

## **Request for Additional Information**

### **Cardinal Health – Ra-223 Radium Dichloride Xofigo® Manufacturing Facility Indianapolis, IN (CN 588680)**

**This RAI follows a telecon with applicant on April 27, 2016**

#### **Participants:**

**NRC:** Bryan Parker, Health Physicist, Materials Licensing Branch, Region III

**Applicant:** Scott Claunch, Corporate Radiation Safety Officer

## **DISCUSSION ITEMS**

1. Please provide the following documents in PDF format to facilitate adding them to the NRC document management system ADAMS:
  - Letter dated April 12, 2016 re: Response to NRC Site Visit on April 7, 2016, with attachments.
  - Letter dated April 15, 2016 re: Dose assessment for Ac-227 releases, with attachments.
  - Letter dated April 18, 2016 re: Dose assessment for Ra-223 releases, with attachments.
2. In Item 1, Bullet 4 of your letter dated April 12, 2016, you requested reference sources with the ranges of atomic nos. 3-83 and 84-95; however, you did not specify possession limits. Please confirm the possession limits proposed for these reference sources or request other limits:
  - A. For any byproduct material with Atomic Nos. 3-83 – 100 millicuries total with no single source to exceed 30 millicuries.
  - B. For any byproduct materials with Atomic Nos. 84-95 – 30 microcuries total with no single source to exceed 10 microcuries.
3. In Item 4 of your letter dated April 12, 2016, you requested that Elizabeth Tindle be named on the license. Although we recognize she is part of the health physics staff, we do not intend to list her on the license. Please acknowledge your understanding that Ms. Tindle will not be listed on the license.

## Parker, Bryan

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**From:** Parker, Bryan  
**Sent:** Thursday, April 28, 2016 2:53 PM  
**To:** 'Claunch, Scott'  
**Cc:** Pelke, Patricia  
**Subject:** RAI from 4/27 telecon  
**Attachments:** Cardinal Health Ra-223 manuf license RAI from 4.27.16 telecon.docx

Hey Scott,

As discussed, please find attached the Request for Additional Information. You may respond by email with an attached **signed** cover letter in PDF format.

**NOTE: Please send the letters requested in Item 1 of the RAI in PDF format as well and as separate documents; however, the attachments within each of those letters may be included with the letter as one document each.**

If you have any questions, please let me know.

Thanks.  
Bryan

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