

PETNET Solutions

October 18, 2017

Bryan Parker
Materials Licensing Branch
U.S. NRC Region III
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532-4352

**Re: Amendment Request to NRC Radioactive Material License
PETNET Indianapolis, IN License #s 41-32720-02MD and 41-32720-01**

Dear Mr. Parker,

The purpose of this letter is to request an amendment to the above-referenced licenses as follows:

1. Add Heather Fry as an Authorized Nuclear Pharmacist under condition 11B of License Number 41-32720-02MD. Documentation of her training and experience is included in Attachment A.
2. Add Heather Fry and Mickey Latham as Authorized Users for Non-Medical Use under condition 12 of License Number 41-32720-01. Documentation of their training and experience is included in Attachment B.

PETNET believes that sufficient information has been provided for the Agency to grant this request. If you have any questions, please contact Cami Still at 317-674-5275, or cami.still@siemens-healthineers.com.

Sincerely,



Roger Moroney, CHP
Sr. Manager Radiation Protection/Corporate RSO
PETNET Solutions, Inc.
Voice: 865-218-2595
Fax: 865-218-3018
william.moroney@siemens-healthineers.com

cc: Joel Readinger, RPh, RSO PETNET Indianapolis

ATTACHMENT A

ANP Documentation for Heather Fry

**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND
EXPERIENCE AND PRECEPTOR ATTESTATION**
[10 CFR 35.55]APPROVED BY OMB: NO. 3150-0120
EXPIRES: 06/30/2019

Name of Proposed Authorized Nuclear Pharmacist

Heather Fry

State or Territory Where Licensed

Indiana

PART I – TRAINING AND EXPERIENCE
(Select one of the two methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the nuclear pharmacy uses.

☐ **1. Board Certification**

- a. Provide a copy of the board certification.
- b. Skip to and complete Part II Preceptor Attestation.

☒ **2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist**

- a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	Purdue University School of Pharmacy Division of Nuclear Pharmacy West Lafayette, IN	86.5	01/2012-05/2015
Radiation protection	Purdue University School of Pharmacy Division of Nuclear Pharmacy West Lafayette, IN	45.5	01/2012-05/2015
Mathematics pertaining to the use and measurement of radioactivity	Purdue University School of Pharmacy Division of Nuclear Pharmacy West Lafayette, IN	23.5	01/2012-05/2015
Chemistry of byproduct material for medical use	Purdue University School of Pharmacy Division of Nuclear Pharmacy West Lafayette, IN	36	01/2012-05/2015
Radiation biology	Purdue University School of Pharmacy Division of Nuclear Pharmacy West Lafayette, IN	20	01/2012-05/2015

Total Hours of Training: 211.5

AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION (continued)2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist (continued)

b. Supervised Practical Experience in a Nuclear Pharmacy.

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Shipping, receiving, and performing related radiation surveys	PETNET Pharmaceuticals 1345 W. 16th St. Rm001 Indianapolis, IN 46202	100	08/29/16-11/23/16
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides	PETNET Pharmaceuticals 1345 W. 16th St. Rm001 Indianapolis, IN 46202	100	08/29/16-11/23/16
Calculating, assaying, and safely preparing dosages for patients or human research subjects	PETNET Pharmaceuticals 1345 W. 16th St. Rm001 Indianapolis, IN 46202	100	08/29/16-11/23/16
Using administrative controls to avoid medical events in administration of byproduct material	PETNET Pharmaceuticals 1345 W. 16th St. Rm001 Indianapolis, IN 46202	100	08/29/16-11/23/16
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures	PETNET Pharmaceuticals 1345 W. 16th St. Rm001 Indianapolis, IN 46202	100	08/29/16-11/23/16
Total Hours of Experience: 500			
Supervising Individual Joel Readinger			

c. Go to and complete Part II Preceptor Attestation.

