

Cardinal Health 414, LLC
Quality & Regulatory
7000 Cardinal Place
Dublin, OH 43017
tel 614.757.4120
fax 614.652.4598

www.cardinalhealth.com



May 28, 2019

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 (PET Manufacturing Services, hereafter Cardinal Health) requests an amendment for the above referenced license to remove Jason Foster as the Radiation Safety Officer (RSO) and add Colten Conrad as the RSO. Colten Conrad is an authorized user and familiar with the radiation safety program. Training documents are attached.

In addition, please increase the maximum quantity of Hydrogen-3 in item 8.Z. to 40 millicuries total for possession and storage prior to sending target water (HTO) for recycling to another authorized location.

Also, in amendments 12 and 13 for the above referenced license, the name of Thomas Morosky in condition 11 or 12 is misspelled. We request that this AU name be spelled correctly as indicated on prior amendments.

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 & Precision Health Solutions

Encl: RSO Training Documents

cc: Colten Conrad, MRSO, Loc. 5860
Rob Symons, Loc. 5860
License File 5860 (3)

RECEIVED MAY 30 2019

ATTACHMENT A

RSO Training Documents



TO: All Employees, Location # 5860, East Lansing, MI
FROM: Glenn Sullivan, Corporate Radiation Safety Officer, Director, Health Physics
DATE: May 24, 2019
SUBJECT: Delegation of Authority


Colten Conrad 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:

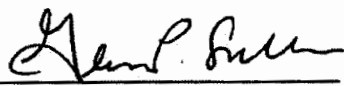
1. Have unhampered access to all activities at his or her facility involving radioactive materials to identify radiation safety problems;
2. Immediately stop, without coordination with management, any activity at his or her facility involving the use of licensed materials by any user that might result 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,


Colten Conrad, MRSO
24 May 19
Date


Glenn Sullivan, CRSO
5/24/2019
Date

I on 1 call completed _____ (DATE), CRSO Initials _____

Cardinal Health
Nuclear Pharmacy Services
Quality and Regulatory Department
7000 Cardinal Place
Dublin, OH 43017
tel 614.757.5000
fax 614.652.4598

www.cardinal.com



CardinalHealth

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) Jason M. Foster

RSO Signature: [Signature] Date: 23 May 19

RSO Designee Name (Print) CORTEN CONRAD

RSO Designee Signature: [Signature] Date: 23 May 19

Cardinal Health
Nuclear Pharmacy Services
Quality & Regulatory
7000 Cardinal Place
Dublin, OH 43017
tel 614.757.5000
fax 614.652.4598

www.cardinal.com



PET Manufacturing Services Training Authorization

January 18, 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 **Colten Conrad** 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.

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

Cardinal Health Manufacturing Training Summary

Colten Conrad has completed the following Cardinal Health Manufacturing training at the East Lansing, Michigan cyclotron site on January 10, 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

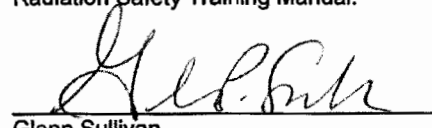
1. Receiving
2. Tracking
3. Batch Record Compliance
4. Record Retention
5. Inventory

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

1/22/18
Date

RADIOISOTOPE HANDLING EXPERIENCE

Name: Colten Conrad

Date 05/23/2019

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
F18	<30,000 mCi	1,3,4,5,6,7	May 2017- May 2019 5520 hrs	#5860 Cardinal Health 846 Service Rd. East Lansing MI, 48824
N13	<1,000 mCi	1,3,4,5,6,7		
Na22	<170.5 uCi	2		
Cs137	<10 uCi	2		

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.

RADIOISOTOPE HANDLING EXPERIENCE

Name: Colten Conrad

Date 01/10/2018

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
F18	<30,000 mCi	1,3,4,5,6,7	May 2017- January 2018 1280 hrs	#5860 Cardinal Health 846 Service Rd. East Lansing MI, 48824
N13	<1,000 mCi	1,3,4,5,6,7		
Na22	<170.5 uCi	2		
Cs137	<10 uCi	2		

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

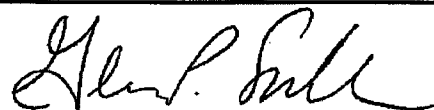
1. Ordering, shipping, receiving radioactive materials and performing related radiation surveys
2. Calibrating, using and performing checks for proper operation of dose calibrators, scintillation detectors, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides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

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	9/11/2017- 10/23/2017	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: 11/14/2017

ORIGIN ID:OSUA (614) 757-5074
 DAN HILL
 CARDINAL HEALTH
 7000 CARDINAL PLACE

DUBLIN, OH 43017
 UNITED STATES US

SHIP DATE: 24MAY19
 ACTWGT: 1.00 LB
 CAD: 104744132/INET4100

BILL SENDER

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

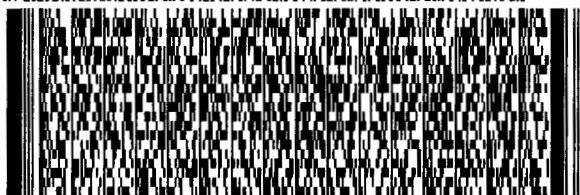
(630) 829-9854

REF: 2250001338

INV:

PO:

DEPT:



565J1D66C23AD

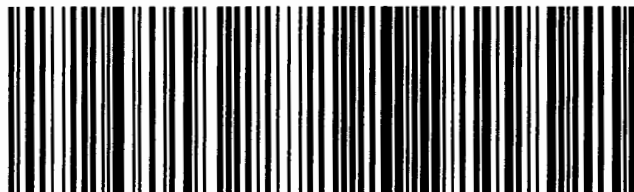
TRK#
 0201

7753 0321 2747

THU - 30 MAY 4:30P
EXPRESS SAVER

SH ENLA

60532
IL-US ORD



RECEIVED MAY 30 2019

After printing this label:

1. Use the 'Print' button on this page to print your label to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

Warning: Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number. Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com. FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of \$100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is \$1,000, e.g., jewelry, precious metals, negotiable instruments and other items listed in our ServiceGuide. Written claims must be filed within strict time limits, see current FedEx Service Guide.