

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

www.cardinalhealth.com



Cardinal Health

Br. 2
03038331

July 12, 2018

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

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 Gbolagade Adetola as a cyclotron operator / authorized user. 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)

REC RG 10719 18M1029

609441
NRC/REGNI MATERIALS-002



PET Manufacturing Services Training Authorization

July 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.

G.E. PETtrace Cyclotron Training (30-60-90 Day Training Documentation)

Basic Radioisotope Handling Techniques Worksheet

Didactic Training Certificate

Therefore, I authorize **Gbolagade Adetola** to act as a 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.

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

Cardinal Health Manufacturing Training Summary

Gbolagade Adetola has completed the following Cardinal Health Manufacturing training at the East Hartford, CT cyclotron site on July 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 Chromatography
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

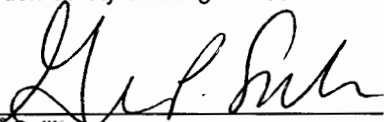
1. Receiving
2. Tracking
3. Batch Record Compliance
4. Record Retention
5. Inventory

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

7/12/2018
Date

RADIOISOTOPE HANDLING EXPERIENCE

Name: *Gbolagade Adetola*

Date *03/1/18*

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
<i>F-18</i>	<i>12,000 mCi</i>	<i>3,4,5,6,7</i>	<i>>300 hr</i> <i>Oct 2017 - Present</i>	<i>Cardinal Health</i>
<i>Na-22</i>	<i>0.100 mCi</i>	<i>2,5,6</i>	<i>>300 hr</i> <i>Oct 2017 - Present</i>	

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: Gbolagade Adetola

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

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

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

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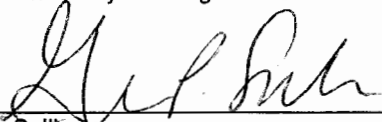
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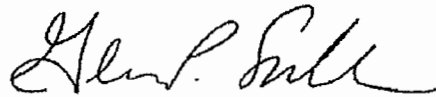
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Signature:



Glenn Sullivan, Corporate Radiation Safety Officer

Date: 06/20/2018



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee Cardinal Health 414, LLC ATTN: Glenn P. Sullivan, Corporate RSO 7000 Cardinal Place Dublin, OH 43017	Date July 23, 2018
	License Number(s) 34-32780-02
	Mail Control Number(s) 609441
	Licensing and/or Technical Reviewer or Branch Commercial, Industrial, R&D, & Academic Branch

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: 07/12/2018

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, or (610) 337-5239