Cardinal Health
Nuclear Pharmacy Services
Quality & Regulatory
7000 Cardinal Place
Dublin, OH 43017
tel 614.757.4120
fax 614.652.4598

www.cardinalhealth.com

Br. 2

CardinalHealth

September 1, 2017

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

03038331

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

Licensing:

Cardinal Health 414, LLC (Nuclear Pharmacy Services and PET Manufacturing Services, hereafter Cardinal Health) requests an amendment for the above referenced license to add the following cyclotron operator / authorized user, previously AU on amendment 16: Scott Lucas. Documentation of training is attached.

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

Sincerely,

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

/dh

Enclosure: Training Documents

cc: Beau Dugas, MRSO loc. 5869
Arshad Mehmood, loc. 5869
Scott Lucas
License File 5869 (3)

600703

Cardinal Health Manufacturing Training Summary

Scott Lucas has completed the following Cardinal Health Manufacturing training at the Columbus cyclotron site on 12/28/2006. This training was performed on a GE PETrace cyclotron by an authorized user and cyclotron operator who received manufacturer or equivalent training on the GE PETrace cyclotron.

PET Trace Cyclotron Training

1. Health, General and Radiation Safety
2. Cyclotron Theory and Physics
3. Controls and Displays
4. Operating Instructions
5. Preventive Maintenance
6. Cyclotron Software
7. Cyclotron Shielding
8. Cyclotron Documentation

100 hours

FDG Chemical Synthesis

1. Chemical Syntheses Theory
2. Materials Preparation
3. Chemical Preparation
4. Coincidence Synthesis Box Preparation
5. Coincidence Synthesis Box Operation
6. Handling up to 3 Ci of FDG
7. GMP Practices
8. Production Abnormalities

60 hours

Quality Control

1. Radionuclidic Identification: Half-life test
2. Ph Testing
3. Chemical Purity of Fludeoxyglucose F-18 Injections: Gas Chromotography
4. Radiochemical Identity and Purity of Fludeoxyglucose F-18 Injection: Radio-TLC
5. Chemical Purity of Fludeoxyglucose F-18 Injection: Kryptofix TLC
6. Bacterial Endotoxin Testing: LAL
7. Membrane Filter Integrity Test
8. Radionucidic Purity of Fludeoxyglucose F-18 injection: MCA Analysis
9. Sterility Testing

80 hours

Radiation Testing and Equipment

1. Radiation Safety Training for Individuals Working in or Frequenting Restricted Areas
2. Portable Survey Meters and Wipe Tests
3. Transport and Receipt of Radioactive Materials
4. Dose Calibrator and Fume Hood

25 hours

Component Materials Management

1. Receiving
2. Tracking
3. Batch Record Compliance
4. Record Retention
5. Inventory

15 hours

TOTAL: 280 hours

Certification of Review of Training

I certify that I have reviewed the training and experience documentation of the above named individual and have determined that the individual has satisfactorily completed the training and experience requirements set forth in the PET Manufacturing Services Radiation Safety Training Manual.

December 28, 2006

Dave Breuning, Health Physicist
Quality and Regulatory

Date

RADIOISOTOPE HANDLING EXPERIENCE

Name: Scott Lucas Date: January 16, 2014

Document the actual use/handling of radioactive material under the supervision of an Authorized User.

ISOTOPE	MAXIMUM ACTIVITY HANDLED	USE See key below: 1,2,3,4,5,6,7	EXPERIENCE Actual clock hours (Include date range of experience)	WHERE EXPERIENCE GAINED
^{18}F	8000 mCi	1,2,3,4,5,6,7	>1000 hours 2/5/01 – 6/30/06	Regional Nuclear Pharmaceuticals
^{18}F	10,000 mCi	1,2,4,5,6,7	100 hours 7/1/06 – 12/31/10	Cardinal Health NPS
^{13}N	250 mCi	1,2,4,5,6,7	100 hours 7/1/06 – 12/31/10	Cardinal Health NPS
^{22}Na	200 uCi	2,6	>1000 hours 2/5/01 – 6/30/06	Regional Nuclear Pharmaceuticals
^{22}Na	200 uCi	2,6	100 hours 7/1/06 – 12/31/10	Cardinal Health NPS

Key for "Use": the number, or numbers, entered under "Use" should correspond to the handling experience for each isotope.