**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION (continued)**

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section

Check one of the following:

Board Certification

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized Nuclear Pharmacist

10 CFR 35.55(a)(1), (a)(2), and (a)(3) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

OR

Structured Educational Program

☒ I attest that Heather Fry _____ has satisfactorily completed a 700-hour structured
Name of Proposed Authorized Nuclear Pharmacist

educational program consisting of both 200 hours of classroom and laboratory training, and practical experience in nuclear pharmacy, as required by 10 CFR 35.55(b)(1) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Second Section

Complete the following for preceptor attestation and signature:

I am an Authorized Nuclear Pharmacist for PETNET Solutions Indianapolis

Nuclear Pharmacy or Medical Facility

IN 26019363A

License/Permit Number

Name of Preceptor	Signature	Telephone Number	Date
Joel Readinger		(317) 278-9600	10/11/2017

PURDUE

UNIVERSITY

COLLEGE OF PHARMACY

August 23, 2017

RE: Heather Fry

To Whom It May Concern:

I would like to offer this letter to verify the nuclear pharmacy didactic training program completed by Heather Fry while a student at Purdue University. During Heather's enrollment in the Purdue University College of Pharmacy, she elected to pursue the nuclear pharmacy elective series, in which she was able to complete approximately 224 hours of training in the areas of radiation physics and instrumentation, radiation protection, math pertaining to radioactivity, radiation biology, radiopharmaceutical chemistry and the clinical applications of radiopharmaceuticals. The course breakdowns by hour are shown in the document entitled "Summary of Course Content in Basic Radioisotope Handling Techniques and Nuclear Pharmacy" which follows this introductory letter. In this document, I have identified the various courses as well as the semester and year that they were completed. In addition, Heather's academic transcript (which she should provide with her request for ANP status) can be referenced as proof of enrollment and of successful completion of the courses. One item to note: the hourly breakdown included in this form includes only the hours that were completed as part of a nuclear pharmacy course for which the student officially registered / paid tuition. Students such as Heather also had opportunities to participate in summer nuclear pharmacy internship activities, as well as coordinated nuclear pharmacy academic clerkship opportunities which are generically listed on the transcript under the Purdue University clerkship course registration number (PIRM 88000, Adv Pharm Practice Experience). Both of these additional offerings include several hours of didactic (as well as experiential) content. Since students are not required to complete these additional activities, these hours are not formally documented on the clock hour breakdown provided.

This document should be sufficient to prove Heather's successful didactic training which can be used as part of her request for Authorized Nuclear Pharmacist status. If you have any additional questions, please do not hesitate to contact me at the number / email listed below.

Best regards,

Kara Duncan Weatherman PharmD, BCNP

Kara Duncan Weatherman, PharmD, BCNP, FAPhA
Clinical Associate Professor of Pharmacy Practice
Director, Nuclear Pharmacy Programs
Purdue University College of Pharmacy
575 Stadium Mall Drive
West Lafayette, IN 47907-2051
Office: 765-496-1815
E-mail: kdwman@purdue.edu



Nuclear Pharmacy Programs, Department of Pharmacy Practice

R. Heise Pharmacy Building, Room 502 • 575 Stadium Mall Drive • West Lafayette, IN 47907-2091
(765) 496-1815 • Fax (765) 496-1806 • nuclearpharmacy@purdue.edu

Revised June, 2016

**SUMMARY OF COURSE CONTENT IN BASIC RADIOISOTOPE HANDLING TECHNIQUES AND NUCLEAR PHARMACY
PURDUE UNIVERSITY COLLEGE OF PHARMACY, NUCLEAR PHARMACY PROGRAMS, WEST LAFAYETTE, INDIANA**

Student: HEATHER FRY

Location of Training			Breakdown of Course Content in Clock Hours							Clinical Applications Of Radiopharm
Location of Training	Semester Offered	Course Title	Total Clock Hours	Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radioactivity	Radiation Biology	Radiopharm. Chemistry	Clinical Applications Of Radiopharm	
Purdue University	Spring Semester 2012-13	PHRM 49000: Intro to Nuclear Pharmacy	32	18.5	7	1.5	4.5	0.5	0	
Purdue University	Fall Semester 2013-14	PHRM 49000: Basics Nuclear Pharmacy Prac	54	24	12	6	3	7	0	
Purdue University	Fall Semester 2013-14	PHRM 49000: Nuc Pharm Prac Daily Operations	42	8	14	2	12	2	4	
Purdue University	Fall Semester 2014-15	NUPH 49400: Clinical Asp of NP Practice	36	17.5	0	1	0	13	4.5	
Purdue University	Spring Semester 2014-15	NUPH 49500: Applied Nuclear Pharmacy	60	18.5	12.5	11	0.5	13.5	4	
Total Possible Hours			224	86.5	45.5	23.5	20	36	12.5	

Reported clock hours represent didactic instruction (lecture and/or laboratory course). Student transcript serves as proof of registration for the course, as well as proof of satisfactory course completion. Students may have also been involved in summer internship experiences and/or clinical rotations which provided additional didactic experiences that are not included in this total.

