Cardinal Health 414, LLC Quality & Regulatory 7000 Cardinal Place Dublin, OH 43017 614.757.4120

614.652.4598

www.cardinalhealth.com



June 3, 2022

Licensing Assistance Team Division of Nuclear Materials Safety U.S. NRC Region I DNMS 2100 Renaissance Road King of Prussia, PA 19406

Amendment Request for Radioactive Materials License number 34-32780-02, Cardinal Health PET Manufacturing Services, East Hartford, CT.

Licensing:

Cardinal Health 414, LLC (PET Manufacturing Services, hereafter Cardinal Health) requests an amendment for the above referenced license to add the following individuals as authorized users:

- Huu Dinh
- Michael Gordon
- Marissa Gross
- Moses Torres
- Nicholas Vinci
- **Thomas Ward**
- Bryan Wetzel

Each of these individuals is currently listed as an authorized user/cyclotron operator on the radioactive materials license for another Cardinal Health cyclotron facility. Copies of these licenses are included for reference, with the names of the requested AUs highlighted. Each of these alternate facilities also have General Electric PETtrace cyclotrons, the same type of machine installed at the East Hartford facility.

Additionally, Cardinal Health requests that Steve Morcos, Andrew Scovill, and Haydn Solomon be removed from the list of authorized users.

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

Sincerely,

Evan T. Western, CHP

Manager, Health Physics Nuclear & Precision Health Solutions

Arshad Mehmood, MRSO loc. 5869 CC:

License File 5869 (3)

ATTACHMENT

Alternate Cardinal Health Radioactive Materials Licenses

Amendment Number: 16 Page 1 of 3

OHIO DEPARTMENT OF HEALTH LICENSE FOR RADIOACTIVE MATERIAL

Pursuant to Chapter 3748 of the Ohio Revised Code, and in reliance on statements and representations made by the licensee, a license is hereby issued authorizing the licensee named herein to receive, acquire, possess, and transfer radioactive material as designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the applications of Chapter 3748 of the Ohio Revised Code and all applicable rules promulgated thereunder. This license is subject to all applicable rules, regulations, and orders of the Ohio Department of Health now or hereinafter in effect and to any conditions specified below.

LICENSEE		LICENSE NUMBER		
1. Cardinal Health 414, LLC Cardinal Health PET Manufacturing Services		3. 02511250002		
g .	EXPIRATION DATE			
2. 7000 Cardinal Place Dublin, Ohio 43017		4. February 1, 2024		
		FILE NUMBER / ID NUMBER		
	T. N.	5. 501474 / <i>17080</i>		
6.	RADIOACTIVE MATERIAL 7. CHEMICAL AND/OR	PHYSICAL FORM 8. MAXIMUM QUANTITY THAT		

RADIOACTIVE MATERIAL		7. CI	HEMICAL AND/OR PHYSICAL FORM	LIC	AXIMUM QUANTITY THAT CENSEE MAY POSSESS AT ANY IE TIME UNDER THIS LICENSE
A.	Any radionuclides with atomic numbers 1-83	A.	Activated products, target body, magnet coils, yoke, vacuum tank, and components of the accelerator shield	A.	185 GBq (5 Ci)
B.	Carbon-11	B.	Any	B.	222 GBq (6 Ci)
C.	Nitrogen-13	C.	Any	C.	370 GBq (10 Ci)
D.	Fluorine-18	D.	Any	D.	2.22 TBq (60 Ci)
E.	Iodine-124	E.	Any	E.	37 GBq (1 Ci)
F.	Actinium-225	F.	Liquid	F.	3.7 GBq (100 mCi)
G.	Indium-111	G.	Liquid	G.	3.7 GBq (100 mCi)
H.	Luteium-177	H.	Liquid	H.	3.7 GBq (100 mCi)
I.	Any radioactive material permitted by OAC 3701:1-58-26	I:	Sealed Sources	I.	37 GBq (1 Ci)
J.	Technetium-99m	J.	liquid	J.	185 GBq (5 Ci)
K.	Hydrogen-3	K.	Any	K.	740 MBq (20 mCi)
L.	Any radionuclides with atomic numbers 3-83, inclusively	L.	Any	L.	1.85 GBq (50 mCi) per radionuclide, 18.5 GBq (500 mCi) total

