

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

www.cardinal.com



November 12, 2018

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

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

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 Brandon Xiong, Hoppe Achuonjei and Brandon McLean as cyclotron operators / authorized users (AU). Training documents are attached.

In addition, please remove the following AU: Corey Damocles and Charles Parraga.

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

Encl: AU Training Documents

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

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PET Manufacturing Services Training Authorization

November 12, 2018

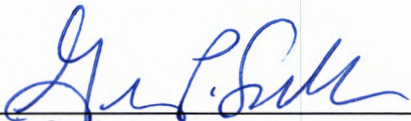
I have reviewed the education and training documents listed below and they meet the training requirements outlined in the PET Manufacturing Services Radiation Safety Manual, Section 9.

PETtrace Cyclotron Training (30-60-90 Day Training Documentation)

Basic Radioisotope Handling Techniques Worksheet

Didactic Training Certificate

Therefore, I authorize **Hoppe Achuonjei** to act as a PET Technician AU/Cyclotron operator on any PET Manufacturing License that grants self-approval for Authorized Users/Cyclotron Operators. A copy of this approval letter must be kept on file at all locations where the above named individual has worked for 5 years after the last date of employment.

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

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

Cardinal Health Manufacturing Training Summary

Hoppe Achuonjei has completed the following Cardinal Health Manufacturing training at the East Lansing, Michigan cyclotron site on November 6, 2018. This training was performed on a GE PETtrace_cyclotron by an authorized user and cyclotron operator who received manufacturer or equivalent training on the GE PETtrace_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
7. Membrane Filter Integrity Test
8. Radionuclidic Purity of Fludeoxyglucose F-18 injection
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

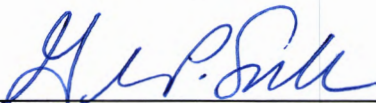
1. Receiving
2. Tracking
3. Batch Record Compliance
4. Record Retention
5. Inventory

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.



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

11/12/18

Date

RADIOISOTOPE HANDLING EXPERIENCE

Name: Brandon Xiong

Date 06NOV18

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
Na22	151mCi	2	04 JUN 18 - 06 NOV 18 800 hrs.	# 5860 Cardinal Health 846 Service Rd East Lansing MI 48824
F18	<30,000mCi	1,2,3,4,5,6,7		
N13	<1,000mCi	1,3,4,5,6,7		

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

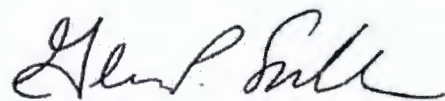
1. Ordering, shipping, receiving radioactive materials and performing related radiation surveys
2. Calibrating, using and performing checks for proper operation of dose calibrators, scintillation detectors, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides
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.

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: Brandon Xiong

Location of Training	Date(s) of Accordance	Course Title	Total Clock Hours of Course	BREAKDOWN OF COURSE CONTENT IN CLOCK HOURS*				
				Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radio-activity	Radiation Biology	Radiopharmaceutical Chemistry
CARDINAL HEALTH DUBLIN, OH	9/4/2018 – 10/22/2018	CARDINAL HEALTH AUTHORIZED USER EDUCATION PROGRAM	200	85	58	25	32	0
*Note: Show a breakdown of hours by institution, dates, and subjects. List each hour only once (i.e., under the most applicable subject category)		TOTAL HOURS	200	85	58	25	32	0

Signature:



Glenn Sullivan, Corporate Radiation Safety Officer

Date: 11/02/2018



PET Manufacturing Services Training Authorization

November 12, 2018

I have reviewed the education and training documents listed below and they meet the training requirements outlined in the PET Manufacturing Services Radiation Safety Manual, Section 9.

PETtrace Cyclotron Training (30-60-90 Day Training Documentation)

Basic Radioisotope Handling Techniques Worksheet

Didactic Training Certificate

Therefore, I authorize **Brandon Xiong** to act as a PET Technician AU/Cyclotron operator on any PET Manufacturing License that grants self-approval for Authorized Users/Cyclotron Operators. A copy of this approval letter must be kept on file at all locations where the above named individual has worked for 5 years after the last date of employment.

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

Cardinal Health Manufacturing Training Summary

Brandon Xiong has completed the following Cardinal Health Manufacturing training at the East Lansing, Michigan cyclotron site on November 6, 2018. This training was performed on a GE PETtrace_cyclotron by an authorized user and cyclotron operator who received manufacturer or equivalent training on the GE PETtrace_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
7. Membrane Filter Integrity Test
8. Radionuclidic Purity of Fludeoxyglucose F-18 injection
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

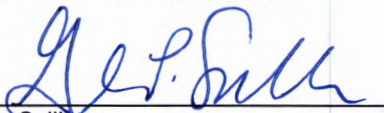
1. Receiving
2. Tracking
3. Batch Record Compliance
4. Record Retention
5. Inventory

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.



