



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

cardinalhealth.com

February 20, 2013

Kevin Null, Health Physicist
United States Nuclear Regulatory Commission
Region III – Division of Nuclear Materials Safety
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

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

Licensing / Mr. Null:

Cardinal Health 414, LLC (Nuclear Pharmacy Services and PET Manufacturing Services, hereafter Cardinal Health) requests an amendment for the above referenced license to add Jacquelyn Lamb as a cyclotron operator / authorized user. Documentation of training is attached. Also, please remove Michael Rosman who is no longer employed and correct the spelling of the name in condition 10 for John Taylor Vernon. Please note that Tuan Le is listed twice in this condition.

In addition, we request the addition of Hydrogen-3 (tritium) with a maximum quantity of 10 millicuries as an activation product incidental to production in the target water ($<10 \mu\text{Ci} / \text{mL}$), which is routinely sent for reprocessing off site.

We have attached a copy of our request dated November 9, 2012 to remove condition 20 with a copy of the letter dated November 5, 2012 from Michigan State University (MSU) regarding their responsibility for decommissioning according to our management agreement. This will confirm that we have satisfied the requirement to show that Cardinal Health is not directly responsible for the cyclotron owner (MSU) Decommissioning Financial Assurance.

If you have any questions regarding these request(s), please contact Dan Hill at 614.757.5074.

Sincerely,

A handwritten signature in black ink, appearing to read "Willie Regits", with a long horizontal stroke extending to the right.

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

/dh

Enclosure(s): Attachment A - Training Documents
Attachment B - Letter dated November 9, 2012 with attachment 11/5/2012

FEB 25 2013

ATTACHMENT A

Authorized User Training Documents



PET Manufacturing Services Training Authorization

August 11, 2010

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 **Jacquelyn Lamb** 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 Regits", written over a horizontal line.

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

Cardinal Health Manufacturing Training Summary

Jacquelyn Lamb has completed the following Cardinal Health Manufacturing training at the Denver CO cyclotron site on June 5, 2010. 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: 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

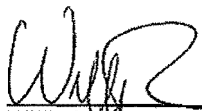
1. Receiving
2. Tracking
3. Batch Record Compliance
4. Record Retention
5. Inventory

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

8/12/10
Date

RADIOISOTOPE HANDLING EXPERIENCE

Name: Jacquelyn Lamb

Date: 8/10/10

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	15Ci	1,2,3,4,5,6,7	2/3/10-present 1040 hours	Cardinal Health Denver
N13	1Ci	2,5,6	2/3/10-present 1040 hours	Cardinal Health Denver
Na22	350uCi	2,5,6,	2/3/10-present 1040 hours	Cardinal Health Denver

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

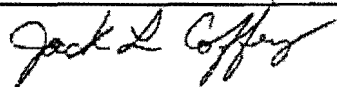
1. Ordering, shipping, receiving radioactive materials and performing related radiation surveys
2. Calibrating, using and performing checks for proper operation of dose calibrators, scintillation detectors, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides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

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	4/5/10 thru 5/17/10	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:

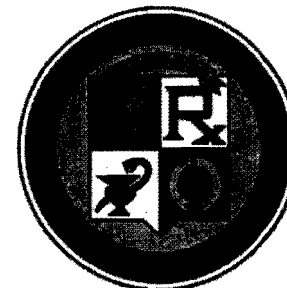


Senior Vice President, Quality and Regulatory

Date: 5/17/10



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



By this certificate warrants that

Jacquelyn Lamb

has satisfactorily fulfilled all requirements
and completed the prescribed course

Authorized User Education Program

May 17, 2010

A handwritten signature in black ink, reading "Jack L. Coffey", written over a horizontal line.

Senior Vice President
Quality and Regulatory
Nuclear Pharmacy Services
Cardinal Health



A handwritten signature in black ink, reading "George L. Smith", written over a horizontal line.