9. Authorized Use

- A. Activation products incident to operation of a particle accelerator for production of isotopes. Activation products will be held for waste or shipped for proper disposal through a licensed radioactive waste firm.
- B.-E. For possession, use, and processing incident to manufacture of radiopharmaceuticals, and transfer to facilities authorized to receive the licensed material pursuant to the terms and conditions of specific licenses issued by the Nuclear Regulatory Commission or Agreement States.
- F.-H. Analytical testing, research, and development.
- I.-J. Check, calibration, and reference sources permitted by OAC 3701:1-58-26.
- K. Radioactive material incident to production for temporary storage prior to shipment for recycle of target water.
- L Possession for analytical testing and decay-in-storage, limited to any radionuclide with a half-life less than 120 days.

OHIO DEPARTMENT OF HEALTH

LICENSE FOR RADIOACTIVE MATERIALS

SUPPLEMENTARY SHEET

Page 2 of 3

License Number: 02511250002

File Number / ID Number: 501474 / 17080

Amendment Number: 16

CONDITIONS

10. Licensed material may only be used at the licensee's facilities located at:

Cardinal Health PET Manufacturing Services 1214 Kinnear Road Columbus, Ohio 43212

- 11. The Radiation Safety Officers for this license are:
 - Glenn Sullivan, Corporate Radiation Safety Officer
 - Lance Reddel, Manufacturing Radiation Safety Officer
- 12. Authorized use of the cyclotron and materials may only be used by, or under the supervision of, the below listed individuals designated in writing:

Authorized User(s)

	Audiorize	u Osei(\bar{n}
A.	Chicoine, Robert - Operator and Maintenance	P.	Moore, Ken - Operator and Maintenance
B.	Droege, Robert - Operator	Q.	Morcos, Steven - Operator
C.	Fischer, Benjamin - Operator	R.	Nilsson, Robert - Operator and Maintenance
D.	Fleshner, Adam - Operator	S.	O'Donnell, John - Operator and Maintenance
E.	Good, Greg - Operator and Maintenance	T.	Parraga, Charles - Operator
F.	Gotti, Paul, R.Ph Operator	U.	Powell, Michael- Operator
G.	Chicoine, Robert - Operator and Maintenance	V.	Reddel, Lance - Operator
H.	Harris, William - Operator and Maintenance	W.	Rodriguez, Jose Rangel - Operator
I.	Husnu, Mehmet - Operator and Maintenance	X.	Solomon, Hadyn - Operator
J.	Jasman, Rachel - Operator	Y.	Stephens, Avery - Operator
K.	Kilian, Jacob - Operator	Z.	Tondreau, Albert - Operator
L.	Legg, Andrew - Operator	AA.	Vega, Misael - Operator
M.	Mamakas, Eleutherios - Operator	BB.	Ward, Thomas-Operator
N.	Martin, Jacob, NPT - Operator	CC.	Western, Evan, CHP - Operator
O.	Medina, Norman - Operator		
	Authorized Nucle	ar Phar	macist(s)
A.	Dolfi, Angela, R.Ph Operator	D.	Reamsnyder, Jacob, R.Ph Operator

- В. Hamilton, James, R.Ph. - Operator Simpson, Julie, R.Ph. - Operator
- C. Marmon, Lisa, R.Ph. - Operator
- 13. The licensee is authorized to transport radioactive materials in accordance with the provisions OAC Chapter 3701:1-50.
- 14. The licensee shall conduct a physical inventory every six (6) months, or at another interval approved by the Director, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for at least three (3) years from the date of each inventory, and shall include: the quantities and kinds of licensed material, manufacturer's name and model numbers, location of the sources and / or devices, and the date of the inventory.
- 15. Sealed and unsealed radioactive material will be safely and securely delivered to mobile medical licensees. Delivery shall be directly to the van /coach only if the van /coach is occupied by mobile medical personnel at the time of delivery.
- 16. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.
- 17. Notwithstanding the possession limits in item 8, the licensee shall further restrict the possession of sealed source licensed materials to quantities below the minimum limit specified in OAC 3701:1-40-17 for establishing decommissioning financial assurance.

