

Cardinal Health
Nuclear Pharmacy Services
7000 Cardinal Place
Dublin, OH 43017
614.757.5000 main
800.234.8701 toll free

cardinalhealth.com



REC RG 1112913 AM0802

November 20, 2013

U.S. NRC - Region I DNMS
Licensing Assistance Team
2100 Renaissance Blvd
King of Prussia, PA 19406

Br. 2

030-38331

Re: Amendment Request for Radioactive Materials License 34-32780-02, Cardinal Health
PET Manufacturing Services, E. 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 Adam Fleshner and Brian Toth as authorized users (AU) cyclotron operators. Documentation of training is attached.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Willie R".

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

/dh

Enclosures: Training Documents

cc: Kurt Hukriede, RSO, Loc. 5869
Sean Waters
License File 5869 (3)

582670

NMSS/RGNI MATERIALS-002

Cardinal Health Advanced Isotopes Training Summary

Brian Toth has completed the following Cardinal Health Advanced Isotopes, LLC training at the West Chester cyclotron site on 12/12/01.

PET Trace Cyclotron Training

1. Health and Safety
2. Cyclotron Theory
3. Controls and Displays
4. Operating Instructions
5. Preventive Maintenance

80 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

50 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

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


20 hours

Component Materials Management

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

10 hours

TOTAL: 240 hours


Willie Regits, PhD
Quality and Regulatory

RADIOISOTOPE HANDLING EXPERIENCE

Name: Brian Toth

Date 4/4/13

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	10,000mCi	1,2,3,4,5,6	08/04/01-04/4/13 >20,000 hours	Cardinal Health PET Manufacturing Services Cincinnati, Louisville and MSU.
N-13	5,000	2,3,4,5,6		
Na-22	199uCi	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: Brian Toth

Date: 12/12/01

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	5000 mCi	1,2,3,4,5,6	08/04/01 – 12/12/01 > 500 hrs	Cardinal Health Pet Manufacturing Services Cincinnati, OH
N-13	300 mCi	2,4,5,6		
Na-22	199 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. Eluting Tc-99m from generator systems, assaying the eluate for Tc-99m and for Mo-99 contaminations, and processing the eluate with reagent kits to prepare Tc-99m labeled radioactive drugs.
8. Production of radioactive materials via bombardment in a nuclear reaction.

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Location of Training	Date(s) of Attendance	Course Title	Total Clock Hours of Course	BREAKDOWN OF COURSE CONTENT IN CLOCK HOURS				
				Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radioactivity	Radiation Biology	Radiation Chemistry
SYNCOR INTL CORPORATION, WOODLAND HILLS, CA	1/14/2002 to 2/1/2002 AND 2/25/2002 to 3/14/2002	SYNCOR AUTHORIZED NUCLEAR PHARMACIST / AUTHORIZED USER TRAINING PROGRAM	227	92	50	24	25	36
*Note: Show a breakdown of hours by instruction, dates, and subjects. List each hour only once (i.e., under the most applicable subject category).			TOTAL HOURS	92	50	24	25	36

