



April 15, 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.

The worst-case release scenario as defined in previous communications with the NRC is an accident scenario affecting the 13 Ci of Actinium-227 present in the hot cells at the facility. This scenario assumes that the exhaust system is inoperative and any activity released is emitted from an exposed duct on the roof of the facility, which is at a height of 10 meters.

Cardinal Health compiled two simulations of this scenario in HotSpot: Scenario One accounts for only the 40 CFR 61 Appendix D release fraction for liquid-phase products (1×10^{-3}) and Scenario Two also takes into account the containment factor of the hot cell release (established to be $8.87 \times 10^{-4} \text{ h}^{-1}$). These simulations utilize 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 Ac-227, which results in the highest dose results and is therefore the most conservative type. Both simulations demonstrate that the dose to an individual member of the public would not exceed 1 rem.

Ac-227 Scenario 1

This scenario utilizes the 40 CFR 61 release fraction only and not the containment factor of the hot cells, which makes this a conservative simulation. Critical 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"): 13 Ci
- 40 CFR 61 Release Fraction ("Airborne Fraction"): 1×10^{-3}
- Physical stack height: 10 m

- Stack velocity: 0 m/s
- Stack effluent temperature: 20 degrees C (70 degrees F)
- Air temperature: 12.8 degrees C (55 degrees F)
 - Assumed as an average temperature for Indianapolis, IN
- 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)
 - Direction chosen is conservative, since the nearest receptor to the stack is in the East direction
 - 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 $4.17 \times 10^{-4} \text{ m}^3/\text{s}$

The nearest receptor point to a member of the public has been determined to be approximately 44 m from the stack emission point in the East direction. Please see the attached for the derivation of this distance value. The maximum dose calculated at or outside this point is 1.4 rem at 44 m. Detailed dose calculations have been generated for distances of 44 m through 80 km from the emission point. The dose output table and parameter list can be found attached.

However, this scenario remains overly conservative as it does not account for the containment factor of the hot cells.

Ac-227 Scenario 2

This scenario is identical to Scenario 1 except that it also includes the containment factor of the hot cells. This additional parameter is defined below.

- Containment factor ("Leakpath Factor"): 8.87×10^{-4}

Scenario 2 results in a maximum dose to a member of the public of 1.3×10^{-3} rem at a distance of 44 m. The dose output table and parameter list are attached.

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: Ac-227 Scenario 1 HotSpot Output
B: Ac-227 Scenario 2 HotSpot Output
C: Site Boundary Determination

ATTACHMENT A

Ac-227 Scenario 1 HotSpot Output

HotSpot Table Output

HotSpot Version 3.0.3 General Plume
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Source Material : Ac-227 F 21.773y
Material-at-Risk (MAR) : 1.3000E+01 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 : 1.30E-02 Ci
Non-respirable Source Term : 0.00E+00 Ci
Physical Stack Height : 10.0 m
Stack Exit Velocity : 0.00 m/s
Stack Diameter : 0.5 m
Stack Effluent Temp. : 20.0 deg C
Air Temperature : 12.8 deg C
Effective Release Height : 10 m
Wind Speed (h=10 m) : 4.30 m/s
Wind Speed (h=H-eff) : 4.30 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 : 0.034 km
MAXIMUM TED : 1.6 rem
Inner Contour Dose : 1.0 rem
Middle Contour Dose : 0.500 rem
Outer Contour Dose : 0.250 rem
Exceeds Inner Dose Out To : 0.062 km
Exceeds Middle Dose Out To : 0.097 km
Exceeds Outer Dose Out To : 0.14 km

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

DISTANCE	T E D	RESPIRABLE TIME-INTEGRATED AIR CONCENTRATION (Ci-sec)/m3	GROUND SURFACE DEPOSITION (uCi/m2)	GROUND SHINE DOSE RATE (rem/hr)	ARRIVAL TIME (hour:min)
km	(rem)				
0.044	1.4E+00	6.0E-06	1.8E-02	5.7E-11	<00:01
0.080	6.8E-01	2.8E-06	8.6E-03	2.7E-11	<00:01
0.100	4.7E-01	2.0E-06	5.9E-03	1.9E-11	<00:01
0.200	1.3E-01	5.5E-07	1.6E-03	5.2E-12	<00:01