OHIO DEPARTMENT OF HEALTH

LICENSE FOR RADIOACTIVE MATERIALS

SUPPLEMENTARY SHEET

Page 3 of 3			
License Number: 02511250002			
File Number / ID Number: 501474 / 17080			
Amendment Number: 16			

18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Ohio Department of Health's regulations shall govern unless statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated December 10, 2018; Letter dated December 10, 2018 and electronic correspondence dated January 29, 2019 and February 4, 2019. Amendment 10 of license 02511250002; renewed in its entirety.

- B. Letters dated May 13, 2019 and June 21, 2019. Electronic correspondences dated June 5, 2019, June 20, 2019, and June 21, 2019. (Amendment 11)
- C. Letter dated July 23, 2020 and electronic correspondence date August 31, 2020 (Amendment 12)
- Letter dated March 16, 2021; electronic correspondence dated April 2, 2021 and April 5, 2021 (Amendment 13) D.

BY:

- E. Letter dated March 29, 2021 (Amendment 14)
- Letter dated July 23, 2021 (Amendment 15) F.
- G. Letter dated March 4, 2022 (Amendment 16)

ATE

For the Ohio Department of Health

April 6, 2022 DATE:

> W. Gene Phillips, MBA, REHS Chief, Bureau of Environmental Health and Radiation Protection on behalf of the Director of Health



RADIOLOGICAL HEALTH PROGRAM RADIOACTIVE MATERIAL LICENSE

Page 1 of 4

Pursuant to the Maryland Radiation Act, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess and transfer radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. The license is subject to all applicable rules, regulations and orders of the Maryland State Department of the Environment, now or hereinafter in effect and to any conditions specified below.

Environment, now or hereinafter in effect and to any conditions specified below.								
1. 2.	Name: Address:	Cardinal Health 7000 Cardinal Place Dublin, Ohio 43017	 3. License No.: MD- 33-198-02 4. Amendment No.: 06: Code 02500 5. Expiration date: August 31, 2024 			: Code 02500		
6.	Radioactive & mass num	e material (element mber):	7.	Chemical ar	nd/o	r physical form:	8.	Maximum amount of activity which licensee may possess at any one time:
A.	Fluorine-1	8	A.	Any			A.	40 curies.
B.	Nitrogen-1	3	В.	Any			В	10 curies.
C.	Oxygen-15	5	C.	Any			C.	5 curies.
D.	Carbon-11		D.	Any			D.	5 curies.
E.	atomic nur	nuclides with mbers 1-83 radioactive material.)	E.		ivate ım t	activated target ed magnet coils, ank and	E.	5 curies.
F.	•	nuclides with mbers 3-83 inclusive	F.		ed u ied b	nder specific by the USNRC	F.	Total not to exceed 30 millicuries; no single source to exceed 15 millicuries.
G.	Sodium-22	2	G.	Sealed Sour Ziegler Mod		•	G.	10 millicuries.
H.	Sodium-22	2	Н.	Sealed Sour Ziegler Mod		Eckert & GF-022 Type R)	H.	2 microcuries.
I.	Technetiur	m-99m	I.	Liquid			I.	5 curies.
J.	Hydrogen-	3	J.	Liquid			J.	40 millicuries.



