Parker, Bryan

From: Parker, Bryan
Sent: Wednesday, February 11, 2015 5:23 PM
To: 'Sullivan, Glenn'
Cc: Pelke, Patricia; Lee, Peter; Forster, Sara
Subject: NRC Comments for Site Visit
Attachments: Cardinal Health 2.18.15 site visit comments and questions.docx

Hey Glenn,

As promised, attached are the comments/questions for the site visit next Wed., Feb. 18, 2015. See you then at 9:00a.

If you need anything else from me, just let me know.

Thanks.
Bryan

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Parker, Bryan

From: Parker, Bryan
Sent: Tuesday, February 24, 2015 10:46 AM
To: 'Sullivan, Glenn'
Cc: Pelke, Patricia
Subject: RE: good afternoon

Hey Glenn,

We thought the visit was very beneficial as well. It will definitely help in moving forward with this action.

The NRC folks in attendance, other than me, were:

Patty Pelke, Chief, Materials Licensing Branch, RIII - 630-829-9868
Peter Lee, CHP, Reactor Inspector (Decommissioning), RIII - 630-829-9870
Sara Forster, Health Physicist, RIII – 630-829-9892

One other item -- Upon further discussion with Patty after our visit, we had one other item we would like you to address in the response:

Additional Request:
Please provide information related to what routine maintenance you will conduct on the barrier isolators. This should include a description of the types of maintenance, who will perform the maintenance and what frequency the maintenance activities will be performed.

If you have any questions, please let me know.

Thanks.
Bryan

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From: Sullivan, Glenn [mailto:glenn.sullivan@cardinalhealth.com]
Sent: Thursday, February 19, 2015 2:22 PM
To: Parker, Bryan
Subject: good afternoon

I am working on getting the information together that the NRC is requesting. I wanted to take a moment and thank you again for coming to the pharmacy. We greatly appreciate your insight into the program. When you work with different groups you get a different perspective and that is a good think.

Also, if you would, could you forward to me the full names of Rose and Peter and their associated numbers. I have misplaced their cards.

Thanks again. I hope your trip home was uneventful.

g

CardinalHealth

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Region III Comments/Questions for
Cardinal Health Site Visit
related to the
New License Application for a
Radium-223 (Ra-223) distribution facility
February 18, 2015

NOTE: THESE COMMENTS AND QUESTIONS ALL REFER TO THE REQUEST FOR ADDITIONAL INFORMATION (RAI) THAT WAS SENT TO CARDINAL ON NOVEMBER 19, 2014, AND THE WRITTEN RESPONSE TO THE RAI PROVIDED BY CARDINAL IN LETTER DATED JANUARY 5, 2015.

- Regarding Item 1 of the RAI, it appears that a "standard" authorization for 35.65 sources will be acceptable to Cardinal; however, let's discuss further.

- Regarding Item 2 of the RAI, it is still not clear what the proposed uses are for Ra-223.
  Original application says:
  "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."

  Response is worded:
  "Radioactive material will be used for storage, preparation, and/or transfer of bulk radioactive drugs and reference sources, according to 10 CFR 35.65(c) to authorized recipients."

  [For reference: 35.65(c) says: Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi).]

  Will Cardinal be making up unit doses, bulk doses, references sources or some combination thereof? Let's discuss further.

- Regarding Item 3 of the RAI, sufficient documentation was provided to show all proposed ANPs for the new license are currently approved ANPs on the Cardinal License No. 34-29200-01; therefore, no additional information is needed for this item.

- Regarding Item 4 of the RAI, training forms were submitted in the response, but still no description of the program for non-pharmacist authorized users. Attachment D of the response indicates Cardinal will use the same program approved in License No. 34-29200-01; however, this information will need to be submitted since this is a separate license. Let's discuss further.

- Regarding Item 5 of the RAI, Attachment E of the response refers to the computer-based training (CBT) coursework, buts gives no description on what the CBT fully entails. Let's discuss further.