Signature: Kara D. Weatherman, PharmD, BCNP, FAPhA
Clinical Associate Professor
Director, Nuclear Pharmacy Programs
Purdue University College of Pharmacy
West Lafayette, IN
766-496-1815
kowman@purdue.edu

Kara D. Weatherman, PharmD, BCNP, FAPhA



STATE OF INDIANA

Eric J. Holcomb

Indiana Professional Licensing Agency
402 W. Washington St. Room W072
Indianapolis, IN 46204
Phone: (317) 232-2960
Fax: (317) 233-4236

Official Proof of Licensure Digitally Certified Record

Personal Information

Name: Heather Michelle Fry
Address: 1017 Nottingham Lane
Kokomo, IN 48902

Date of Birth: 06/13/1991

License Information

Number Issued: 26026951A
License Type: Pharmacist
Status: Active
Issue date: 02/13/2017
Expiration Date: 06/30/2018
Obtained By: Examination

This licensee has met ALL requirements for licensure in the State of Indiana - including successfully passing all required exams.

For disciplinary action information, please visit our License Search & Verify service at www.in.gov/pla/3119.htm. Disciplinary action will either show under Previous Action or Violations. For additional information including questions regarding Disciplinary Action, contact the appropriate Board or Commission at <http://www.in.gov/pla/boards.htm>.

Digitally Certified on: Wed Oct 04 04:53:19 AM EST 2017

Training Certificate

This certificate is awarded to:

Heather Fry

*In recognition of successful completion of the Transportation of Radioactive Materials Class,
on regulations of the United States Department of Transportation, concerning the legal
transportation of materials designated as hazardous and for achieving a passing grade.*

D.O.T./Hazardous Materials Training

October 11-20, 2016

*This training is designed to satisfy the General Awareness, Function-Specific and Safety Training Requirement of 49 CFR 172.704(A).
Training was conducted by Siemens Medical Solutions Molecular Imaging Radiological Compliance Department
for PETNET Pharmaceuticals, Inc. in Knoxville, Tennessee.*

SIEMENS

PETNET Solutions

April Chance, Sr. Manager EHS

Instructor Name and Title

April Chance
Instructor Signature

October 20, 2016

Date Issued



Training Certificate

This certificate is awarded to:

Heather Fry

**Radiation Protection Training
for Nuclear Pharmacy Employees**

October 11-20, 2016

*This training is designed to satisfy the General Awareness, Function-Specific and Safety Training Requirement of 49 CFR 172.704(A).
Training was conducted by Siemens Medical Solutions Molecular Imaging Radiological Compliance Department for
PETNET Pharmaceuticals, Inc. in Knoxville, Tennessee.*

SIEMENS

PETNET Solutions

April Chance, Sr. Manager EHS

Instructor Name and Title

April Chance

Instructor Signature

October 20, 2016

Date Issued



ATTACHMENT B

Cyclotron Operator Documentation for Heather Fry and
Mickey Latham

Training Certificate

This certificate is awarded to:

Heather Fry

*In recognition of successful completion of the Transportation of Radioactive Materials Class,
on regulations of the United States Department of Transportation, concerning the legal
transportation of materials designated as hazardous and for achieving a passing grade.*

D.O.T./Hazardous Materials Training

October 11-20, 2016

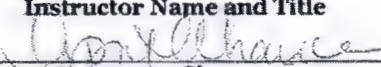
*This training is designed to satisfy the General Awareness, Function-Specific and Safety Training Requirement of 49 CFR 172.704(A).
Training was conducted by Siemens Medical Solutions Molecular Imaging Radiological Compliance Department
for PETNET Pharmaceuticals, Inc. in Knoxville, Tennessee.*

SIEMENS

PETNET Solutions

April Chance, Sr. Manager EHS

Instructor Name and Title


Instructor Signature

October 20, 2016

Date Issued



Training Certificate

This certificate is awarded to:

Heather Fry

**Radiation Protection Training
for Nuclear Pharmacy Employees**

October 11-20, 2016

*This training is designed to satisfy the General Awareness, Function-Specific and Safety Training Requirement of 49 CFR 172.704(A).
Training was conducted by Siemens Medical Solutions Molecular Imaging Radiological Compliance Department for
PETNET Pharmaceuticals, Inc. in Knoxville, Tennessee.*

