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Nuclear Pharmacy Services
Quality & Regulatory
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CardinalHealth

August 1, 2016

Kevin Null
Radioactive Materials Licensing
U.S. NRC Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532

RE: Additional Information for Amendment Request for Radioactive Material License Number 34-32840-01, Cardinal Health PET Manufacturing Services, East Lansing, MI, control number 591400.

Mr. Null:

Cardinal Health 414, LLC (Nuclear Pharmacy Services and PET Manufacturing Services, hereafter Cardinal Health) submits the following information as discussed in a July 27, 2016 telephone conversation between the NRC and Cardinal Health regarding the amendment request letter dated July 6, 2016. The previous request is clarified as follows.

Cardinal Health proposes delivering the cyclotron to the East Lansing facility and placing it in storage in the existing empty concrete vault within the restricted area, as described in the previous letter. The cyclotron will remain non-operational until a future amendment request is submitted and approved to allow the operation of the unit.

In addition, taking possession of the cyclotron at East Lansing is not expected to exceed the licensed possession limits on the existing radioactive materials license. Cardinal Health will verify that limits will not be exceeded when the activity in the cyclotron is characterized prior to shipment from the St. Louis, Missouri facility. This characterization will be performed by Ameriphsysics, Inc., with whom Cardinal Health has contracted to prepare the cyclotron for transport.

Surveys of the cyclotron in its current location in St. Louis are attached. Based on these results, the cyclotron will be sufficiently shielded by the vault (which is comprised of concrete walls no less than four feet thick) such that radiation levels on the outside of the vault will not be elevated above existing levels. Authorized users at the facility may access the cyclotron in the vault to perform area surveys and to place cables and delivery lines in order to prepare the cyclotron for use. When accessing the cyclotron, Cardinal Health will use radiation safety practices as described in the existing radioactive materials license. However, the cyclotron itself will not be connected and will remain non-operational.

Kevin Null
NRC Region III Licensing
August 1, 2016

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If you have any questions regarding this request, please contact Evan Western at 614.553.4555.

Sincerely,

A handwritten signature in dark ink, appearing to read "Glenn Sullivan", written over a horizontal line.

Glenn Sullivan
Corporate Radiation Safety Officer
Director, Health Physics
Quality and Regulatory
Nuclear Pharmacy Services

Encl: Cyclotron Survey Summary

cc: Jason Foster, MRSO, Loc. 5860
Rob Symons, Loc. 5860
License File 5860 (3)
Rick Hasselkus

ATTACHMENT A

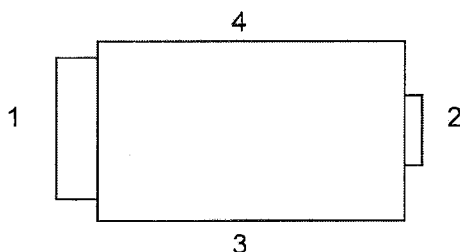
Cyclotron Survey Summary
St. Louis, MO

Cyclotron Survey Summary St. Louis, MO

Surveys performed by:
Robert Grudowski, senior cyclotron engineer
July 31, 2016

The GE PETtrace cyclotron located at the Cardinal Health PET Manufacturing Facility at 10718 Trenton Avenue, St. Louis, Missouri was surveyed on July 31 to quantify the exposure rates and radiation hazards associated with the machine.

Three primary sides of the cyclotron were surveyed: (1) the target area, (2) the RF input, and (3) the magnet door, with survey measurements taken on the surface and at distances of one foot and three feet. A diagram of the cyclotron is below, with these survey locations noted. Due to the placement of the cyclotron in the vault, the side of the machine opposite the surveyed magnet door (noted as location 4) is located against the existing vault wall, and was not accessible for survey. However, based on the symmetry of the machine's beam line, which runs along the center axis of the machine from location 1 to location 2, it is expected that exposure rates on this side of the cyclotron are similar to those measured at location 3.



Results of the surveys are located in the table below.

Location	1 (target)	2 (RF)	3 (magnet)
Surface maximum	10 mR/hr	5.0 mR/hr	0.3 mR/hr
One foot	6.0 mR/hr	3.0 mR/hr	0.3 mR/hr
Three feet	3.0 mR/hr	2.0 mR/hr	0.4 mR/hr

The instrumentation used to perform the surveys is as follows. The instrument calibration certificate is included on the next page.