- Regarding Items 6, 7 and 8 of the RAI, please see the comments/questions below pertaining to Air Sampling, Bioassay, Effluent Monitoring and Instrumentation.

Air sampling

1. Due to the transfer of raw materials or products, the routine breathing zone air sampling should be performed outside the barrier isolator area.

2. Most of the internal exposure comes from inhalation. The air sampling results can be used to determine if the performance of bioassay measurement is needed. For example, if the sampling result exceeds 10 % of DAC, perform the bioassay measurement to assess the dose. If concentration is below 10 % DAC, then assign dose by DAC-hours. **However, in case of accident, such as spill, the bioassay should be performed to assess the intake by inhalation or/and ingestion.**

Urine Bioassay (Gamma Spectrum Analyses)

1. The detection sensitivity increases as sample volume increases. Sometimes it may be difficult for worker to collect required volume, especially 2L. Verify the proposed MDC of 25 pCi/L for 2L sample stated in the response letter. Counting time? water or urine sample? For urine sample the MDC could be as high as 100 pCi/L, due to NORM, such as K-40 in the urine.

2. Clarify the time post intake to start the 24-hr urine collection. If one day post intake, based on the NUREG-4884, the IRF should be 8.27E-4 instead of 6.03E-3 as stated in the license application (ingestion), 1.08E-3 instead of 3.77E-3 (inhalation). For example, if the 24-hr urine collection starts one day post intake, based on the MDC, 25 pCi/L, the undetected intake could be up to 4.6% of inhalation ALI. The undetected intake will exceed action level of 10% of inhalation ALI, if 24-hr urine collection several days post intake or the MDC well above 25 pCi/L. In order to detect intake 10% of ALI, other more sensitive analyses may be required, such as alpha count by chemical separation.

3. If the Ra-223 cannot be identified, due to insufficient sampling volume or/and counting time, or urine containing other radioactive materials such NORM resulting in higher Compton continuum under Ra-223 peak regions of interest, the MDC from gamma spectrum analytical report should be used to assess the intake. **Suggest the licensee to provide the required MDC to the vendor, based on the urine concentration derived from post intake of 10% ALI.** Then vendor can provide the required volume of sample and the method for the analyses.

Real-time Effluence monitoring

1. Provide the sampling data to demonstrate 6 x 10^{-13} uCi/ml can be detected in 2-hrs sampling window as stated in the response letter. Also, as stated in the response, the real-time air monitoring system will be operating when Ra-223 dichloride is dispensed. Does it take more than 2-hrs to dispense the Ra-223 dichloride? If not, 6 x 10^{-13} uCi/ml cannot be detected during real-time monitoring. (Part 20 effluent concentration limit 9 x 10^{-13} uCi/ml)

2. Please clarify the alarm setting of 8 DAC. The air monitoring is for the effluent release, not work area. The alarm setting should be based on the effluent concentration limit of 9 x 10^{-13} uCi/ml, not DAC, 3 x 10^{-10} uCi/ml.

3. Provide the parameters will be used for Comply Code to assess the public dose. Determine if the Comply Code is applicable to the release, such as any structure around the release point, air intake of the building, exit velocity of gas, etc. (**Tour the roof where the exhaust stack located to assess the release**)

4. Cross Check the Real-time Monitoring

   If air sampling filter will be replaced in a short period of time, such as about $T_{1/2}$ of Ra-223, suggest licensee to count the replaced filter and determine the collected Ra-223 activity with the decay correction. Then, based on the volume of air collected during real-time monitoring, determine the concentration and compare it with the real-time measurement.

5. Negative Pressure in Dispensing Room

   Please confirm the return air will be discharged directly to the filtration exhaust system.

Survey and analytical instrument

Evaluate the calibration, detection sensitivity of the following instruments:

1. Alpha counter
2. Dose rate survey meter
3. Portal monitor – personnel and equipment exit. Exit criteria?