DIPLÓMA OF ACHIEVEMENT

Presented to
Brian Toth

IN RECOGNITION
OF HAVING COMPLETED
THE PRESCRIBED COURSE
OF STUDY FOR

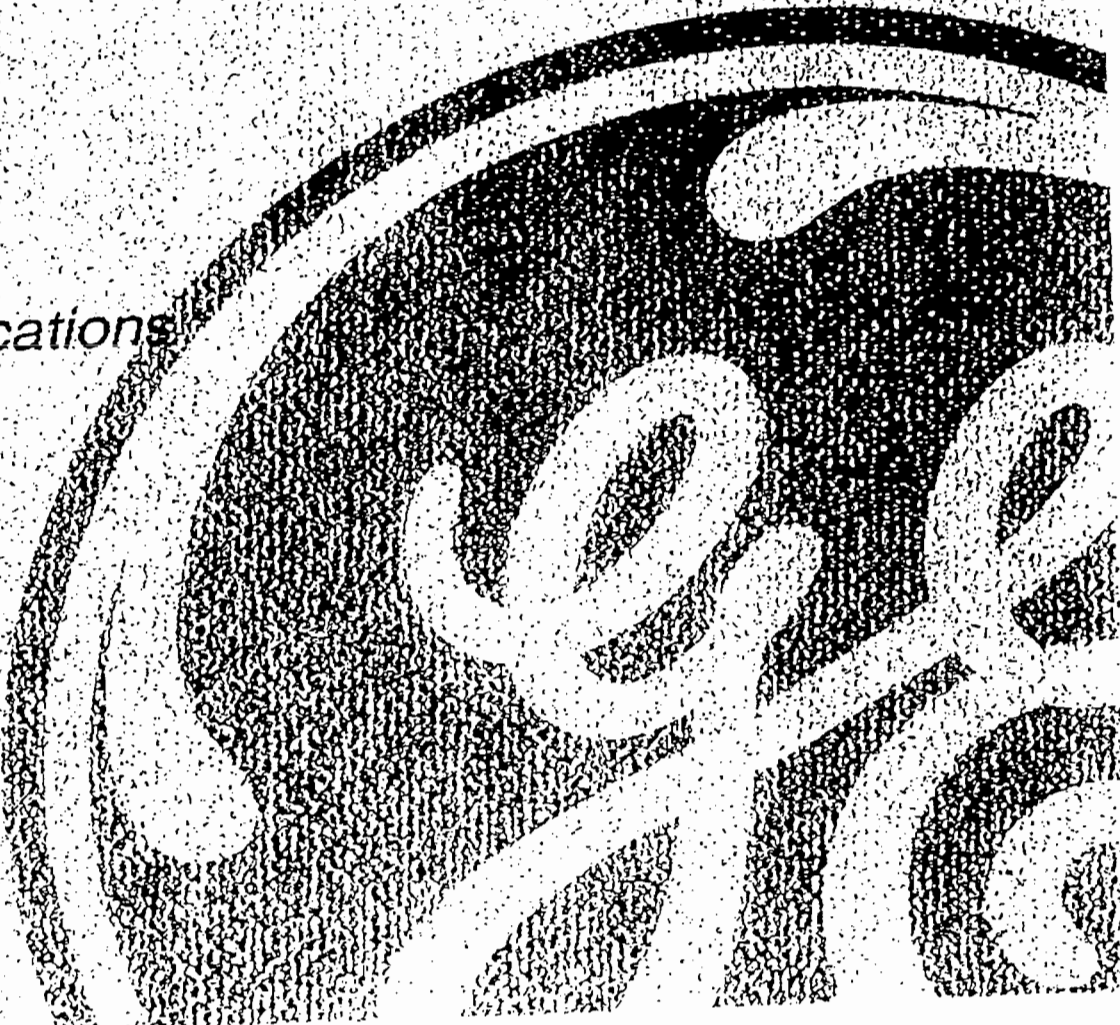
Petrace Cyclotron Applications
August 31st, 2001

Stephen Downey

GE MEDICAL SYSTEMS TRAINING



GE Medical Systems



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

July 24, 2012

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 Adam Fleshner 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 dark ink, appearing to read "Willie Regits", written over a horizontal line.

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

Cardinal Health Manufacturing Training Summary

Adam Fleshner has completed the following Cardinal Health Manufacturing training at the St. Louis, Missouri cyclotron site on October 9, 2001. This training was performed on a G.E. PETtrace cyclotron by an authorized user and cyclotron operator who received manufacturer or equivalent training on the G.E. 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: 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

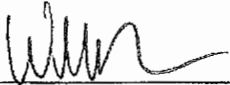
1. Receiving
2. Tracking
3. Batch Record Compliance
4. Record Retention
5. Inventory

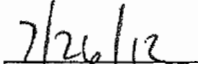
15 hours

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.
Director, Health Physics
Quality and Regulatory


Date

RADIOISOTOPE HANDLING EXPERIENCE

Name: Adam Fleshner

Date 11/20/2013

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) 5/9/95-11/20/13	WHERE EXPERIENCE GAINED
F-18	15Ci	1,2,3,4,5,6	Total Hours 37000 hours	Syncor Internation Corp. St. Louis, MO
N-13	8Ci	1,2,3,4,5,6		
Mo-99	15Ci	1,5,7		Syncor Advanced Isotopes St. Louis, MO.
Tc-99m	10Ci	1,3,4,5,6,7		
I-131	300mCi	1,3,4,5,6		Cardinal Health St. Louis, MO
Xe-133	1.0Ci	1,3,4,5,6		Cardinal Health Tampa, FL
I-123	4mCi	1,3,4,5		
Ga-67	80mCi	1,3,4,5		
Tl-201	150mCi	1,3,4,5		
Co-57	5mCi	2		
Tl-201	260uCi	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.

