Parker, Bryan

From: Parker, Bryan
Sent: Wednesday, November 19, 2014 10:57 AM
To: 'Sullivan, Glenn'
Subject: NRC Request for Additional Info re: CN584197
Attachments: Cardinal Health Ra-223 license RAI.docx

Hey Glenn,

In order to continue the review of the Radium-223 facility in Indianapolis, IN, we have a Request for Additional Information. Please see the attached document.

You may formally respond by letter and/or you can provide the response to me by e-mail. If you send by e-mail, please attach the response as a **PDF file with a *signed* cover letter**. As soon as I receive your response, I will continue the review.

If you have any questions on this or have problems with the attachment, please let me know.

Thanks.
Bryan

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U.S.NRC
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Protecting People and the Environment

Request for Additional Information

Cardinal Health – Radium-223 Facility, Indianapolis, IN (CN584197)

1. In Item 5 (Page 5 – 1), under **Radioactive Material**, Subitem B, it indicates: "Any radioactive material Atomic Nos. 3-83 or reference standard permitted by 10 CFR 35.65."

   Please clarify this request, because we normally only list authorization for 35.65 sources similar to Subitems 6 thru 8.H. of your NRC License No. 34-29200-01MD.

2. In Item 5 (Page 5 – 1), under **Uses**, Subitem A, it indicates: "Radioactive material will be used for storage, preparation, dispensing, calibration and references sources per 10 CFR 35.65, and/or distributing prepared radioactive drugs to authorized recipients."

   This proposed use does not appear to match with the material specified above that in Subitem A under **Radioactive Material** (radium-223). Please clarify the proposed use(s) of radium-223.

3. In Item 7.2, **Authorized Nuclear Pharmacists**, you list the individuals you wish to add as ANPs to the license. While each individual appears to be qualified to be an ANP, the preceptors presented for each do not appear to meet the requirement as preceptor ANPs since they are not yet ANPs. See table below outlining this:

Proposed ANP	**Preceptor Attestation signed by:**
Keith Koontz, RPh	Adam Timm, RPh
Adam Timm, RPh	Keith Koontz, RPh
Greg Even, RPh	Keith Koontz, RPh
Benjamin Ellert, RPh	Keith Koontz, RPh
Melissa George, RPh	Keith Koontz, RPh
Amanda Jehl, RPh	Keith Koontz, RPh
Ryan Kunkel, RPh	Keith Koontz, RPh

   Please provide further documentation to show that Mr. Timm and/or Mr. Koontz are already listed as ANPs on a license, thereby making them acceptable preceptors, or provide other preceptor attestations for these proposed ANPs.

4. The last sentence in Item 7.3, **Non-pharmacist Authorized Users,** indicates "The scope of the training is described in this application Radiation Safety Program, Section 10, "Instructions to Workers."" However, this information does not appear to be in the application.

   Please provide the information as noted in Item 7.3.

5. Item 8.1, **Occupationally Exposed Workers and Ancillary Personnel**, refers to a list of computer-based courses in Attachment A. Please further describe these courses briefly.

6. Item 9, **Facilities and Equipment**

   A. Section 3, (3rd bullet under Administrative Controls) indicates "Each isolator will exhaust air at a minimum rate of ____ CFM."

      Please explain why this is blank and/or provide the minimum air exhaust rate.

   B. Section 3, ISO 5 Barrier Isolator:

      Please provide a justification for not including air monitoring in the work place outside the Barrier Isolator.

   C. Section 7 (2nd paragraph):

      Based on the Lab Impex, the low end of the detection limit is 2.7 E-13 uCi/ml. Please provide the MDC calculation to demonstrate the CAM can detect 2.7 E-13 uCi/ml. Also provide the detection sensitivity based on concentration times sampling time. In other words, determine the sampling time required to detect 2.7 E-13 uCi/ml.

   D. Section 7 (3rd paragraph) indicates "A back up system will be available to ensure continuous air effluent monitoring."

      Please further describe this back up system.

7. Item 10, **Radiation Safety Program,** Section 2.1, Precautionary Measures for Handling Quantities of Radium-223 (also see Section 4.2, Bioassay Procedures and Attachment E)

   A. Will the capability to analyze bioassays be onsite? If not, is there (or will there be) an agreement in place with an outside vendor to facilitate analyses in order to make them more timely??

   B. The proposed bioassay measurement is only based on the ingestion. Please provide a justification for not including bioassay measurement from inhalation intake.

   C. Please provide further justification/calculations to show that the minimum detectable activity (MDA) is such that the investigational and action levels of 0.02 and 0.1 ALI, respectively, will be detected.

8. Item 10, **Radiation Safety Program,** Section 8, Public Dose:

   Please provide the method to assess the release resulting in public dose not exceeding constraints limit of 10 mrem/yr, such as Comply Code or concentration at the release point.