RADIOLOGICAL HEALTH PROGRAM RADIOACTIVE MATERIAL LICENSE

Page 2 of 4

License No.: MD-33-198-02

Amendment No.: 06

- 9. Authorized Use(s):
 - A-D. Produced via accelerated proton induced nuclear reaction using a G.E. PETtrace 16.5 MeV cyclotron. Positron emitting isotopes, such as F-18 will be processed to a radiochemical form NaF or FDG) for distribution to facilities authorized to possess such material. The remaining radionuclides are a result of production and used for synthesis methods testing at the facility.
 - E, J. Target foils, target bodies or machine components to be held for decay onsite or shipped for disposal through a licensed entity. H-3 will be shipped to the manufacturer for recycling in target water.
 - F-H. Sealed sources used for instrument calibrations and quality checks.
 - I. Unsealed source calibration of instruments.

LICENSE CONDITIONS

- 10. The authorized place of use is 7051 Muirkirk Meadows Drive, Suite L, Beltsville, Maryland 20705. The licensee must notify the Radiological Health Program 30 days prior to vacating a permanent use address.
- 11A. The radiation protection program shall be under the supervision of Vincent Kim.
- 11B. Radioactive material shall be used by, or under the supervision of:
 - ➤ Mehmet Husnu
 - ▶ Bob Chicoine
 - ➤ Adam Miller
 - > Albert Tondreau
 - ➤ Sum Tang
 - > Samuel Whang
 - ➤ Kevin Williams
 - > Adam Fleshner
 - Sean Waters
 - ➤ Olaf Robert Nilsson
 - ➤ Vincent Kim
 - > Avery Stephens
 - > Francovna Beauvais
 - > Brian Jefferson
 - Paul Gotti, R.Ph.
 - David Engstrom, R.Ph.
 - Norman Medina
 - Gwynn Marshall Reel

- Erdem Akdag
- > Alfonso Garcia
- Charles Parraga
- > Jose Luis Rangel Rodriguez
- Kumail Zaidi
- > Huu Dinh
- > Charles Fjeldheim
- Marissa Gross
- > William Jackson
- Nicholas Vinci
- > Jesus Benhumea
- > Robert Grudowski
- > William Harris
- > Frank Iverson
- > Bharat Kapoor
- > Ken Moore
- > Nelson Paree
- > Moses Torres
- 12. The licensee shall comply with all appropriate provisions of COMAR 26.12.01.01 "Regulations for the Control of Ionizing Radiation," and shall possess a copy of these regulations.
- 13. Leak Testing of sealed sources shall be conducted in accordance with COMAR 26.12.01.01 § G.67.



RADIOLOGICAL HEALTH PROGRAM RADIOACTIVE MATERIAL LICENSE

Page 3 of 4

License No.: MD-33-198-02 Amendment No.: **06**

CONDITIONS CONTINUED

- 14. The licensee shall conduct a physical inventory every six- (6) months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained for three (3) years from the date of the inventory for inspection by the Department, and shall include the quantities and kinds of radioactive material, location of sealed sources, and the date of the inventory.
- 15. Any proposed changes in packaging, shielding or labeling shall be submitted for review to the Program Manager, Radiological Health Program, 1800 Washington **Boulevard, Suite 750**, Baltimore, Maryland 21230.
- 16. Sealed sources containing radioactive material shall not be opened.
- 17. The licensee shall not allow eating, drinking, smoking or applying cosmetics in the licensee's areas utilizing radioactive materials.
- 18. Transportation of radioactive material in the State of Maryland shall be in compliance with Part T, Section T.5 "Transportation of Licensed Material" of COMAR 26.12.01.01.
- 19A. The licensee shall not make any false statement, representation, or certification in any application, record, report, plan, or other document regarding radiation levels, tests performed or radiation safety conditions or practices. Additionally, the licensee shall not falsify, tamper with, or render inaccurate any monitoring device or method.
- 19B. Violation of any term, condition, or regulation could subject the licensee to administrative or civil penalty or criminal prosecution, as specified in Title 8, Radiation, of the Article Environment of the Annotated Code of Maryland.
- 20. The licensee shall not transfer ownership and/or control of this license to any person or entity without providing required information regarding the transfer for the Agency's review and without receiving written authorization for the transfer by the Agency.