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

Training in Partnership

TiP™

GE Medical Systems certifies

Jacquelyn S. Lamb

has satisfactorily completed

GE PETtrace Cyclotron Operation and Applications

November 12th 2010

Date

Stephen BMJ Downey

GE Representative



GE Medical Systems
Training in Partnership

ATTACHMENT B

**Request for Removal of Condition 20
dated 11/9/2012**

**MSU Statement of Intent to Provide DFA
dated 11/5/2012**

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



CardinalHealth

COPY

cardinalhealth.com

November 9, 2012

Chief, Nuclear Materials Licensing Branch
U.S. NRC Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

ATTN: Kevin Null, Health Physicist

RE: Monthly DFA Report for NRC license number 34-32840-01, Docket Number 030-38511, Cardinal Health PET Manufacturing Services, East Lansing, MI.

Licensing / Mr. Null:

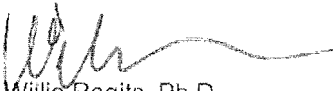
Cardinal Health 414, LLC (PET Manufacturing Services and Nuclear Pharmacy Services, hereafter Cardinal Health) submits this monthly report with reference to the letter dated October 11, 2012 and the requirements of the above referenced U.S. Nuclear Regulatory Commission (NRC) license condition 20.

Cardinal Health previously provided a copy of our Amended and Restated Operating License Agreement (agreement) with Michigan State University (MSU), East Lansing, Michigan. MSU previously operated the cyclotron under the provisions of the university broad scope NRC radioactive material license number 21-00021-29. The cyclotron operations are now authorized by the above referenced license effective October 11, 2012.

In accordance with the Memo of Understanding and the agreement dated August 1, 2011 between Cardinal Health and MSU, MSU is to provide DFA. Please see the attached copy of the letter dated November 5, 2012 to notify NRC that MSU is in compliance with 10 CFR 30.35 requirements. Therefore, Cardinal Health requests that condition 20 be removed from the above referenced license.

If you have any questions or concerns regarding this response, please contact my office at 614.757.4120.

Sincerely,



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

/dh

Enclosure: MSU letter dated November 5, 2012

cc: Jason Foster, RSO, Loc. 5860
License File 5860 (2) FA
Thomas Ward

COPY

**MICHIGAN STATE
UNIVERSITY**

November 5, 2012

Kevin Null, Chief
Nuclear Materials Licensing Branch
U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Rd.
Lisle, IL 60532-4352

Dear Mr. Null:

This letter is a Statement of Intent for Michigan State University to provide Financial Assurance of the ability to fund decommissioning of U.S. Nuclear Regulatory Commission License Number 21-00021-29 as specified in 10 CFR Part 30 for the facilities operated by Cardinal Health PET Manufacturing Services, East Lansing, MI.

In compliance with 10 CFR Part 30, Section 30.35, we estimate the decommissioning costs to be at or below \$500,000. Funds for decommissioning will be obtained when necessary.

The facilities for which this Statement of Intent provides financial assurance are the activities with licensed materials conducted on the property specified in License No. 21-00021-29 for the PET facilities operated by Cardinal Health, NRC license number 34-32840-01.

Copies will be maintained with copies of the NRC license at Michigan State University and with copies of the NRC license at Cardinal Health PET Manufacturing Services.

Sincerely,



Fred Poston
Vice President for Finance and Operations

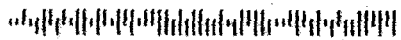
Cc: Jean Chisnell, Radiation Safety Officer, MSU
Karen Frederici, Chairperson, Radiation Safety Committee, MSU
J.R. Haywood, Assistant Vice President for Regulatory Affairs
Cardinal Health PET Manufacturing Services



**Office of the
Vice President
for Finance and
Operations**

Michigan State University
Administration Building
426 Auditorium Road
Room 412
East Lansing, MI 48824

517-355-5014
Fax: 517-353-6772
vpfo.msu.edu



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US Nuclear Regulatory Commission
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