1. Ordering, shipping, receiving radioactive materials and performing related radiation surveys

2. Calibrating, using and performing checks for proper operation of dose calibrators, scintillation detectors, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides

3. Calculating, assaying and safely preparing dosages for patients or human research subjects

4. Using appropriate internal controls to avoid mistakes in the labeling and/or administration of by product or accelerator material

5. Using procedures to prevent or minimize contamination and using proper decontamination procedures

6. Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests

7. Production of radioactive materials via bombardment in a nuclear reaction.

Radiation Safety Officer

Certificate

Awarded to

Scott Lucas

recognizing completion of 40 hours of specialized instruction

February 26-March 2, 2001

Presented By

CSI-Radiation Safety Academy
481 North Frederick Avenue, Suite 302
Gaithersburg, Maryland 20877

AAHP has awarded this course 32 Continuing Education Credits, 99-00-011
ABIH has awarded this course 4.5 CM Points, CM Approval #13421

Ray Johnson

Raymond Johnson, CHP, PE, RSO
Training Director

Certificate of Training

This Certifies That

Scott Lucas

on March 1, 2001

has successfully completed the

DOT Training Requirements for Shipping & Receiving Radioactive Materials

Presented By

CSI-Radiation Safety Academy
481 North Frederick Avenue, Suite 302
Gaithersburg, Maryland 20877

Ray Johnson

Raymond Johnson, CHP, PE, RSO
Training Director

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 16

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 70 and 71, 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 byproduct, source, and special nuclear material 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 regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with letter dated August 31, 2016,	4. Expiration Date: July 31, 2021
1. Cardinal Health 414, LLC 2. 7000 Cardinal Place Dublin, OH 43017	3. License number: 34-32780-02 is amended in its entirety to read as follows:	5. Docket No.: 030-38331 Reference No.:

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number
34-32780-02

Amendment No. 16

Docket or Reference Number
030-38331

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
A. Carbon-11	A. Any	A. 10 curies total	A. (1) For production, possession, or handling of radiochemicals and sealed sources for transfer to person authorized to receive the licensed material in accordance with the terms and conditions of a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State. (2) For packaging and distribution of produced radiochemicals and sealed sources to persons authorized to receive licensed materials in accordance with the terms and conditions of specific licenses issued by the U.S. Nuclear Regulatory Commission or Agreement States. This material should not be distributed as a radiopharmaceutical or radioactive drug.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number: 34-32780-02
Amendment No. 16
Docket or Reference Number: 030-38331

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
B. Nitrogen-13	B. Any	B. 10 curies total	B. (1) For production, possession, or handling of radiochemicals and sealed sources for transfer to person authorized to receive the licensed material in accordance with the terms and conditions of a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State. (2) For packaging and distribution of produced radiochemicals and sealed sources to persons authorized to receive licensed materials in accordance with the terms and conditions of specific licenses issued by the U.S. Nuclear Regulatory Commission or Agreement States. This material should not be distributed as a radiopharmaceutical or radioactive drug.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number: 34-32780-02
Amendment No. 16
Docket or Reference Number: 030-38331

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
C. Oxygen-15	C. Any	C. 10 curies total	C. (1) For production, possession, or handling of radiochemicals and sealed sources for transfer to person authorized to receive the licensed material in accordance with the terms and conditions of a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State. (2) For packaging and distribution of produced radiochemicals and sealed sources to persons authorized to receive licensed materials in accordance with the terms and conditions of specific licenses issued by the U.S. Nuclear Regulatory Commission or Agreement States. This material should not be distributed as a radiopharmaceutical or radioactive drug.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number: 34-32780-02
Amendment No. 16
Docket or Reference Number: 030-38331

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
D. Fluorine-18	D. Any	D. 30 curies total	D. (1) For production, possession, or handling of radiochemicals and sealed sources for transfer to person authorized to receive the licensed material in accordance with the terms and conditions of a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State. (2) For packaging and distribution of produced radiochemicals and sealed sources to persons authorized to receive licensed materials in accordance with the terms and conditions of specific licenses issued by the U.S. Nuclear Regulatory Commission or Agreement States. This material should not be distributed as a radiopharmaceutical or radioactive drug.
E. Any byproduct material with Atomic Numbers 1 through 83 with half-life less than or equal to 120 days	E. Incidentally activated products	E. 1 curie per radionuclide and 5 curies total	E. For possession and storage of byproduct materials incidental to radionuclide production.
F. Hydrogen-3	F. Incidentally activated products	F. 10 millicuries total	F. For possession and storage of byproduct materials incidental to radionuclide production.
G. Manganese-54	G. Incidentally activated products	G. 10 millicuries total	G. For possession and storage of byproduct materials incidental to radionuclide production.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number: 34-32780-02
Amendment No. 16
Docket or Reference Number: 030-38331

