

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

www.cardinal.com



April 6, 2015

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 Michael Gannon Connolly-Ng as a cyclotron operator / authorized user (AU). Training documents are attached.

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

Sincerely,

A handwritten signature in blue ink, appearing to read "Glenn Sullivan".

Glenn Sullivan
Manager, Health Physics
Quality and Regulatory
Nuclear Pharmacy Services

Encl: AU Training Documents

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

RECEIVED APR 09 2015



PET Manufacturing Services Training Authorization

April 6, 2015

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 **Michael Gannon Connolly-Ng** 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
Manager, Health Physics
Quality and Regulatory
Nuclear Pharmacy Services

Cardinal Health Manufacturing Training Summary

Michael Gannon Connolly-Ng has completed the following Cardinal Health Manufacturing training at the East Lansing, Michigan cyclotron site on January 19, 2015. 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

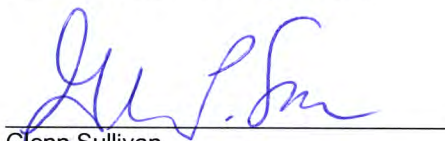
1. Receiving
2. Tracking
3. Batch Record Compliance
4. Record Retention
5. Inventory

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
Manager, Health Physics
Quality and Regulatory

4/16/15
Date

RADIOISOTOPE HANDLING EXPERIENCE

Name: Michael Connolly - N₃

Date 02 APR 15

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 |
|--------------|--------------------------|--|--|---|
| <u>F-18</u> | <u><15,000 mCi</u> | <u>1,3,4,5,6,7</u> | <u>1240 hrs</u> <u>11 AUG 2014 -</u> <u>02 APR 2015</u> | <u># 5860</u> <u>Cardinal</u> <u>Health</u> <u>846 S. Service Rd.</u> <u>East Lansing, MI</u> <u>48824</u> |
| <u>N-13</u> | <u><1,000 mCi</u> | <u>1,3,4,5,6,7</u> | | |
| <u>Na-22</u> | <u>146 µCi</u> | <u>2</u> | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

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

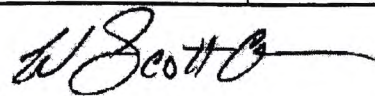
1. Ordering, shipping, receiving radioactive materials and performing related radiation surveys
2. Calibrating, using and performing checks for proper operation of dose calibrators, scintillation detectors, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides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

| 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 | 1/12/2015 to 2/23/2015 | 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:



Scott Claunch, Corporate Radiation Safety Officer

Date: 3/3/2015

From: (614) 757-5074
Dan Hill
Cardinal Health
7000 Cardinal Place
Dublin, OH 43017

Origin ID: OSUA



Ship Date: 06APR15
ActWgt: 1.0 LB
CAD: 104744132/NET3610

Delivery Address Bar Code



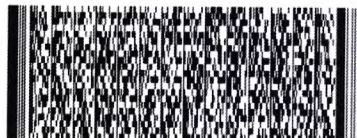
SHIP TO: (630) 829-9854
NMSS Licensing
US NRC Region III
2443 Warrenville Road
Suite 210
LISLE, IL 60532

BILL SENDER

Ref # 2250001338
Invoice #
PO #
Dept #

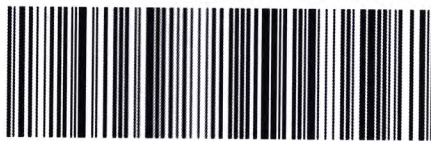
THU - 09 APR AA
EXPRESS SAVER

TRK# 7732 9535 4991
0201



SH ENLA

60532
IL-US
ORD



5374/RF10:EE4B

RECEIVED

RECEIVED APR 09 2015

RECEIVED APR