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

cardinalhealth.com

CardinalHealth

October 18, 2013

Br. 2

Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. NRC Region I DNMS
2100 Renaissance Road
King of Prussia, PA 19406

030-38331

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 add the following Cyclotron Operators / Authorized Users (AU): Eric Dumas and Jessica Giacchetta. Documentation of Manufacturing AU training is enclosed.

In addition, please remove the following AU's: Wally Cotto-Bellido, Jacob Killian and Andy Rodriguez.

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

/dh

Enclosures: AU Training Documents

cc: Kurt Hukriede, MRSO (loc. 5869)
Arshad Mehmood
James R. Matthews
John Taylor Vernon
License File 5869 (3)

582474

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

www.cardinal.com

CardinalHealth

PET Manufacturing Services Training Authorization

October 14, 2013

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 **Jessica Giacchetta** 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.
Corporate Radiation Safety Officer
Director, Health Physics
Nuclear Pharmacy Services

Cardinal Health Manufacturing Training Summary

Jessica Giacchetta has completed the following Cardinal Health Manufacturing training at the East Hartford, CT cyclotron site on September 26, 2013. 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. 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

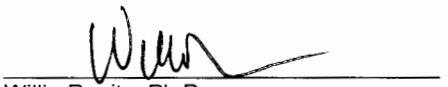
1. Receiving
2. Tracking
3. Batch Record Compliance
4. Record Retention
5. Inventory

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

11/4/13
Date

FIGURE 9-7

RADIOISOTOPE HANDLING EXPERIENCE

T.E.A 26Sep13

Name: Jessica B Giacchetta Date: 26Sep13

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

ISOTOPE	MAXIMUM ACTIVITY HANDLED	USE See key below: 1,2,3,4,5,6,7,8	EXPERIENCE Actual clock hours (Include date range of experience)	WHERE EXPERIENCE GAINED
Co-57	0.0100 mci	2	4/15/13 - present >300hr	CAH
F-18	10,000 mci	3, 7	4/15/13 - present >300hr	CAH
N-13	500 mci	2	4/15/13 - present >300hr	CAH
Na-22	0.1022 mci	2	4/15/13 - present >300hr	CAH

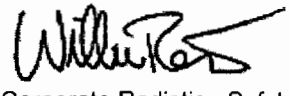
Key for "Use": the number, or numbers, entered under "Use" should correspond to the handling experience for each isotope.

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

Name: Jessica Giacchetta

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	6/17/2013 – 8/16/2013	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: 8/23/2013

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PET Manufacturing Services Training Authorization

October 14, 2013

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G.E. PETtrace Cyclotron Training (30-60-90 Day Training Documentation)

Basic Radioisotope Handling Techniques Worksheet

Didactic Training Certificate

Therefore, I authorize **Eric Dumas** 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.
Corporate Radiation Safety Officer
Director, Health Physics
Nuclear Pharmacy Services

Cardinal Health Manufacturing Training Summary

Eric Dumas has completed the following Cardinal Health Manufacturing training at the East Hartford, CT cyclotron site on October 3, 2013. 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
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7. Cyclotron Shielding
8. Cyclotron Documentation

100 hours

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7. Membrane Filter Integrity Test
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9. Sterility Testing

80 hours

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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

11/4/13
Date

FIGURE 9-7

RADIOISOTOPE HANDLING EXPERIENCE

Name: Eric Dumas Date: 03 Oct 13

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

ISOTOPE	MAXIMUM ACTIVITY HANDLED	USE See key below: 1,2,3,4,5,6,7,8	EXPERIENCE Actual clock hours (Include date range of experience)	WHERE EXPERIENCE GAINED
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Key for "Use": the number, or numbers, entered under "Use" should correspond to the handling experience for each isotope.

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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
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8. Production of radioactive materials via bombardment in a nuclear reaction.

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: Eric Dumas

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	6/17/2013 – 8/5/2013	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: 8/23/2013

This is to acknowledge the receipt of your (letter)/application dated

10/18/2013, 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

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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** 582474.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader