

Parker, Bryan

From: Parker, Bryan
Sent: Tuesday, April 14, 2015 9:13 AM
To: 'Sullivan, Glenn'
Cc: Pelke, Patricia
Subject: RAI from 4/10 call
Attachments: Cardinal Health Ra-223 lic RAI after 4 10 15 call final.docx

Glenn,

Attached is the Request for Additional Information as discussed in our 4/10 conference call. Please feel free to contact me with any questions or clarifications.

Bryan

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Request for Additional Information

Cardinal Health – Radium-223 (Ra-223) Dispensing Facility, Indianapolis, IN (CN 584197)

This RAI follows a conference call with G. Sullivan and other representatives of Cardinal Health:

Call details: 04/10/15, 10:00-11:30am ET

Participants:

NRC: Patty Pelke, Chief, Materials Licensing Branch, Region III

Bryan Parker, Health Physicist, Lead Reviewer, Region III

Licensee: Glenn Sullivan, Manager, HP

Scott Claunch, Corporate RSO

Cami Still, Auditor and Authorized User

Stacy Sternberg, HP Consultant

DISCUSSION ITEMS

1. Please provide the MDC calculations for both the in-room monitoring system and the post-filter sampling system.
2. Please "define" the zero reading on the in-room monitoring and post-filter sampling system readouts.
3. Please provide the calibration procedures for both the in-room monitoring and post-filter sampling systems. Also, please include the frequency of calibration and who will be performing the calibrations.

Also, please describe functional tests of these systems and the frequencies at which they will be performed on each system. Please clarify the source(s) to be used for functional tests, including the make and model numbers of said sources.

Per our discussion, here are several references regarding air monitor calibration and the Part 20 requirement:

- American National Standards Institute (ANSI) document (ANSI N13.10-1974 and ANSI N42.18-2004), Specification and Performance of On-Site Instrumentation for Continuously Monitoring Radioactivity in Effluents.
- NRC Regulatory Guide 4.15, Revisions 1 & 2, Quality Assurance for Radiological Monitoring Programs – Effluent Streams and the Environment. NRC Regulatory Guide 1.21, Revisions 1 & 2, Measuring, Evaluating and Reporting Radioactivity in Solid Wastes and Releases of Radioactive Material in Liquid and Gaseous Effluents from Light Water Cooled Nuclear Power Plants.
- NRC Health Physics Positions Database (NUREG/CR-5569, Revision 1), HPPPOS # 040, Effluent Radiation Monitor Calibrations.

- **NRC Information Notice 2013-13, Deficiencies with Effluent Radiation Monitoring System Instrumentation.**

10 CFR 20.1501(c) requires that the instrument be periodically calibrated "for the radiation measured." The aforementioned ANSI Standards specify that a thorough "primary" calibration that encompasses the entire system be performed after the system has been installed using a radionuclide of known concentration(s) that permits calibrating the range of energy and rate capabilities intended for the system. As provided in the ANSI standards, traceability to the National Bureau of Standards shall be maintained for the radionuclides used.

4. **Please provide your technical basis for monitoring for bismuth-211 (Bi-211) concentrations and further explain why that is an appropriate isotope of interest. Your discussion should also demonstrate why the concentration of Bi-211 accurately represents the concentration of Ra-223 without applying any correction factors.**
5. **Please provide a "worst case scenario" involving a reasonable accident/event that could result in a significant release of Ra-223 product. Include measures that will be taken to determine doses to workers and the public. This should also include calculations showing what the maximum activity that could be "spilled" and still maintain releases within regulatory limits.**
6. **Please provide an updated diagram showing the in-room monitoring and post-filter sampling systems and how they interact with the overall air handling system.**