FIGURE 9-2

2-27-02

FIGURE 2. DOCUMENTING RADIOISOTOPE HANDLING EXPERIENCE

Name: Adam Fleisher

EXPERIENCE WITH RADIOACTIVE MATERIAL (Actual Use of Radioisotopes Under the Supervision of an Authorized User)

ISOTOPE	MAXIMUM AMOUNT USED AT ONE TIME	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE (actual clock hours)	TYPE OF USE 1,2,3,4,5,6 (see key below)
F-18	6 Ci	Syntron Advanced Isotopes 10718 Trenton Ave. St. Louis, Mo. 63132	7-8-01-present 1360 hours	2,3,4,5,

Key for "Type of Use"

The number or numbers entered under "Type of Use" correspond to experience in the following activities:

1. Ordering, receiving, and unpacking radioactive materials safely, including performance of related radiation surveys.
2. Calibration of dose calibrator, scintillation detectors, and survey meters.
3. Calculation, dispensing, and calibration of patient doses, including proper use of radiation shields.
4. Appropriate internal control procedures to prevent mislabeling errors.
5. Emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys and wipe tests.
6. Elution of Technetium-99m generator systems, assay and testing of the elute for Molybdenum-99 contamination, and processing the elute with reagent kits to prepare Technetium-99m labeled radiopharmaceuticals.

RADIOISOTOPE HANDLING EXPERIENCE

Name: Adam Fleshtner

Date: 5-12-00

Document the actual use/handling of radioactive material under the supervision of an Authorized Nuclear Pharmacist.

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
Mo-99	15 Ci	1,5,7	5/9/95 - 5/1/00 > 2000 hours total hours: 10400 hrs	Syncor International Corporation St. Louis, Mo. 63114
Tc-99m	10 Ci	1,3,4,5,6,7		
I-131	300 mCi	1,3,4,5,6		
Xe-133	1.0 Ci	1,3,4,5,6		
I-123	4 mCi	1,3,4,5		
Ga-67	80 mCi	1,3,4,5		
Tl-201	150 mCi	1,3,4,5		
Co-57	5 mCi	2		
Cs-137	250 µCi	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 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. Eluting Tc-99m from generator systems, assaying the eluate for Tc-99m and for Mo-99 contaminations, and processing the eluate with reagent kits to prepare Tc-99m labeled radioactive drugs

TRAINING RECEIVED IN BASIC RADIOSOTOPE HANDLING TECHNIQUES

Name Adam Fleshner

Location of Training	Date(s) of Accordance	Course Title	Clock Hours of Course	Physics & Instrumentation	Protection	Pertaining to Radioactivity	Biology	Chemistry
Syncor Int'l Corp. Woodland Hills, CA.	07-26-1999 to 08-13-1999 and 09-13-1999 to 09-30-1999	Syncor Authorized User Training Program	227	92	50	24	25	36
*Note: Show a breakdown of hours by institution, dates, and subjects. List each hour only once (i.e., under the most applicable subject category)			227	92	50	24	25	36
TOTAL HOURS								

SYNOR INTERNATIONAL CORPORATION

certifies that

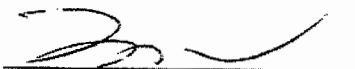
Adam Fleshner

successfully completed the

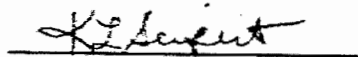
Authorized Users Training Program

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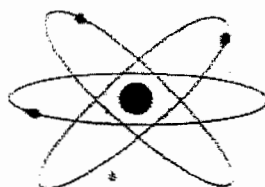
December 16, 1999



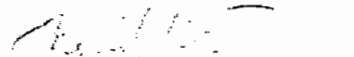
Chairman of the Board



Director Regulatory



President and Chief Executive Officer



Program Manager Educational Resources

This is to acknowledge the receipt of your letter application dated

11/20/2013, 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** 582670.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.