" (IND) or approved "New Drug Application" (NDA) uses without prior approval and technical review through the licensing process. (Application First Paragraph Item 5.a.)
- 4) Please state if you plan to use unsealed alpha-emitters (ie. Ra-223), and if so, provide a description of what special instrumentation, training, and safety procedures you have incorporated into the program.

We will continue our review upon receipt of this information. Please reply to my attention at the Region IV Office and refer to Mail Control No. 581048. Please respond to this e-mail ASAP. You may reply via e-mail as long as the response is attached in a PDF format or by fax to 817-200-1188.

Please don't hesitate to contact me if you have any questions.

Best Regards,

*Michelle M. Hammond, M.Sc.
Health Physicist
Region IV-Division of Nuclear Materials Safety, Branch B
office) 817-200-1127
fax) 817-200-1188*



PUBLIC

- ☐ Immediate Release
☒ Normal Release

NON-PUBLIC

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

Reviewer:  Date: 11/19/13

RECEIVED

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DNMS

November 19, 2013

U.S. Nuclear Regulatory Commission
Michelle Hammond, Licensing Branch Region IV
1600 East Lamar Blvd.
Arlington, TX 76011-4511

Dear Ms. Hammond,

This correspondence is regarding the Request for Addition Information, regarding Radioactive Materials License #40-16775-01 (Prairie Lakes Health Care Systems, Inc., P.O. Box 1210, 401 9th Avenue NW; Watertown, SD 57201-6210). Please include the following addition information in BLUE to our application;

1. Please provide contact information for the proposed RSO, William N. Salk, M.S. (phone and e-mail address).
 - Office Phone: 218-786-1027 E-mail: rads4u@aol.com
 - Cell Phone: 320-267-4144 billsalk@essentiahealth.org
2. Please confirm that you possess Co-57 (25mCi) as sealed source for calibration of Gamma Camera, in accordance with 35.65(a) and that it does not need to be listed on the license, as in previous license.
 - We confirm that this facility does possess Co-57 Flood Source (25 mCi) for the calibration of Gamma Cameras. We acknowledge this source does not need to be listed on the license, as stated in 35.65(a). However, these sources will be included on our inventory and leak tested as required.
3. Please confirm and acknowledge that this license will not authorize "Notice of Claimed Investigational Exemption of New Drug" (IND) or approved "New Drug Application" (NDA) uses without prior approval and technical review through the licensing process. (Application First Paragraph Item 5.a)
 - We confirm and acknowledge that this facility will not authorize "Notice of Claimed Investigational Exemption of a New Drug (IND)" or approved "New Drug Application (NDA)" until an amendment / request has been submitted and approved by the NRC and our facility has received the new RAM License as verification.

4. Please state if you plan to use unsealed alpha-emitters (ie. Ra-223), and if so, provide a description of what special instrumentation, training, and safety procedures you have incorporated into the program.

-Since the submission of our Radioactive Materials License Application, our facility has begun the use of unsealed alpha-emitter Ra-223 Dichloride Xofigo.

Training: Training was initially provided by Bayer/Algeta company representatives.

Special Instrumentation: There is no special instrumentation required for the administration for the administration of Ra-223 Xofigo. The dose calibrator was calibrated with a NIST traceable source and a calibration number, specifically for Ra-223, was established and entered into the dose calibrator.

Safety Procedures: We have developed and maintained procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301 and as stated in Item 10e of our application.

Should you have any further questions, please do not hesitate in contacting me.

Kind Regards,

Sebastiano Anzalone

Radiation Safety Officer