Request for Additional Information (RAI)

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

This RAI follows a teleconference conducted on February 22, 2016.

NOTE: All references to the "application" in the items below refer to Cardinal's license application dated August 28, 2015, and all references to "RAI" in items below refer to Cardinal's Response to RAI dated January 11, 2016.

Telecon Participants:

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

Bryan Parker, Health Physicist, Lead Reviewer, Region III

Sara Forster, Health Physicist, Reviewer, Region III

Applicant: ***Scott Claunch, Corporate RSO***

Glenn Sullivan, Manager, HP

Cami Still, Site RSO (proposed)

DISCUSSION ITEMS

1. Please provide the status of the Decommissioning Funding Plan (DFP) that is being formulated to address the financial assurance (FA) matters associated with this license application. The NRC cannot issue the license until we receive a DFP and FA instrument. FA is required for possession of actinium-227 in unsealed quantities greater than 10 microcuries.

2. With regard to RAI Item 1 (Narrative, Section III.9.), please clarify that supervision by the Manufacturing RSO (MRSO) will include "physical presence" during receipt of all actinium-227 generators (A-gens).

3. With regard to RAI Item 2 (RAM):

   A. Please clarify that an initial 2 curie (74 GBq) possession limit will allow possession of a sufficient number of A-gens to initiate start-up operations for testing, validation, etc. As discussed, a 2 curie limit will eliminate the immediate need for an Emergency Plan (EP), under 10 CFR 30.32(i). However, you will need to provide further information as outlined in 30.32 (i)(1) and (2) to determine whether an EP is required for higher possession limits.

   B. Please clarify how you plan to ultimately dispose of the A-gens.

C. Please include the potential "impurities" of radium-226 and thorium-228 that were part of the original application with appropriate possession limits.

4. With regard to RAI Item 6 (Authorized Users (AUs)):

   A. Please define the roles and responsibilities of the proposed AUs. Please also include site-specific training, as well as other training related to their duties at the new facility.

   B. Please confirm that Cami Still (identified in your application as the Manufacturing Radiation Safety Officer (MRSO) will be the only RSO listed on the license.

   C. Please provide your provisions for backing up the MRSO in that individual's absence. As discussed, the provision in Application Item 7.1 (page 7-1), paragraph 4, that states "In absence of MRSO, another AU must assume duties..." is not acceptable. Anyone assuming MRSO duties must be equally qualified as an RSO.

5. With regard to RAI Item 8 (Training):

   A. Please specify which AUs listed in the RAI Item 6 will have the responsibility for oversight of each of the employee groups.

   B. Please clarify that future AUs will be approved and listed on the NRC license prior to assuming responsibility for oversight of each employee group. Please provide the training that will be required for future AUs to include the areas noted below in Item C.

   C. Please refer to NUREG 1556, Volume 12, Appendix H, pages H-1 to H-5 for guidance in information that the NRC expects will be submitted as part of a Radiation Safety Training Program. Submitted information should clearly specify:
      i. Length (e.g. total hours) of each required training course.
      ii. Topics covered (topics listed in Appendix H including licensee-specific topics; for manufacturer-provided or other externally provided courses, please include a copy of the syllabus) in each training course.
      iii. Format (e.g. e-learning module, hands-on, classroom) of each required training course.
      iv. Instructor qualifications (e.g. equipment manufacturer, RSO, AU) for each required training course.
      v. How knowledge is assessed (e.g. written test, observation of the individual in performance of assigned duties). For written tests, include the percentage of correct responses needed to respond, and what remedial training will be provided for any missed test questions. For other

apparent weaknesses, describe additional remedial action that will be taken or additional formal training that will be used to cover deficient areas.

vi. When training will be conducted (e.g. before assuming duties with, or in the vicinity of, radioactive materials; whenever there is a significant change in duties, regulations, or the terms of the license; annually (refresher training)).

D. Please clarify wording on who must be trained in each area (i.e., Section III says "certain employees in the following work groups..." – why not ALL?)

E. Please indicate what minimum training will be provided to Group A (Admin).

6. With regard to RAI Item 9 (Facilities):

A. Please provide the calculations and analysis for air effluent monitoring, to include radioisotopes monitored for, MDA calculations and a description of the monitoring equipment. Please also include how and when the equipment will be calibrated and checked.

B. With reference to Page 1, 4th paragraph, please describe how and when the redundant fans in Stack 1 would be tested. Also, please describe how and when you would verify 100% capacity of the Stack 2 fans (since they will normally operate at 50% each, but will each be the backup to the other).

7. With regard to RAI Item 10 (Rad Safety Program):

A. Please provide the receipt and opening procedures for the A-gen receipts, to include the trigger points for not opening, what actions to take if damaged, etc.

B. Please clarify how other RAM packages will be received at the facility and describe the flowpath.

8. With regard to RAI Item 13 (Preventative Maintenance):

A. Please further define the terms "quarterly", "semi-annual", and "annual".

B. Please indicate PM measures in place for all Material Airlocks (MALs) and Personnel Airlocks (PALs) (in addition to the MAL for Hot Cell 5 noted in the current table).

C. Please clarify the PM frequencies of the items in the sections for "Fume Hoods/Isolators/Glove Boxes" and for "Uninterrupted Power Supply(UPS)/Generator".

D. Several of the systems installed at your facility are monitored by the Building Management System (BMS). Please provide the PM and testing performed on the BMS (include frequency of testing and documentation maintained) to ensure the BMS itself is functioning properly.

E. Please identify the systems and components that will not be serviced or maintained by the Cardinal Health staff and specify who will provide those services and maintenance (vendor/manufacturer, etc.).

9. With regard to RAI Item 14 (Audits):

   A. Please further define the terms "annual" and "biennial".

   B. Please review NUREG-1556, Volume 12 and address ALL components of a comprehensive audit program (objective, scope, qualifications of auditors, etc).

10. With regard to RAI Item 17 (Decay Plenum tests), please provide the testing results using xenon-133 when available.

Parker, Bryan

From: Parker, Bryan
Sent: Wednesday, February 24, 2016 4:49 PM
To: 'Claunch, Scott'
Cc: Sullivan, Glenn; Still, Cami; Pelke, Patricia; Forster, Sara
Subject: RAI from Monday's Telecon
Attachments: Cardinal Health Ra-223 manuf license RAI from 2.22.16 telecon.docx

Hey Scott,

Attached is the Request for Additional Information from our teleconference this past Monday. Please look over it carefully and let me know if there are questions or concerns. As discussed, these are most of the items needing to be addressed from our review with the exception of Surveys, and the Respiratory Protection/Bioassay Program. These areas will be addressed very soon.

As discussed, if you would like to submit your response in portions, that will be fine. As before, please respond using the Item Nos. as listed in the RAI.

As always, please don't hesitate to contact me if you have any questions.

Thank you.
Bryan

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