

Cardinal Health 414, LLC
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CardinalHealth

April 28, 2016

Bryan A. Parker
U.S. Nuclear Regulatory Commission
Region III – Division of Nuclear Materials Safety
2443 Warrenville Rd, Suite 210
Lisle, IL 60532-4352

Re: Response to April 27th Request for Additional Information received April 28th

Licensing / Mr. Parker:

Cardinal Health 414, LLC (Nuclear Pharmacy Services, hereafter Cardinal Health) respectfully submits the following additional information after the discussion had via telephone on April 28th, 2016.

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, with attachments

 - **We confirm that the above documents are provided as separate attachments. We confirm that each previous document provided (as detailed above) have not been altered in any way, except for conversion from word to pdf. Please note that we are also including the previous attachments to this April 7 response, per our discussion today, (e.g. Ms. Tindle resume, results of the Xenon Xe-133 gas test, package receipt instructions for other**

than actinium-227). These attachments have also not been altered in any way.

- Please see each pdf document named:
 - "Response to NRC visit 160407_final.pdf"
 - "1604015 HotSpot Dose Assessment.pdf"
 - "1604018 HotSpot Ra-223 Dose Assessment.pdf"

- 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.
 - For any byproduct material with Atomic Nos. 3-83 – 100 millicuries total with no single source to exceed 30 millicuries.
 - For any byproduct materials with Atomic Nos. 84-95 – 30 microcuries total with no single source to exceed 10 microcuries.

 - **We confirm that the following possession limits will be acceptable for the Cardinal Health Xofigo Manufacturing Facility located at 4343 W. 62nd Street, Indianapolis, IN 46268**
 - **For any byproduct material with Atomic Nos. 3-83: 100 millicuries total with no single source to exceed 30 millicuries**
 - **For any byproduct material with Atomic Nos. 84-95: 50 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.
 - **We confirm and acknowledge that Elizabeth Tindle will not be named on the license and understand NRC's position to exclude Ms. Tindle from the license at this time.**

If you have any questions regarding this request, please contact me at 614.757.3173.

Sincerely,

A handwritten signature in cursive script, appearing to read "Scott Claunch".

W. Scott Claunch, RPh
Director, QRA Management, CRSO
Quality and Regulatory
Nuclear Pharmacy Services

cc: Cami Still, MRSO
Glenn Sullivan, Manager, Health Physics
NRC Region III (2 Copies)
NRC Mfg License File (2)

Taylor, Tiresha

From: Tomczak, Tammy
Sent: Thursday, April 28, 2016 4:16 PM
To: Taylor, Tiresha
Subject: FW: Response to Request for Information received today
Attachments: Reponse to NRC discussion 160428.pdf; response to NRC visit 160407_final.pdf; Tindle_resume (002).pdf; Xenon 133 Delay Line Test 24Mar2016.pdf; 8-22 Package Receipt_other RAM.pdf; 160415 HotSpot Dose Assessment.pdf; 160418 HotSpot Ra-223 Dose Assessment.pdf; Cardinal 2 665.pdf

This is the email that I referred to on the document in your scanning box...

From: Parker, Bryan
Sent: Thursday, April 28, 2016 3:58 PM
To: Tomczak, Tammy <Tammy.Tomczak@nrc.gov>
Cc: Pelke, Patricia <Patricia.Pelke@nrc.gov>
Subject: FW: Response to Request for Information received today

Hey Tammy,

Here are the Cardinal items we need to add or replace in ADAMS:

- 1) "Response to NRC... 160428" – this is NEW, so I have attached a 665 for it ("Cardinal 2 665.pdf")
- 2) The following documents need to go together and REPLACE current ML16118A496:
 - A. "Response to NRC... 160407" letter
 - B. Attachment 1 – "Tindle resume..."
 - C. Attachment 2 – "Xenon 133 Delay..."
 - D. Attachment 3 – "8-22 Package receipt..."
- 3) The following document needs to REPLACE current ML16118A340: "160415 HotSpot..."
- 4) The following document needs to REPLACE current ML16118A341: "160418 HotSpot..."

Since Nos. 2, 3 and 4 are just being replaced, I'm hoping their respective 665s are sufficient – the documents have not changed, they are just PDF's instead of Word docs.

If there are questions, please let me know.

Thanks!!
Bryan

From: Claunch, Scott [<mailto:Scott.Claunch@cardinalhealth.com>]
Sent: Thursday, April 28, 2016 4:29 PM
To: Parker, Bryan <Bryan.Parker@nrc.gov>
Cc: Pelke, Patricia <Patricia.Pelke@nrc.gov>; Sullivan, Glenn <glenn.sullivan@cardinalhealth.com>; Still, Cami <Cami.Still@Cardinalhealth.com>
Subject: [External_Sender] Response to Request for Information received today

Hi Bryan –

Attached please find our response to the NRC Request for Information submitted today. I will also send this information hard copy to both you and Patty but wanted to send electronically as well, in the interest of time.

Attachments are as follows:

1. "Response to NRC discussion 160428" – is our response to the RAI from today
2. "Response to NRC visit 160407" – is the last response to the last RAI which was received from the final walk through conducted on April 7th. This document was not altered in any way, besides conversion from word to pdf.
3. "Tindle Resume" – is the first attachment originally provided as an attachment to item 2 above. Including this per our discussion. The document was not altered in any way.
4. "Xenon 133 Delay Line Test 24 Mar 2016" – is the second attachment originally provided as an attachment to item 2 above. This document was not altered in any way.
5. "8-22 Package Receipt other RAM" – is the third attachment originally provided as a an attachment to item 2 above. This document was not altered in any way.
6. "160415 HotSpot Dose Assessment" – is the HotSpot assessment as part of our Emergency Plan Evaluation using HotSpot and submitted previously to Jenny. The document has not been altered in any way, besides conversion from word to pdf.
7. "160418 HotSpot Ra-223 Dose Assessment" – is the Hotspot assessment as part of our Emergency Plan Evaluation using HotSpot and submitted previously to Jenny. The document has not been altered in any way, besides conversion from word to pdf.

Please let me know if you have any questions relative to the above.

As discussed, we are trying to manage a very tight program timeline and therefore having the final license to facilitate the ordering of A-generators is very much appreciated.

Thanks,
Scott Claunch
(o) 614-757-3173
(c) 614-330-9978

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