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
H. Cobalt-57	H. Incidentally activated products	H. 100 millicuries total	H. For possession and storage of byproduct materials incidental to radionuclide production.
I. Cobalt-60	I. Incidentally activated products	I. 15 millicuries total	I. For possession and storage of byproduct materials incidental to radionuclide production.
J. Zinc-65	J. Incidentally activated products	J. 15 millicuries total	J. For possession and storage of byproduct materials incidental to radionuclide production.
K. Niobium-93m	K. Incidentally activated products	K. 15 millicuries total	K. For possession and storage of byproduct materials incidental to radionuclide production.
L. Niobium-94m	L. Incidentally activated products	L. 100 millicuries total	L. For possession and storage of byproduct materials incidental to radionuclide production.
M. Sodium-22	M. Sealed Sources (Eckert & Ziegler Isotope Products, Model RV-022)	M. 200 microcuries per source and 400 microcuries total	M. For use in calibration and checking of the licensee's instruments.
N. Sodium-22	N. Sealed Sources (Eckert & Ziegler Isotope Products, Model Type R)	N. 1 microcurie per source and 2 microcuries total	N. For use in calibration and checking of the licensee's instruments.
O. Technetium-99m	O. Any	O. 5 curies total	O. For use in calibration and checking of the licensee's instruments.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 131 East Hartland Street, East Hartford, Connecticut.

MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number 34-32780-02	Docket or Reference Number 030-38331
	Amendment No. 16	

11. Licensed material shall only be used by, or under the supervision of,

Authorized Users	Material and Use
Robert Chicoine	ALL
Robert Droege	ALL
Paul Gotti	ALL
James Matthews	ALL
Norman Medina	ALL
Arshad Mehmood	ALL
David Missildine	ALL
Olof Robert Nilsson	ALL
Jessica Giacchetta	ALL
Adam Fleshner	ALL
Brian Toth	ALL
Bharat Kapoor	ALL
Ryan Reganato	ALL
Beau Dugas	ALL
Tiandra Allen	ALL
John Taylor Vernon	ALL
Samantha Berrios	ALL
Scott Lucas	ALL
Charles Parraga	ALL

12. The Radiation Safety Officer (RSO) for this license is Beau Dugas.

MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number 34-32780-02	Docket or Reference Number 030-38331
	Amendment No. 16	

13. This license does not authorize commercial distribution of licensed material pursuant to 10 CFR 32.72 or 10 CFR 32.74 to persons generally licensed pursuant to 10 CFR Part 31 or equivalent regulations of any Agreement State; or to persons exempt from licensing pursuant to 10 CFR 30.14 through 10 CFR 30.20 inclusive, or equivalent regulations of any Agreement State.

14. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State. In the absence of a registration certificate, sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 6 months, or at such other intervals as specified.

B. Not withstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

D. Sealed sources need not be tested if they contain only hydrogen 3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.

E. Sealed sources need not be tested if they are in storage and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The leak test shall be capable of detecting the presence of 185 becquerels (0.005 microcuries) of radioactive material on the test sample. If the test reveals the presence of 185 becquerels (0.005 microcuries) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.

MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number 34-32780-02	Docket or Reference Number 030-38331
	Amendment No. 16	

G. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

H. Records of leak test results shall be kept in units of becquerels (microcuries) and shall be maintained for 3 years.

15. The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sealed sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 3 years from the date of each inventory, and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders or foil sources removed from detector cells by the licensee, except as specifically authorized.

17. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash provided:

A. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

B. A record of each such disposal permitted under this license condition shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number 34-32780-02	Docket or Reference Number 030-38331
	Amendment No. 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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated April 15, 2011 (ML111170516 and ML111570417)
B. Letter dated April 22, 2011 (ML111170560)
C. Letter dated July 6, 2011 (ML111940279)
D. Letters dated October 23 and 24, 2012 (ML12312A410)
E. Letter received November 27, 2012 (ML12347A288)
F. Letter dated May 24, 2016 (ML16161A513)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: October 26, 2016

By: _____
Dennis Lawyer
Region 1

THE COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH
RADIATION CONTROL PROGRAM
MATERIALS LICENSE

Pursuant to Massachusetts General Laws Chapter 111, Sections 3, 5M, 5N, 5O and 5P and Massachusetts Regulations for the Control of Radiation, Section 120.100, Licensing of Radioactive Material, and in reliance on statements and representation heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer radioactive materials 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 regulations 105 CMR 120.000. This license shall be deemed to contain the conditions specified in 105 CMR 120.000 and is subjected to all applicable rules, regulations of the Department of Public Health, Commonwealth of Massachusetts, now or hereafter in effect and to any conditions specified below.

Licensee	3. License Number: 41-0366 **is amended in its entirety, in accordance with the letter dated December 2, 2016, to read as follows:**
1. Cardinal Health	Amendment No: 40
2. 7000 Cardinal Place Dublin, Ohio 43017	4. Expiration Date: March 31, 2018
	5. Docket No: 09-2848

6.	**Radioactive Material**	7.	**Chemical / Physical Form**	8.	**Maximum Possession Limit**
A.	Hydrogen-3	A.	Any	A.	10 millicuries
B.	Fluorine-18	B.	Any	B.	20 Curies
C.	Carbon-11	C.	Any	C.	2 Curies
D.	Nitrogen-13	D.	Any	D.	10 Curies
E.	Oxygen-15	E.	Any	E.	2 Curies
F.	Any radionuclide with atomic numbers 3-83	F.	Activated foils, target body, magnet coils, yokes, vacuum tank, and concrete shield	F.	5 Curies
G.	Any radionuclide with atomic numbers 3-83	G.	Sealed source	G.	Not to exceed 15 millicuries per source; 100 millicuries total
H.	Sodium-22	H.	Sealed source (As listed in SS&D Registry Sheet CA-0406-S-148-S)	H.	Not to exceed 6 millicuries per source; 10 millicuries total

COMMONWEALTH OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH RADIATION CONTROL PROGRAM MATERIALS LICENSE SUPPLEMENTARY SHEET	LICENSE NUMBER: 41-0366 DOCKET NUMBER: 09-2848 AMENDMENT NUMBER: 40

6.	**Radioactive Material**	7.	**Chemical / Physical Form**	8.	**Maximum Possession Limit**
I.	Sodium-22	I.	Sealed source (As listed in SS&D Registry Sheet CA-0406-S-107-S)	I.	Not to exceed 220 microcuries per source; 300 microcuries total
J.	Cobalt-57	J.	Sealed source (As listed in SS&D Registry Sheet CA-0510-S-114-S)	J.	Not to exceed 15 millicuries per source; 30 millicuries total
K.	Technetium-99m	K.	Unsealed source	K.	5 Curies

9. Authorized use:

A.	Byproduct material incidental to production process.
B.	For production, possession, handling, packaging, and distribution of radiochemicals to persons authorized to receive the licensed material pursuant to the terms and conditions of specific licenses issued by the Agency, the U.S. Nuclear Regulatory Commission, or any Agreement State (Non-Human Use).
C. through E.	For production and methods testing (Non-Human Use).
F.	Activation products. For storage and disposal only.
G. through J.	Calibration of instruments.
K.	Dose calibrator quality assurance testing.

CONDITIONS

10. Radioactive material shall be only used or stored at the licensee's facilities located at Cardinal Health, 25 Sixth Road, Woburn, Massachusetts.

COMMONWEALTH OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH RADIATION CONTROL PROGRAM MATERIALS LICENSE SUPPLEMENTARY SHEET	LICENSE NUMBER: 41-0366 DOCKET NUMBER: 09-2848 AMENDMENT NUMBER: 40

11. This license is subject to an annual fee as determined by the Executive Office for Administration and Finance.

12. Licensed material shall be used by, and cyclotron operation conducted, or under the supervision of, Gavin Black, Steve Bostjancic, Robert Chicoine, Michael Correale, Shangara Dehal, Robert Droege, Adam Fleshner, Paul Gotti, R.Ph., Mehmet Husnu, Patrick Kane, Jacob Kilian, Scott R. Lucas, James Matthews, David Missildine, Ken Moore, Steve Morcos, Joseph Tavano, Albert Tondreau, Paul Tremiti, John Taylor Vernon, Nathan Yetton, or Danny Phoun.