			HotSpot Table Output		
0.300	6.1E-02	2.5E-07	7.6E-04	2.4E-12	00:01
0.400	3.5E-02	1.5E-07	4.4E-04	1.4E-12	00:01
0.500	2.3E-02	9.5E-08	2.8E-04	9.0E-13	00:01
0.600	1.6E-02	6.7E-08	2.0E-04	6.3E-13	00:02
0.700	1.2E-02	5.0E-08	1.5E-04	4.7E-13	00:02
0.800	9.4E-03	3.9E-08	1.2E-04	3.7E-13	00:03
0.900	7.5E-03	3.1E-08	9.4E-05	3.0E-13	00:03
1.000	6.2E-03	2.6E-08	7.7E-05	2.4E-13	00:03
3.000	8.6E-04	3.6E-09	1.1E-05	3.4E-14	00:11
6.000	2.7E-04	1.1E-09	3.3E-06	1.0E-14	00:23
8.000	1.7E-04	6.9E-10	2.1E-06	6.5E-15	00:31
10.000	1.2E-04	4.8E-10	1.4E-06	4.6E-15	00:38
20.000	3.9E-05	1.6E-10	4.8E-07	1.5E-15	01:17
40.000	1.3E-05	5.5E-11	1.7E-07	5.2E-16	02:35
60.000	7.2E-06	3.0E-11	8.9E-08	2.8E-16	03:52
80.000	4.6E-06	1.9E-11	5.8E-08	1.8E-16	05:10

ATTACHMENT B

Ac-227 Scenario 2 HotSpot Output

HotSpot Table Output

HotSpot Version 3.0.3 General Plume
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Source Material : Ac-227 F 21.773y
Material-at-Risk (MAR) : 1.3000E+01 Ci
Damage Ratio (DR) : 1.00
Airborne Fraction (ARF) : 1.00E-03
Respirable Fraction (RF) : 1.00E+00
Leakpath Factor (LPF) : 8.87E-04
Respirable Source Term : 1.15E-05 Ci
Non-respirable Source Term : 0.00E+00 Ci
Physical Stack Height : 10.0 m
Stack Exit Velocity : 0.00 m/s
Stack Diameter : 0.5 m
Stack Effluent Temp. : 20.0 deg C
Air Temperature : 12.8 deg C
Effective Release Height : 10 m
Wind Speed (h=10 m) : 4.30 m/s
Wind Speed (h=H-eff) : 4.30 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 : 0.034 km
MAXIMUM TED : 1.42E-03 rem
Inner Contour Dose : 1.0 rem
Middle Contour Dose : 0.500 rem
Outer Contour Dose : 0.250 rem
Exceeds Inner Dose Out To : Not Exceeded
Exceeds Middle Dose Out To : Not Exceeded
Exceeds Outer Dose Out To : Not Exceeded

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

DISTANCE	T E D	RESPIRABLE TIME-INTEGRATED AIR CONCENTRATION (Ci-sec)/m3	GROUND SURFACE DEPOSITION (uCi/m2)	GROUND SHINE DOSE RATE (rem/hr)	ARRIVAL TIME (hour:min)
km	(rem)				
0.044	1.3E-03	5.3E-09	1.6E-05	5.0E-14	<00:01
0.080	6.1E-04	2.5E-09	7.6E-06	2.4E-14	<00:01
0.100	4.2E-04	1.7E-09	5.2E-06	1.6E-14	<00:01
0.200	1.2E-04	4.9E-10	1.5E-06	4.6E-15	<00:01

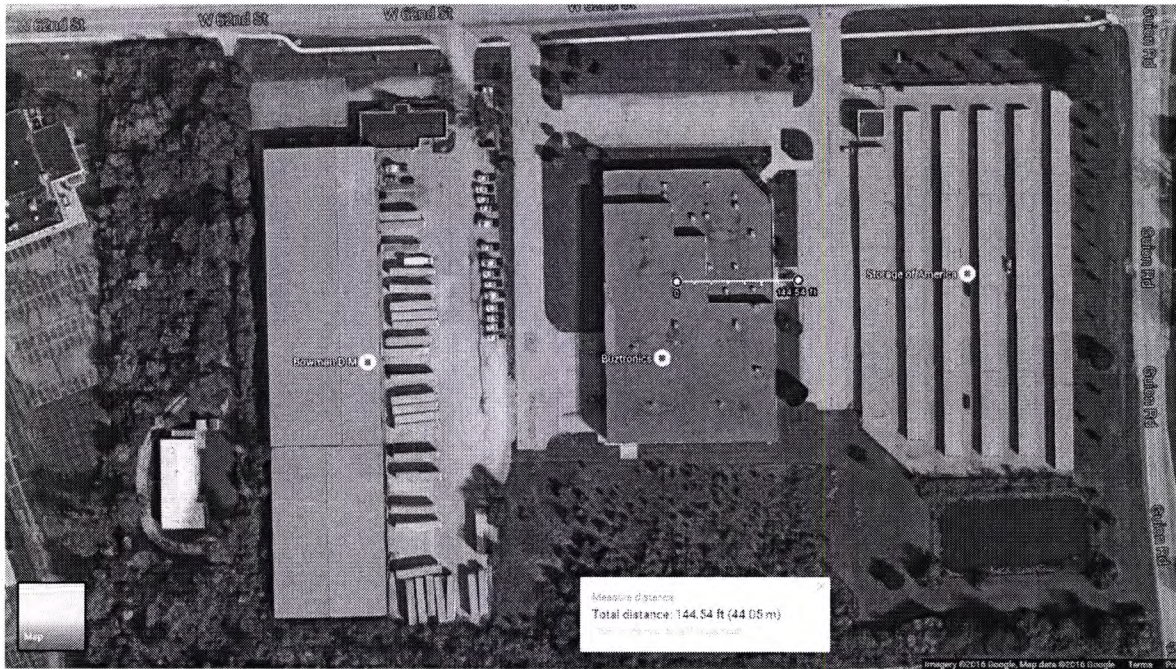
			HotSpot Table Output		
0.300	5.4E-05	2.2E-10	6.7E-07	2.1E-15	00:01
0.400	3.1E-05	1.3E-10	3.9E-07	1.2E-15	00:01
0.500	2.0E-05	8.4E-11	2.5E-07	8.0E-16	00:01
0.600	1.4E-05	5.9E-11	1.8E-07	5.6E-16	00:02
0.700	1.1E-05	4.4E-11	1.3E-07	4.2E-16	00:02
0.800	8.3E-06	3.4E-11	1.0E-07	3.3E-16	00:03
0.900	6.7E-06	2.8E-11	8.3E-08	2.6E-16	00:03
1.000	5.5E-06	2.3E-11	6.8E-08	2.2E-16	00:03
3.000	7.6E-07	3.2E-12	9.5E-09	3.0E-17	00:11
6.000	2.4E-07	9.8E-13	2.9E-09	9.3E-18	00:23
8.000	1.5E-07	6.1E-13	1.8E-09	5.8E-18	00:31
10.000	1.0E-07	4.3E-13	1.3E-09	4.0E-18	00:38
20.000	3.4E-08	1.4E-13	4.3E-10	1.4E-18	01:17
40.000	1.2E-08	4.9E-14	1.5E-10	0.0E+00	02:35
60.000	6.4E-09	2.6E-14	7.9E-11	0.0E+00	03:52
80.000	4.1E-09	1.7E-14	5.1E-11	0.0E+00	05:10