RADIOLOGICAL HEALTH PROGRAM RADIOACTIVE MATERIAL LICENSE

Page 4 of 4

License No.: MD-33-198-02

Amendment No.: 06

CONDITIONS CONTINUED

- 21. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material authorized by this license in accordance with statements representations, and procedures contained in:
 - Renewal application dated December 14, 2016.
 - E-mail received July 24, 2017.
 - Letter with attachments dated September 8, 2017, adding David Fabio and Erdem Akdag and deleting Gavin Black and Cami Still as Authorized Users.
 - Letter with attachments dated June 27, 2018 requesting to install a HEPA pass through window.
 - Letter with attachments dated June 3, 2019, adding Vincent Kim, Jose Luis Rangel Rodriguez, Kumail Zaidi and Matthew Anderson removing Joseph Tavano, Courtland Farrington, David Missildine and Scott R. Lucas as authorized users. Updated procedures for transfer of radioactive drug from the licensee to the authorized recipient adjacent (co-located) pharmacy with license number MD-33-198-01; increasing the maximum quantity of Hydrogen-3 to 40 millicuries, total possession and storage.
 - Letter with attachments dated February 4, 2020 adding Misael Vega; removing John Taylor Vernon and Matthew Anderson as authorized users.
 - Email with attachments dated March 11, 2021 updating the Radiation Safety Officer to Vincent Kim.
 - ► Letter with attachments dated March 28, 2022 (Withdrawn)
 - Letter with attachments dated April 1, 2022 requesting the addition of the following individuals as Authorized Users: Huu Dinh, Charles Fjeldheim, Marissa Gross, William Jackson, Nicholas Vinci, Jesus Benhumea, Robert Grudowski, William Harris, Frank Iverson, Bharat Kapoor, Ken Moore, and Nelson Paree, and requesting the removal of the following individuals as Authorized Users: Steven Bostjancic, David Fabio, Steve Morcos, Misael Vega, and Christian Walker.
 - > Letter with attachments dated May 16, 2022 requesting to add Moses Torres as an authorized user for the cyclotron.

COMAR 26.12.01.01 "Regulations for the Control of Ionizing Radiation" shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

FOR THE MARYLAND DEPARTMENT OF THE ENVIRONMENT

May 17, 2022

CAN 9/17/2022 HOW / 19/202

Eva S. Nair, Program Manager IV Radiological Health Program Air and Radiation Administration



NEW YORK STATE DEPARTMENT OF HEALTH RADIOACTIVE MATERIALS LICENSE

Pursuant to the Public Health Law, Part 16 of the New York State Sanitary Code, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing radioactive material(s) for the purpose(s), and at the place(s) designated below. The license is subject to all applicable rules, regulations, and orders now or hereafter in effect of all appropriate regulatory agencies and to any conditions specified below.

1. NAME OF LICENSEE		3. LICENSE NUMBER		
FEIN	85-0229124	C3152		
Cardinal Health 414, LLC	- Gamilia	4. EXPIRATION DATE	-	
dba Cardinal Health Nuclear Pharmacy Services		T 20 2025		
Phone	(585) 461-1320	June 29, 2035		
2. ADDRESS OF LICENSEE	-	5a. REFERENCE	b. AMENDMENT NO.	
110 Rochester Science Parkway, Suite	DHs 14-845, 18-275,	18		
Rochester, New York 14620		19-347, 21-126		
		& 21-492		

This license is subject to the following conditions:

Conditions 6 through 9 – Authorized Materials, Form, Possession Limits and Uses Condition 10 – Authorized Users, Radiation Safety Officer and Health Physicists Condition 11 – Documents Incorporated by Reference Condition 12 and beyond – License Conditions

