

Cardinal Health 414, LLC
Quality & Regulatory
7000 Cardinal Place
Dublin, OH 43017
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June 26, 2020

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

Re: Amendment Request for Radioactive Materials License 34-31473-03MD
Cardinal Health, Dublin, OH.

Dear Mr. Parker:

Cardinal Health 414, LLC (Indianapolis Radium-223 Pharmacy, hereafter Cardinal Health) would like to update Section 12 of our license application to utilize a new Xofigo Plastic Pig (XPP) for the distribution of Ra-223. The XPP is an all plastic pig that will eliminate lead disposal for customers. Please accept additional information provided in Attachment A: radiation levels comparing XLP and XPP shields.

If you have any questions regarding this request, please contact me at 614.757.9586.

Sincerely,

A handwritten signature in blue ink, appearing to read "Glenn P. Sullivan".

Glenn P. Sullivan, Ph.D.
Corporate Radiation Safety Officer
Director, Health Physics
Nuclear & Precision Health Solutions

Enclosure: Attachment A – XLP vs XPP

cc: Ben Ellert, RSO, Loc. 7220
License File, Loc. 7220 (3)

Attachment A

XLP vs XPP

Worksheet

Plastic

Xofigo™ Package Protocol

Date: 6/22/2018

Dose Calibrator:

Manufacturer: Capintec

Model: CRC-25R

Serial Number: 252617

Participant	Job Function
Rachael Hender	Pharmacy Technician (Drew Doses)
Andrew Maurer	Pharmacist in Charge (Oversight)
Nick Merills	Pharmacy Tech (Supplies/Equip)
Willie Regits	Consultant (Performed Tests)

Survey Instrument:

Type	Manufacturer	Model	Serial No.	Cal Date	PreOp Test	Probe Radius (mm)
Ion	Fluke/Victoreen	451b-ryr	3647	6/24/2017	PASS	49
ECGM	Ludlum	3 w/44-38	306033	9/27/2017	PASS	16.5

Syringe:

Syringe	Volume (mL)	Activity (MBq)	Reference Date/Time
1 (S1)	X = 9	ACT1= 11.914	T1= 6/22/2018 10:09 MDT
2 (S2)	Y= 9	ACT2= 11.951	T2= 6/22/2018 10:11 MDT

Package Measurements:

Location/object	Length (mm)	Width (mm)	Height (mm)
Styrofoam Insert	290	140	145
Inner Box	295	145	155

Box Wall Thickness: 3 mm + 3 mm inner liner

Syringe to Surface:

Syringe #	S#CT (mm)	S#W (mm)	S#CB (mm)	S1S2 (mm)
1	74.5	50	66	40
2	74.5	50	66	

Exposure Rate Measurements:

Instrument	Value	BKG	Max Surface	0.5 m	1 m	1.5 m	2 m
Ion Chamber	Exposure Rate (mR/hr)	0.01	5.3	0.27	0.06	0.02	0.01
	Measurement Time	10:24	10:39	10:42	10:44	10:46	10:50
ECGM	Exposure Rate (mR/hr)	0.04	10	3	0.11	0.065	0.05
	Measurement Time	10:25	10:40	10:43	10:45	10:48	10:51

Worksheet

Lead

Xofigo™ Package Protocol

Date: 6/22/2018

Dose Calibrator:

Manufacturer: Capintec

Model: CRC-25R

Serial Number: 252617

Participant	Job Function
Rachael Hender	Pharmacy Technician (Drew Doses)
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Survey Instrument:

Type	Manufacturer	Model	Serial No.	Cal Date	PreOp Test	Probe Radius (mm)
Ion	Fluke/Victoreen	451b-ryr	3647	6/24/2017	PASS	49
ECGM	Ludlum	3 w/44-38	306033	9/27/2017	PASS	16.5

Syringe:

Syringe	Volume (mL)	Activity (MBq)	Reference Date/Time
1 (S1)	X = 9	ACT1= 11.914	T1= 6/22/2018 10:09 MDT
2 (S2)	Y = 9	ACT2= 11.951	T2= 6/22/2018 10:11 MDT

Package Measurements:

Location/object	Length (mm)	Width (mm)	Height (mm)
Styrofoam Insert	290	142	150
Inner Box	292	145	155

Box Wall Thickness: 3 mm + 3 mm inner liner

Syringe to Surface:

Syringe #	S#CT (mm)	S#W (mm)	S#CB (mm)	S1S2 (mm)
1	85	40	70	55
2	85	40	70	

Exposure Rate Measurements:

Instrument	Value	BKG	Max Surface	0.5 m	1 m	1.5 m	2 m
Ion Chamber	Exposure Rate (mR/hr)	0.01	0.92	0.03	0.01	< 0.01	< 0.01
	Measurement Time	10:24	11:03	11:05	11:07	11:09	11:11
ECGM	Exposure Rate (mR/hr)	0.04	2.0	0.08	0.04	<0.04	< 0.04
	Measurement Time	10:25	11:04	11:06	11:08	11:10	11:12

Song, Taehoon

From: Sullivan, Glenn <glenn.sullivan@cardinalhealth.com>
Sent: Friday, August 21, 2020 8:26 AM
To: Parker, Bryan
Subject: [External_Sender] RE: RE: RE: Xofigo plastic pig.
Attachments: 200821 Section 12 update for XPP additional info.pdf

Here is the comparison of the lead pig versus the plastic pig. As I said we have been working on this for years.

g



Glenn P. Sullivan, Ph.D.
*Director Health Physics /Corporate
Radiation Safety Officer
Nuclear & Precision Health Solutions*
5100 Rings Road
Dublin, OH 43017
614/757-9586 tel

I am *Essential to care*

Restorative, Learner, Achiever, Individualization, Harmony

ISFJ (The Defender).

From: Parker, Bryan <Bryan.Parker@nrc.gov>
Sent: Wednesday, August 19, 2020 11:40 AM
To: Sullivan, Glenn <glenn.sullivan@cardinalhealth.com>
Subject: RE: RE: RE: Xofigo plastic pig.

External Email – Please use caution before opening attachments or clicking links

OK, got it – thanks. Could you send me the info on the current packaging as discussed yesterday?

Thanks.
Bryan

From: Sullivan, Glenn <glenn.sullivan@cardinalhealth.com>
Sent: Wednesday, August 19, 2020 11:37 AM
To: Parker, Bryan <Bryan.Parker@nrc.gov>
Subject: [External_Sender] RE: RE: Xofigo plastic pig.

No they do not. They ship full vials to the pharmacies for dispensing from Indy Radium or Denver Radium.

Thanks for asking

g



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I am Essential to care

ISFJ (The Defender).

From: Parker, Bryan <Bryan.Parker@nrc.gov>
Sent: Wednesday, August 19, 2020 11:28 AM
To: Sullivan, Glenn <glenn.sullivan@cardinalhealth.com>
Subject: RE: RE: Xofigo plastic pig.

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Hey Glenn,

I'm working on the amendment for distribution pharmacy re: the new Xofigo packaging and it made me think – does the manufacturing license need to be amended too for the new packaging?

Just checking.

Bryan

From: Sullivan, Glenn <glenn.sullivan@cardinalhealth.com>
Sent: Tuesday, August 18, 2020 3:35 PM
To: Parker, Bryan <Bryan.Parker@nrc.gov>
Subject: [External_Sender] RE: Xofigo plastic pig.

That is fine. You can call the number 614-757-9586.

Thanks

g



Glenn P. Sullivan, Ph.D.
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Radiation Safety Officer*
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5100 Rings Road
Dublin, OH 43017
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ISFJ (The Defender).

From: Parker, Bryan <Bryan.Parker@nrc.gov>
Sent: Tuesday, August 18, 2020 3:15 PM
To: Sullivan, Glenn <glenn.sullivan@cardinalhealth.com>
Subject: RE: Xofigo plastic pig.

External Email – Please use caution before opening attachments or clicking links

Hey Glenn,

Sorry for the late reply. Can we discuss this by phone? I have a 3:30p ET call today, but I could do it after that (maybe 4:30p ET?), or most anytime tomorrow.

What is the best number to reach you at?

Thanks.
Bryan

From: Sullivan, Glenn <glenn.sullivan@cardinalhealth.com>
Sent: Friday, August 14, 2020 9:18 AM
To: Parker, Bryan <Bryan.Parker@nrc.gov>
Subject: [External_Sender] Xofigo plastic pig.

Just checking in. We were hoping to start a test run of the pig with some sites throughout the US.

I appreciate your time and attention to this matter.

Thanks
g



Glenn P. Sullivan, Ph.D.
*Director Health Physics /Corporate
Radiation Safety Officer
Nuclear & Precision Health Solutions*
5100 Rings Road
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ISFJ (The Defender).

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