ATTACHMENT C

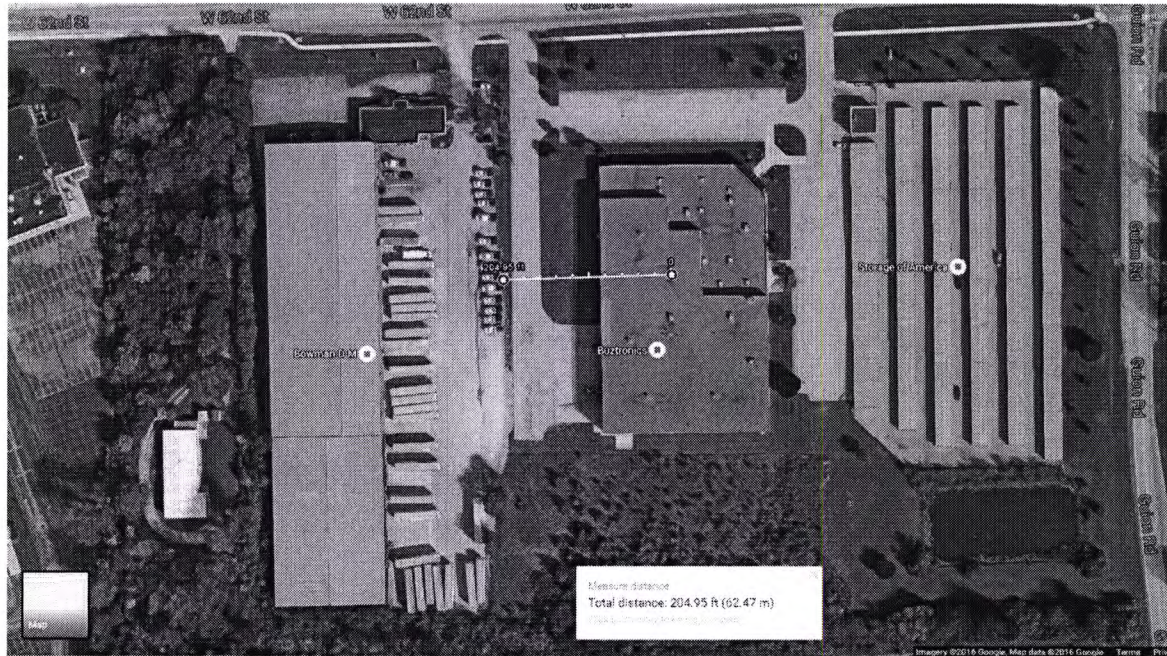
Site Boundary Determination

The definitions of Actinium-227 release scenarios A and B involves a release of activity at the roof line at the point at which exhaust ductwork penetrates the roof. This location is shown on the engineering drawing on the next page. Distances to the facility boundary have been measured using Google Maps' measurement tool and find that the shortest distance to the boundary is 44 meters to the East of the assumed emission point.

Distance measurement – East Direction



Distance measurement – West Direction



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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Svenska: <http://www.cardinalhealth.com/en/support/terms-and-conditions-english.html>