13. The Radiation Safety Officer for this license is Patrick Kane.

14. In addition to the possession limits in Item 8 above, the licensee shall further restrict the possession of licensed material to quantities below the limit specified in 105 CMR 120.125(C)(1)(d) for establishing decommissioning financial assurance.

15. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in 105 CMR 120.196, Table III which require consideration of the need for an emergency plan for responding to a release of licensed material.

16. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed the intervals as are specified in the certificate of registration referred to in 105 CMR 120.128(N).

    B. In the absence of a certificate from a transferor indicating that a test has been made within the intervals specified in the certificate of registration referred to in 105 CMR 120.128(N) prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

    C. Sealed sources need not be leak tested if they are in storage and not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

COMMONWEALTH OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH RADIATION CONTROL PROGRAM MATERIALS LICENSE SUPPLEMENTARY SHEET	LICENSE NUMBER: 41-0366 DOCKET NUMBER: 09-2848 AMENDMENT NUMBER: 40

D. The leak test shall be capable of detecting the presence of 185 becquerel (0.005 microcurie) of radioactive material on the test sample. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Agency. If the test reveals the presence of 185 becquerel (0.005 microcurie) or more of removable contamination, a report shall be filed with the Agency and the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the Massachusetts Department of Public Health, ATTN: Director, Radiation Control Program. The report shall specify the source involved, the test results, and corrective action taken.

E. The licensee is authorized to collect leak test samples for analysis by the licensee or persons specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

17. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash, provided:

A. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

B. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

18. Sealed sources containing licensed material shall not be opened or sources removed from the device by the licensee.

COMMONWEALTH OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH RADIATION CONTROL PROGRAM MATERIALS LICENSE SUPPLEMENTARY SHEET	LICENSE NUMBER: 41-0366 DOCKET NUMBER: 09-2848 AMENDMENT NUMBER: 40

19. 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 inventories shall be maintained until inspection by the Radiation Control Program and shall include the quantities and kinds of radioactive material, location of sealed sources and the date of the inventory.

20. The licensee shall only transport radioactive material or deliver radioactive material to a carrier for transport in accordance with the provisions of 49 CFR Parts 170 through 189, 10 CFR Part 71, and 105 CMR 120.770 "Transportation of Radioactive Material".

21. Except as specifically provided otherwise by this license, the licensee shall conduct its program in accordance with statements, representations and procedures contained in the documents, including any enclosures listed below. The Massachusetts Regulations for the Control of Radiation, 105 CMR 120.000, shall govern, unless statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Renewal application dated November 15, 2012
B. Letter dated January 18, 2013
C. Letter dated March 27, 2013
D. Letter dated July 30, 2013
E. Letter dated November 20, 2013
F. Letter dated January 15, 2014
G. Letter dated July 7, 2014
H. Letter dated October 6, 2014
I. Letter dated December 8, 2014
J. Letter dated June 30, 2015
K. Letter dated May 5, 2016
L. Letter dated December 2, 2016 with attachments

COMMONWEALTH OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH RADIATION CONTROL PROGRAM MATERIALS LICENSE SUPPLEMENTARY SHEET	LICENSE NUMBER: 41-0366 DOCKET NUMBER: 09-2848 AMENDMENT NUMBER: 40

FOR THE COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH
RADIATION CONTROL PROGRAM

Date 3/7/17

By _____
John M. Priest, Jr., Director

NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Glenn P. Sullivan
Corporate Radiation Safety Officer
Cardinal Health 414, LLC
7000 Cardinal Place
Dublin, Ohio 43017

Date
September 7, 2017

License Number(s)
34-32780-02

Mail Control Number(s)
600703

Licensing and/or Technical Reviewer or Branch
Commercial, Industrial, R&D, and Academic Branch

This is to acknowledge receipt of your: ☑ **Letter and/or** ☐ **Application** **Dated:** 9/1/2017

The initial processing, which included an administrative review, has been performed.

☑ **Amendment** ☐ **Termination** ☐ **New License** ☐ **Renewal**

☑ **There were no administrative omissions identified during our initial review.**

☐ **This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.**

☐ **Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf**

Follow the instructions on the form for submission.

☐ **The following administrative omissions have been identified:**

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
U. S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, (610) 337-5239