

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

June 23, 2015

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 remove Michael Kelly as the Radiation Safety Officer (RSO) and Authorized User (AU). Please add Ryan Reganato as the RSO. Ryan Reganato is an AU on the license and is familiar with the radiation safety program. Documentation of training is enclosed.

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

Sincerely,

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

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

/dh

Enclosures: Training Documents

cc: Ryan Reganato, MRSO loc. 5869
Arshad Mehmood, loc. 5869
John Taylor Vernon
License File 5869 (3)

588272
NMSS/RGNI MATERIALS-002

RECEIVED 07/15/2015

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CardinalHealth

TO: All Employees, PMS Location 5889, East Hartford, Connecticut

FROM: W. Scott Claunch, R.Ph., Corporate Radiation Safety Officer, Director, Pharmacy Safety & Practice, Nuclear Pharmacy Services

DATE: June 23, 2015

SUBJECT: Delegation of Authority

Ryan Reganato has been appointed Manufacturing Radiation Safety Officer (MRSO) and is responsible for ensuring the safe use of radioactive materials. The MRSO 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 MRSO 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 Agreement State requirements;
3. Initiate, recommend, or implement appropriate corrective actions; and
4. Verify the implementation of actions taken to correct radiation safety problems.

The MRSO 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 refer you to one of our six values: "The health and safety of our employees, customers and community will never be compromised."

I understand and accept the responsibilities associated with being MRSO.



Ryan Reganato, MRSO

6/27/15
Date



W. Scott Claunch, CRSO

6/26/15
Date

I on 1 call completed 6/24/15 Date, CRSO Initials WPS

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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) John Taylor Vernon

RSO Signature: John Taylor Vernon Date: 22 Jun 2015

RSO Designee Name (Print) Ryan Reganato

RSO Designee Signature: [Signature] Date: 22 Jun 15

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PET Manufacturing Services Training Authorization

April 24, 2014

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 **Ryan Reganato** 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.

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

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

Cardinal Health Manufacturing Training Summary

Ryan Reganato has completed the following Cardinal Health Manufacturing training at the East Hartford, CT cyclotron site on April 4, 2014. 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: LAL
7. Membrane Filter Integrity Test
8. Radionuclidic 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

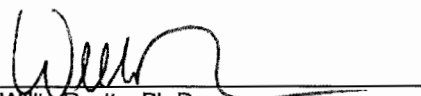
1. Receiving
2. Tracking
3. Batch Record Compliance
4. Record Retention
5. Inventory

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.
Corporate Radiation Safety Officer
Director, Health Physics
Quality and Regulatory

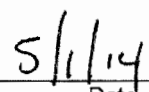

Date

FIGURE 9-7

RADIOISOTOPE HANDLING EXPERIENCE

Name: *Ryan Reganato*

Date *17 April 14*

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>Co-57</i>	<i>0.0100 mCi</i>	<i>2</i>	<i>November 2013 - Present > 300 hr</i>	<i>CAH</i>
<i>F-18</i>	<i>10,000 mCi</i>	<i>3 and 7</i>	<i>Nov. 2013 - Present > 300 hr</i>	
<i>Na-22</i>	<i>0.1022 mCi</i>	<i>2</i>	<i>Nov. 2013 - Present > 300 hr</i>	
<i>N-13</i>	<i>500 mCi</i>	<i>2</i>	<i>Nov. 2013 - Present > 300 hr</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: Ryan Reganato

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	1/13/2014- 2/24/2014	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:


 Corporate Radiation Safety Officer

Date: 2/27/2014

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BY NRC. NO COPY OF THIS INFORMATION
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MCPHS University

UPON RECOMMENDATION OF THE FACULTY,
AND BY AUTHORITY OF THE BOARD OF TRUSTEES OF
MASSACHUSETTS COLLEGE OF PHARMACY AND HEALTH SCIENCES,
CONFERS UPON

RYAN THOMAS REGANATO

THE DEGREE OF

BACHELOR OF SCIENCE

WITH ALL THE HONORS, RIGHTS, PRIVILEGES AND RESPONSIBILITIES PERTAINING THERE TO
IN WITNESS WHEREOF THIS DIPLOMA HAS BEEN SIGNED BY THE DULY AUTHORIZED OFFICERS
OF THE UNIVERSITY AND THE BOARD OF TRUSTEES AND SEALED WITH ITS CORPORATE SEAL



[Signature]

[Signature]

PERSONAL INFORMATION WAS REMOVED
BY NRC. NO COPY OF THIS INFORMATION
WAS RETAINED BY THE NRC.

This is to acknowledge the receipt of your letter application dated

06/23/2015, and to inform you that the initial processing which includes an administrative review has been performed.

34-32780-02 (Amendment)
 There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 588272
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.