SIEMENS
PETNET Solutions

April Chance, Sr. Manager EHS

Instructor Name and Title

April Chance

Instructor Signature

October 20, 2016

Date Issued



SIEMENS

www.siemens.com/healthcare

CERTIFICATE

Ms. Heather Fry

has attended the course

**Operation of the Radioisotope Delivery System 'Eclipse'
MI8ECLIPS**

from May 23, 2017 to May 25, 2017
at Knoxville, TN


with the following course contents:

- Principles of operation
- Safety for accelerator operations
- Control system
- Simulator operation
- Automatic operations
- Targetry operations
- Power failure recovery
- Vacuum system operation


Dr. Patrick Amertellio
Global Training Center Head

Date: 25/05/2017

Identification Number: AAGILIF - KNO


Instructor

Training Certificate

This certificate is awarded to:



Mickey Latham

*In recognition of successful completion of the Transportation of Radioactive Materials Class,
on regulations of the United States Department of Transportation, concerning the legal
transportation of materials designated as hazardous and for achieving a passing grade.*

D.O.T./Hazardous Materials Training

October 6 - 15, 2015

*This training is designed to satisfy the General Awareness, Function-Specific and Safety Training Requirement of 49 CFR 172.704(A).
Training was conducted by Siemens Medical Solutions Molecular Imaging Radiological Compliance Department
for PETNET Pharmaceuticals, Inc. in Knoxville, Tennessee.*

SIEMENS

PETNET Solutions

April Chance, Sr. Manager EHS

Instructor Name and Title

April Chance

Instructor Signature

October 15, 2015

Date Issued



Training Certificate

This certificate is awarded to:

Mickey Latham

 COPY

Radiation Protection Training for Nuclear Pharmacy Employees

October 6 - 15, 2015

*This training is designed to satisfy the General Awareness, Function-Specific and Safety Training Requirement of 49 CFR 172.704(A).
Training was conducted by Siemens Medical Solutions Molecular Imaging Radiological Compliance Department for
PETNET Pharmaceuticals, Inc. in Knoxville, Tennessee.*

SIEMENS
PETNET Solutions

April Chance, Sr. Manager EHS

Instructor Name and Title


Instructor Signature

October 15, 2015

Date Issued



SIEMENS

www.siemens.com/healthcare

CERTIFICATE

Mr. Mickey Latham

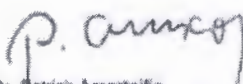
has attended the course

**Eclipse Systems Part Two
MI3ECLIPS**

from May 2, 2016 to May 13, 2016
at Knoxville, TN


with the following course contents:

- Review of Safety
- Vacuum system fault recovery
- Ion Source diagnostics and troubleshooting
- System calibrations
- RF Amplifier design and rebuild
- RF amp tuning and troubleshooting
- RF control system diagnostics
- Targetry troubleshooting
- Control system and interlocks troubleshooting
- Operating Software Upgrade and Maintenance


Dr. Patrick Amarteifio
Global Training Center Head

Date: 13.05.2016

Identification Number: **AAGDCRE**


Instructor:

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ORIGIN ID: RKWA
APRIL CHANCE
810 INNOVATION DRIVE
KNOXVILLE, TN 37932
UNITED STATES US

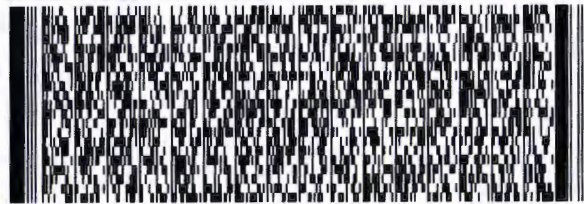
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CAD: 105091792/INET3920

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TO **BRYAN PARKER**
US NUCLEAR REGULATORY COMM. RIII
2443 WARRENVILLE ROAD
SUITE 210
LISLE IL 60532

(630) 829-9500
INV.
PO:

REF:
DEPT:



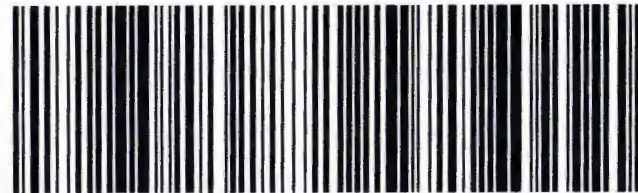
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