In accordance with the renewal application dated February 20, 2015, signed by W. Scott Claunch, RPh; the letter dated April 12, 2018, signed by Glenn Sullivan and Jesus Benhumea; and the letter dated June 3, 2019, signed by Glenn Sullivan, and Sara Berardicurti, New York State Department of Health Radioactive Materials License No. C3152 is hereby amended in its entirety to read as follows:



NEW YORK STATE DEPARTMENT OF HEALTH RADIOACTIVE MATERIALS LICENSE

3. License Number <u>C3152</u> 5a. Reference <u>DHs 14-845, 18-275, 19-347</u>

b. Amendment No. 18

<u>21-126 & 21-492</u>

AUTHORIZED MATERIALS, FORM, POSSESSION LIMITS AND USES

- 6. Radioactive Materials (element & mass no.)
- 7. Chemical and/or Physical Form
- 8. Maximum quantity licensee may possess at one time

A. Fluorine 18

A. Any

A. 50 curies

B. Nitrogen 13

B. Any

B. 3 curies

- C. Any radionuclides with atomic numbers 1 to 83
- C. Incidentally activated cyclotron products
- C. 3.2 curies

D. Hydrogen 3

- D. Activated targets
- D. 40 millicuries
- 9. Authorized use for materials listed in Conditions 6, 7 and 8:
 - A. and B. As produced incident to the operation of the General Electric PETTrace Model #2132402 cyclotron (NYS Dept. of Health Registration No. 27023431).
 - C. and D. As produced incident to the operation of the General Electric PETTrace Model #2132402 cyclotron (NYS Dept. of Health Registration No. 27023431).

AUTHORIZED USERS, RADIATION SAFETY OFFICER, AND HEALTH PHYSICISTS

- 10. A. The Radiation Safety Officer (RSO) for this License is Bryan Wetzel.
 - B. The General Electric PETTrace Model #2132402 cyclotron may be operated for the purpose of producing Fluorine 18 and/or Nitrogen 13 by or under the direct supervision of the following:

Jesus	Benhumea	Jaston	Foster
Sara	Berardicurti	Greg	Good
Christorpher	Berg	Michael	Gordon
Robert	Best	Paul	Gotti
Robert	Chicoine	Teresa	Greer
Robert	Droege	Jeremy	Guilbeau
David	Engstrom	William	Harris
Adam	Fleshner	Frank	Iverson



NEW YORK STATE DEPARTMENT OF HEALTH RADIOACTIVE MATERIALS LICENSE

3. License Number <u>C3152</u> 5a. Reference <u>DHs 14-845, 18-275, 19-347</u> b. Amendment No. <u>18</u> 21-126 & 21-492

Jeremy	Johnson	Travis	Sill
Eleutherios	Mamakas	Haydn	Solomon
Lisa	Marmon	Jose	Suarez
James R.	Matthews	Marshall	Thompson
Kenneth	Moore	Albert	Tondreau
Steve	Morcos	Misael	Vega
Joseph	Nieznanski	Thomas	Ward
Robert	Nilsson	Sean	Waters
John	O'Donnell	Evan	Western
Clayton	Otis	Bryan	Wetzel
Charles	Parraga	David	Zeller
Jose	Rodriguez		

C. The RSO will be provided with regular on-site health physics support by Stacy C. Sternberg. This individual shall be physically available and able to respond to accidents and incidents in a timely manner and shall visit this facility for at least one working day per month to provide the routine support described in Appendix A of the Radiation Guide 1.8 (rev. 4/95). One of these individuals shall also conduct or participate in the required annual audits of the licensee's radiation protection program and performance of the RSO.

DOCUMENTS INCORPORATED BY REFERENCE

- 11. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7 and 8 of this license, in accordance with statements, representations, and procedures contained in the documents (including any enclosures) listed below:
 - A. Renewal Application for New York State Department of Health Radioactive Materials License dated February 20, 2015, signed by W. Scott Claunch.
 - B. Letter dated May 24, 2018, signed by Glenn Sullivan and Sara Berardicurti.

