Cardinal Health
Nuclear Pharmacy Services
7000 Cardinal Place
Dublin, OH 43017
614.757.5000 main
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cardinalhealth.com

CardinalHealth

October 30, 2012

Kevin Null
Licensing Assistance Team
U.S. NRC Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532

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

Licensing / Mr. Null:

Cardinal Health Nuclear Pharmacy Services and Manufacturing Services (hereafter Cardinal Health) requests an amendment for the above referenced license to remove Robert Symons as the Radiation Safety Officer, and add Jason Foster as the RSO. Jason Foster is an authorized user on the license and is familiar with the radiation safety program. The after-hours on-site RSO contact number is updated with regard to our new license application, as follows: 517-358-5379 or email healthphysics@cardinalhealth.com. Documentation of training is enclosed.

If you have any questions regarding this request, please contact Dan Hill at 614.757.5074.

Sincerely,

Willie Regits, Ph D.
Corporate Radiation Safety Officer
Director, Health Physics
Nuclear Pharmacy Services

Encl: Training Documents

cc: Jason Foster, MRSO, Loc. 5860
License File 5860 (3)
Thomas Ward

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TO: All Employees, Location # 5860, East Lansing, MI

FROM: Willie Regits, Ph.D., Corporate Radiation Safety Officer, Director, Health Physics Nuclear Pharmacy Services

DATE: October 30, 2012

SUBJECT: Delegation of Authority

Jason Foster has been appointed Manufacturing Radiation Safety Officer and is responsible for ensuring the safe use of radioactive materials. The Manufacturing Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Manufacturing Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities. This specifically includes having sufficient authority, organizational freedom, and management prerogative to:

1. Have unhampered access to all activities at his or her facility involving radioactive materials to identify radiation safety problems;

2. Immediately stop, without coordination with management, any activity at his or her facility involving the use of licensed materials by any user that might result in an unsafe situation or a violation of Federal requirements;

3. Initiate, recommend, or implement appropriate corrective actions; and

4. Verify the implementation of actions taken to correct radiation safety problems.

The Manufacturing Radiation Safety Officer is also responsible for assisting the Corporate Radiation Safety Committee and Corporate Radiation Safety Officer in the performance of their duties.

All of us have a critical responsibility in ensuring the safe use of radioactive materials. I ask that you lend your full support to this important function.

I understand and accept the above duties and responsibilities,

Jason Foster, MRSO — 06NOV2012 Date

Willie Regits, Ph.D. CRSO — 10/30/12 Date

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DOCUMENTATION OF PET MANUFACTURING SERVICES RADIATION SAFETY OFFICER TRAINING

I hereby certify that the individual below has satisfactorily received 200 hours didactic training and 500 hours of practical radioisotope handling experience and that the individual has achieved a level of competency sufficient to independently operate as a PET Manufacturing Services radiation safety officer. This includes training as radiation safety officer under a current radiation safety officer.

RSO Name (Print) Robert Symons

RSO Signature: _____ Date: 30OCT2012

RSO Designee Name (Print) Jason M. Foster

RSO Designee Signature: _____ Date: 30OCT2012

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PET Manufacturing Services Training Authorization

October 26, 2011

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.

PET Trace Cyclotron Training (30-60-90 Day Training Documentation)

Basic Radioisotope Handling Techniques Worksheet

Didactic Training Certificate

Therefore, I authorize Jason Foster 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.

Willie Regits, Ph D.
Director, Health Physics
Nuclear Pharmacy Services

Cardinal Health Manufacturing Training Summary

Jason Foster has completed the following Cardinal Health Manufacturing training at the East Lansing, MI, cyclotron site on 12/10/2010. 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.

Willie Regits, Ph D.
Director, Health Physics
Quality and Regulatory

10/27/4
Date

Cardinal Health
Nuclear Pharmacy Services
and
The Ohio State University
College of Pharmacy

By this certificate warrants that

Jason Foster

has satisfactorily fulfilled all requirements
and completed the prescribed course

Authorized User Education Program

December 20, 2010

Senior Vice President
Quality and Regulatory
Nuclear Pharmacy Services
Cardinal Health

Director, Nuclear Pharmacy Services
Associate Professor of Pharmacy
College of Pharmacy
The Ohio State University

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: Jason Foster

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	11/18/10 Thru 12/20/10	CARDINAL HEALTH NUCLEAR PHARMACIST /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: _____
Corporate Radiation Safety Officer

Date: 12/20/10

RADIOISOTOPE HANDLING EXPERIENCE

Name: Jason Foster Date 16 AUG 2011

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
F-18	14 Curies	1,2,3,4,5,6,7	04-01-2010 to 08-16-2011 Approx 2240hrs	MSU #5860 East Lansing
N-13	600 millicuries	1,2,3,4,5,6,7		

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.

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US Nuclear Regulatory Commission
Region III-Division of Nuclear
Material Safety
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