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April 18, 2016

Bryan Parker
Nuclear Regulatory Commission

Re: Acute Dose Assessment for the Cardinal Health Xofigo Manufacturing Facility in
Indianapolis, IN

Mr. Parker:

Due to delays in obtaining clearance to use the RASCAL software to generate acute release dose assessments related to the Xofigo Manufacturing Facility in Indianapolis, Indiana, Cardinal Health Nuclear Pharmacy Services has obtained the HotSpot software for this purpose. HotSpot is published by Lawrence Livermore National Laboratory and is used by the Department of Energy for acute dose assessment.

One potential accident scenario involves the simultaneous breakage and spill of all final product vials, resulting in the spill of 3.0 Curies of liquid Radium-223. The spill is assumed to occur at ground level in the warehouse area, and the exposure rate to a member of the public resulting from external radiation from this scenario has been computed previously to be 12.4 mR/hour. This value was previously submitted to the NRC.

To compute the total effective dose to a member of the public resulting from airborne radioactivity, Cardinal Health compiled a simulation in HotSpot, accounting for the 40 CFR 61 Appendix D release fraction for liquid-phase products (1×10^{-3}). This simulation utilizes the Federal Guidance Report 13 (FGR-13) dose conversion coefficients, which use the most up-to-date values from ICRP series 60/70 reports. Cardinal Health also utilized the "Fast" absorption type for Ra-223, which results in the highest dose results and is therefore the most conservative type. This simulation demonstrates that the dose to an individual member of the public would not exceed 1 rem.

Ra-223 Spill Scenario

This scenario utilizes the 40 CFR 61 release fraction. Relevant parameters for HotSpot are given below, with additional description or explanation where relevant. Any non-site-specific parameters were entered as the conservative program defaults.

- Total activity affected ("Material-At-Risk"): 3 Ci
- 40 CFR 61 Release Fraction ("Airborne Fraction"): 1×10^{-3}
- Physical stack height: 0 m

- Stack velocity: 0 m/s
- Wind Speed and direction: 4.3 m/s, wind from the West
 - Speed was obtained from the average wind speed in Indianapolis, IN from the National Weather Service (reported as 9.6 miles per hour)
 - Stability class is automatically chosen by the program based on wind speed and city terrain
- Receptor information was set at the default for a reference man as defined in the program
 - Height 1.5 m, breathing rate $4.17 \times 10^{-4} \text{ m}^3/\text{s}$

In previous communications, the closest distance that a member of the public could occupy would be 13 meters from the spill. Therefore, doses have been calculated for receptor distances ranging from 13 meters to 50 kilometers. To be conservative, this simulation assumes that the air in the warehouse area is not exhausted and is instead fully exposed to the outside of the building. The maximum computed total effective dose was $6.7 \times 10^{-3} \text{ rem}$ (6.7 mrem) at the 13 meter distance and the full dose output table and parameter list can be found attached.

Assuming the member of the public is present for one hour at the nearest location, this person's maximum dose would be approximately $12.4 \text{ mrem} + 6.7 \text{ mrem} = 19.1 \text{ mrem}$ (assuming $1 \text{ mR} = 1 \text{ mrem}$).

If you have any questions regarding this letter or the dose assessment results, please contact me or Evan Western at 614.553.4555.

Sincerely,



W. Scott Claunch
Corporate Radiation Safety Officer
Quality and Regulatory
Nuclear Pharmacy Services

Encl: A: Ra-223 Spill Scenario HotSpot Output

ATTACHMENT A

Ra-223 Spill Scenario HotSpot Output

HotSpot Table Output

HotSpot Version 3.0.3 General Plume
Apr 18, 2016 09:39 AM

Source Material : Ra-223 F 11.434d
Material-at-Risk (MAR) : 3.0000E+00 Ci
Damage Ratio (DR) : 1.00
Airborne Fraction (ARF) : 1.00E-03
Respirable Fraction (RF) : 1.00E+00
Leakpath Factor (LPF) : 1.000
Respirable Source Term : 3.00E-03 Ci
Non-respirable Source Term : 0.00E+00 Ci
Effective Release Height : 0.00 m
Wind Speed (h=10 m) : 4.30 m/s
Wind Speed (h=H-eff) : 3.12 m/s
Stability Class (City) : C
Respirable Dep. Vel. : 0.30 cm/s
Non-respirable Dep. Vel. : 8.00 cm/s
Receptor Height : 1.5 m
Inversion Layer Height : None
Sample Time : 10.000 min
Breathing Rate : 4.17E-04 m³/sec
Distance Coordinates : All distances are on the Plume Centerline

Maximum Dose Distance : 0.010 km
MAXIMUM TED : 0.010 rem
Inner Contour Dose : 1.0 rem
Middle Contour Dose : 0.100 rem
Outer Contour Dose : 0.010 rem
Exceeds Inner Dose Out To : Not Exceeded
Exceeds Middle Dose Out To : Not Exceeded

FGR-13 Dose Conversion Data - Total Effective Dose (TED)

DISTANCE	T E D	RESPIRABLE TIME-INTEGRATED AIR CONCENTRATION	GROUND SURFACE DEPOSITION	GROUND SHINE DOSE RATE	ARRIVAL TIME
km	(rem)	(Ci-sec)/m ³	(uCi/m ²)	(rem/hr)	(hour:min)
0.013	6.7E-03	3.5E-05	1.2E-01	2.1E-07	<00:01
0.040	8.2E-04	4.3E-06	1.3E-02	2.2E-08	<00:01
0.070	2.7E-04	1.4E-06	4.3E-03	7.3E-09	<00:01
0.100	1.3E-04	7.0E-07	2.1E-03	3.6E-09	<00:01
0.200	3.4E-05	1.8E-07	5.4E-04	9.1E-10	00:01
0.300	1.5E-05	8.1E-08	2.4E-04	4.1E-10	00:01
0.400	8.8E-06	4.6E-08	1.4E-04	2.3E-10	00:02
0.500	5.7E-06	3.0E-08	9.0E-05	1.5E-10	00:02
0.600	4.1E-06	2.1E-08	6.4E-05	1.1E-10	00:03
0.700	3.0E-06	1.6E-08	4.7E-05	8.0E-11	00:03

HotSpot Table Output					
0.800	2.4E-06	1.2E-08	3.7E-05	6.2E-11	00:04
0.900	1.9E-06	9.8E-09	3.0E-05	5.0E-11	00:04
1.000	1.5E-06	8.1E-09	2.4E-05	4.1E-11	00:05
2.000	4.4E-07	2.3E-09	6.9E-06	1.2E-11	00:10
4.000	1.3E-07	6.9E-10	2.1E-06	3.5E-12	00:21
6.000	6.7E-08	3.5E-10	1.0E-06	1.8E-12	00:32
8.000	4.2E-08	2.2E-10	6.5E-07	1.1E-12	00:42
10.000	2.9E-08	1.5E-10	4.5E-07	7.7E-13	00:53
20.000	9.7E-09	5.1E-11	1.5E-07	2.6E-13	01:46
50.000	2.3E-09	1.2E-11	3.7E-08	6.2E-14	04:27

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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