The New York State Department of Health's regulations shall govern the licensee's statements in applications or letters unless the statements are more restrictive than the regulations.



NEW YORK STATE DEPARTMENT OF HEALTH

RADIOACTIVE MATERIALS LICENSE

3. License Number <u>C3152</u> 5a. Reference <u>DHs 14-845, 18-275, 19-347</u> b. Amendment No. <u>18</u> 21-126 & 21-492

LICENSE CONDITIONS

- 12. Licensed material shall be stored and used at the licensee's installation located at the address indicated in Condition 2, above.
- 13. A. The licensee shall instruct persons before they engage in work under the license, in accordance with 10 NYCRR 16.13(c), and shall provide annual refresher training. Such instruction shall include the licensee's operating and emergency procedures and other information contained in documents incorporated in Condition 11.
 - B. Records of training received pursuant to paragraph A of this Condition shall be maintained for a period of three (3) years and shall include:
 - i) the name of the individual who conducted the training;
 - ii) the name of the individual who received the training;
 - iii) the dates and duration of the training; and
 - iv) a list of topics covered.
- 14. A. The licensee shall submit to the Department a detailed description of any proposed changes to the facilities and equipment, described in the license application and supporting documents, before making any such changes. This shall include, but not be limited to, changes in use, floor plans, ventilation systems and usage of areas contiguous to areas where radioactive materials are used and stored.
 - B. Plans of facilities which the licensee intends to dedicate to operations involving the use of radioactive material shall be submitted to the Department for review and approval prior to such use.
- 15. The licensee shall submit complete decontamination procedures to the Department for approval ninety (90) days prior to the termination of authorized operations involving radioactive material in controlled areas and/or vacating installations pursuant to 10 NYCRR 16.10(b).
- 16. The licensee shall maintain records of information important to safe and effective decommissioning at the location specified in Condition 2 and at other locations as the licensee chooses. The records shall be maintained until this license is terminated by the Department and shall include:
 - A. Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site;
 - B. As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and locations of possible inaccessible contamination, such as buried pipes that may be subject to contamination.



NEW YORK STATE DEPARTMENT OF HEALTH

RADIOACTIVE MATERIALS LICENSE

- 3. License Number <u>C3152</u> 5a. Reference <u>DHs 14-845, 18-275, 19-347</u> b. Amendment No. <u>18</u> 21-126 & 21-492
- 16. C. Records of the cost estimate performed for decommissioning funding plan or the amount certified for decommissioning, and records of the funding method used for assuring funds, if either a funding plan or certification is used.
- 17. The licensee shall submit full information on any proposed changes of ownership or control of licensed premises, at least 90 days prior to the proposed action.
- 18. The licensee is authorized to hold radioactive material with a physical half-life of less than <u>90 days</u> for decay-in-storage before disposal in ordinary trash, provided:
 - A. Affected radioactive waste shall be held for decay a minimum of ten (10) half-lives; and
 - B. Prior to disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
- 19. The licensee shall have available appropriate survey meters which shall be maintained operational and shall be calibrated before initial use and at subsequent intervals not exceeding twelve months by a person specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. Records of all calibrations shall be kept a minimum of three years.
- 20. The license shall implement the requirements in New York State Department of Health LICENSE ADDENDUM Decommissioning and Financial Assurance Requirements, dated 01/02/14.
- 21. The Decommissioning Funding Plan, including a cost estimate, dated July 22, 2019, signed by Evan T. Western and Sara Beradicurti, shall be updated to account for changes in costs or the extent of contamination and resubmitted to the Department at the time of license renewal and at intervals not to exceed 3 years.

FOR THE NEW YORK STATE DEPARTMENT OF HEALTH

Daniel J. Samson, CHP, Chief Radioactive Materials Section

Bureau of Environmental Radiation Protection

Date: SEP 2 8 2021

DJS/DCG:

cc: Dan Hill

Cardinal Health

Nuclear Pharmacy Services

7000 Cardinal Place Dublin, Ohio 43017

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