Manufacturer: Ludlum
Model: 5
Serial: 176168
Last calibration date: May 6, 2016

R. M. Wester & Associates, Inc.

215 Indacom Drive
St. Peters, MO 63376

www.rmwest.com

Ph: (636) 928-9628
Fax: (636) 928-9857

CERTIFICATE OF CALIBRATION

Contact Name	Ken Moore	Instrument Make	Ludlum
Client Name	Cardinal Health PET	Instrument Model	5
Department		Serial Number	176168
Facility Address	10718 Trenton Ave.	Detector Type	Int. GM
Address2	St. Louis, MO	Meter Display	0-2 mR/hr
Zip Code	63132	Battery Check	good
Telephone	636-439-0283		

Instrument Display	Source Distance	Meter Distance	Actual Exposure	Correction Factor	Range Multiplier
mR/hr	mm	mm	mR/hr	C.F.	Range Mult.
1000	181.9	181.9	1000.00	1.00	X1000
500	257.3	257.3	500.00	1.00	X1000
100	575.3	575.3	100.00	1.00	x100
150	469.8	469.8	150.00	1.00	x100
50	813.7	813.7	50.00	1.00	x100
10	1819.4	1819.4	10.00	1.00	x10
15	1485.5	1485.5	15.00	1.00	x10
5	2573	2573	5.00	1.00	x10
1	2876.7	2876.7	1.00	1.00	x1
1.5	2348.8	2348.8	1.50	1.00	x1
0.5	2876.7	2876.7	0.50	1.00	x1
0.1	2274.2	2274.2	0.10	1.00	x0.1
0.15	1856.9	1856.9	0.15	1.00	x0.1
0.05	3216.3	3216.3	0.05	1.00	x0.1

CHECK SOURCE RESPONSE IS: N/A

☒ CESIUM-137 CALIBRATOR (S.N. 11008) SOURCE TYPE (6810 S.N. SCS-0254GH) is directly traceable to NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY. Source output 99.4mR/hr @ 60 cm 12/21/2012.

☐ INSTRUMENT CALIBRATED WITH PULSE GENERATOR (S.N. 20137) AS DETERMINED BY ACTUAL MEASUREMENT PROCEDURES.

THE DETECTOR IDENTIFIED ABOVE HAS A DETECTION CAPABILITY OF: ** N/A ** for Carbon-14 (S.N. 25-1121); ** N/A ** for Iodine-125/129 (S.N. 13137) USING 2 PI GEOMETRY.

*ABSORBERS WERE USED TO ACHIEVE THESE RESULTS

CALIBRATED BY: [Signature] DATE: 5/6/2016 CAL DUE: 5/6/2017

REVIEWED BY: [Signature] DATE: 5/10/16

Tomczak, Tammy

From: Null, Kevin
Sent: Monday, August 01, 2016 10:37 AM
To: Tomczak, Tammy
Subject: FW: RE: Conversation record
Attachments: 160801 Add 2nd Cyclotron Phase I additional info.pdf; NRCform665GENERIC(incoming)
CARDINALhealth082016.docx

Hi Tammy,

The attached letter needs to get into ADAMS. I have also attached a 665.

Thanks,

Kevin

From: Western, Evan [mailto:evan.western@cardinalhealth.com]
Sent: Monday, August 01, 2016 9:56 AM
To: Null, Kevin <Kevin.Null@nrc.gov>
Subject: [External_Sender] RE: Conversation record

Kevin,

Please see attached for the letter we discussed last week regarding licensing of the second cyclotron at the East Lansing facility.

Surveys of the machine are included in the letter as we discussed. Please feel free to call or email with any questions you may have.

Once again, thank you for your flexibility and attention!

Sincerely,
Evan Western



Evan T. Western
Manager, Health Physics
PET Manufacturing, Nuclear Pharmacy Services
7200 Cardinal Place, Dublin, OH 43017
614.553.4555 dir | 614.553.9763 fax

From: Western, Evan
Sent: Thursday, July 28, 2016 11:53 AM
To: 'Null, Kevin' <Kevin.Null@nrc.gov>
Subject: RE: Conversation record

Thanks, Kevin!

No questions on the record – everything matches what I remember us discussing. I expect to have the follow-up letter (Phase I) over to you Monday.



Logistics
Product
Business
Patient

Evan T. Western
Manager, Health Physics
PET Manufacturing, Nuclear Pharmacy Services
7200 Cardinal Place, Dublin, OH 43017
614.553.4555 dir | 614.553.9763 fax

From: Null, Kevin [<mailto:Kevin.Null@nrc.gov>]
Sent: Thursday, July 28, 2016 11:01 AM
To: Western, Evan <evan.western@cardinalhealth.com>
Subject: Conversation record

[External Email]

Hi Evan,

Attached is a record of our conversation from yesterday. Please review and let me know if you have any questions.

Please also let me know when you think that you will be able to submit a response. I will begin to work on the amendment as soon as I receive your response. Please e-mail your response to me and make sure it has an original signature, is on letterhead, is dated and scanned in.

Thanks,

Kevin Null

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