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

11/12/18
Date

RADIOISOTOPE HANDLING EXPERIENCE

Name: Hoppe Achuonjei

Date 06 Nov 2018

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
Na22	177 μ Ci	2	25 SEP 17 -	#5860 Cardinal Health 846 Service Rd. East Lansing MI 48824
F18	<30,000 mCi	1,2,3,4,5,6,7	06 NOV 18	
N13	<1,000 mCi	1,3,4,5,6,7	2160 hrs.	

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

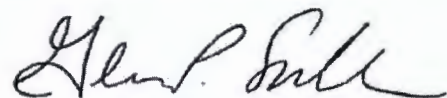
1. Ordering, shipping, receiving radioactive materials and performing related radiation surveys
2. Calibrating, using and performing checks for proper operation of dose calibrators, scintillation detectors, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides
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.

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: Hoppe Achuonjei

Location of Training	Date(s) of Accordance	Course Title	Total Clock Hours of Course	BREAKDOWN OF COURSE CONTENT IN CLOCK HOURS*				
				Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radio-activity	Radiation Biology	Radiopharmaceutical Chemistry
CARDINAL HEALTH DUBLIN, OH	4/23/2018 – 6/4/2018	CARDINAL HEALTH AUTHORIZED USER EDUCATION PROGRAM	200	85	58	25	32	0
*Note: Show a breakdown of hours by institution, dates, and subjects. List each hour only once (i.e., under the most applicable subject category)		TOTAL HOURS	200	85	58	25	32	0

Signature:



Glenn Sullivan, Corporate Radiation Safety Officer

Date: 06/20/2018



PET Manufacturing Services Training Authorization

November 12, 2018

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Basic Radioisotope Handling Techniques Worksheet

Didactic Training Certificate

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

Cardinal Health Manufacturing Training Summary

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100 hours

FDG Chemical Synthesis

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60 hours

Quality Control

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6. Bacterial Endotoxin Testing
7. Membrane Filter Integrity Test
8. Radionuclidic Purity of Fludeoxyglucose F-18 injection
9. Sterility Testing

80 hours

Radiation Testing and Equipment

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25 hours

Component Materials Management

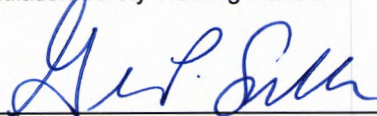
1. Receiving
2. Tracking
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4. Record Retention
5. Inventory

15 hours

TOTAL: 280 hours

Certification of Review of Training

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

11/12/18
Date

RADIOISOTOPE HANDLING EXPERIENCE

Name: Brandon McLean

Date 06 NOV 2018

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
Na 22	151 mCi	2	29 JUN 18 -	#5860 Cardinal Health 846 Service Rd. East Lansing MI 48824
F 18	<30,000 mCi	1,2,3,4,5,6,7	06 NOV 18	
N 13	<1,000 mCi	1,3,4,5,6,7	840 hrs	

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

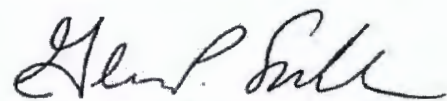
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TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: Brandon McLean

Location of Training	Date(s) of Accordance	Course Title	Total Clock Hours of Course	BREAKDOWN OF COURSE CONTENT IN CLOCK HOURS*				
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CARDINAL HEALTH DUBLIN, OH	9/4/2018 – 10/22/2018	CARDINAL HEALTH AUTHORIZED USER EDUCATION PROGRAM	200	85	58	25	32	0
*Note: Show a breakdown of hours by institution, dates, and subjects. List each hour only once (i.e., under the most applicable subject category)		TOTAL HOURS	200	85	58	25	32	0

Signature:



Glenn Sullivan, Corporate Radiation Safety Officer

Date: 11/02/2018

ORIGIN ID:OSUA (614) 757-5074
DAN HILL
CARDINAL HEALTH
7000 CARDINAL PLACE
DUBLIN, OH 43017
UNITED STATES US

SHIP DATE: 09NOV18
ACTWGT: 1.00 LB
CAD: 104744132/NET4040

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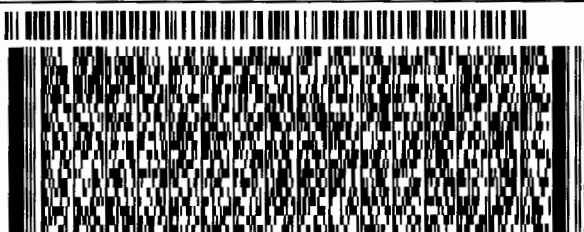
TO NMSS LICENSING
US NRC REGION III
2443 WARRENVILLE ROAD
SUITE 210
LISLE IL 60532

(630) 829-9854

REF: 2250001338

INV

DEPT:



FedEx
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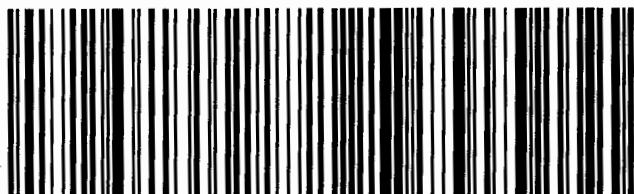
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