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



31.)

cardinalhealth.com

August 28, 2013

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

03038569 ND RLJ

Re:

Amendment Request for Radioactive Materials License 34-31473-02, Cardinal Health PR 120, Inc., Guaynabo, Puerto Rico.

Licensing:

Cardinal Health 414, LLC and Cardinal Health P.R. 120, Inc. (FKA Borschow Hospital & Medical Supplies, Inc.), hereafter Cardinal Health, requests an amendment for the above referenced radioactive materials license to add Jeremy A. Erxleben, R.Ph. as an Authorized Nuclear Pharmacist. Documentation of training is enclosed.

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

Encl: Training Documents

Original + 1 copy

CC:

Alexis Gomez, PRSO, Loc. 7650

Wayne Boudreaux License File 7650 (3)

NMSS/RGN1 MATERIALS-002

Cardinal Health Quality and Regulatory Department 7000 Cardinal Place Dublin, OH 43017 tel 614.757.6000

vovw.cardinal.com



DOCUMENTATION OF AUTHORIZED NUCLEAR PHARMACIST TRAINING

The training outline in the Authorized Nuclear Pharmacist Guideline has been completed. The Pharmacist is qualified to assume the duties and responsibilities outlined in the guideline.

I hereby certify that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

Pharmacist Name (Print) Jeverny A.	Erxleben
Pharmacist Signature: Seremy a &	mallben Date: 8/28/13
Preceptor Name (Print) Shirley J.	DANNER
Preceptor Signature: Slundy 1, A	Jenner Date: 08/28/13
	,

Send this document with a completed **Radioisotope Handling Experience Form** and a photocopy of the **pharmacist's license** to the Quality and Regulatory Department.

RADIOISOTOPE HANDLING EXPERIENCE

Name: Jeremy A. Erxleben Date: 8/28/13

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

Nuclear Phar	maci	ol			
ISOTO	ÞΕ	SINGLE HIGHEST mCl 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
Co-57	,	5,3 m Ci	1,2	5/9 - 5/10 96h	Cardinal Health
Cs-13	7	194,9 MCi	1,2	,	San Juan
F-18				6/3-6/28	P.R
Ga-67		asmci	1,3,4,5	7/1 - 7/3, 7/5	Loc # 7650
I-123				718-812	
1-131		200 mCi	1,3,4,5,6	192hrs	
ln-111				8/5 - 8/23	
Mo-99)	19 Ci	1.3,4,5,7	8/19-8/23	
Tc-99r	n	15 Ci	1, 2,3,4,5,6,7	8/26-8/27 88hrs	
TI-201	**************************************	20 mCi	1,3,4,5		
Xe-13	3			Total 536 hrs.	
Y-90		7 - 7 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -			

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
- 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
- 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
- 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

Form Updated 08/11

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES*

Trainee: Jeremy Erxleben Date issued: August 21, 2013

	7	T		Brea	kdown of Cou	rse Content in	Clock Hours	
Location of Training	Date(s) of Attendance	Nuclear Pharmacy Certificate Program	Total Clock Hours of Course	Radiation Physics & Instru- mentation	Radiation Protection	Math Pertaining to Radio- activity	Radiation Biology	Radio- pharma- ceutical Chemistry
Purdue University	June 2013 - August 2013	DVD- Workbook	150	51	33	13	21	32
	August 2013	On-Site	65	34	13	10	o	8
Total Hours Received Hourly breakdown by topic		215		Salakan da kananan da				
			85	46	23	21	40	

^{*} This form is representative of that which is used to apply for an NRC license amendment for an authorized user.

Director of Nuclear Pharmacy Training Programs:

Kara Duncan Weatherman, PharmD, BCNP, FAPhA Clinical Assistant Professor of Pharmacy Practice

Purdue University

Nuclear Pharmacy Programs

ESTADO LIBRE ASOCIADO DE PUERTO RICO Commonwealth of Puerto Rico.

DEPARTAMENTO DE SALUD Department of Health

OFICINA DE REGLAMENTACION Y CERTIFICACION Office of Regulation and Certification DE PROFESIONALES DE LA SALUD of Health Professionals

CERTIFICADO DE REGISTRO (REGISTRY CERTIFICATE)

NOMBRE (NAME)	JEREMY ERXLEBEN HAUGHTON
PROFESIÓN (PROFESSION)	Farmacéutico (a)
NÚM, DE LICENCIA (LICENSE NO.)	5468
núm, de registro (registry no.)	135843
VÁLIDO DESDE (VALID FROM)	17/AGO/2013
VENCE EN (DUE DATE)	16/AGO/2016
the first than the state of the	

CERTIFICAMOS QUE ESTE PROFESIONAL CUMPLIÓ CON EL REQUISITO ESTABLECIDO POR LA (WE CERTIFY THAT THIS PROFESSIONAL HAS COMPLIED WITH REQUISITES ESTABLISHED)

LEY NÚM. 11 DE 23 DE JUNIO DE 1976 SEGÚN ENMENDADA. (BY ACT NO., 11 OF JUNE 23, 1976 AS AMENDED)

LA LICENCIA DEBERÁ RECERTIFICARSE A LA FECHA DE VENCIMIENTO O ANTES. (THE LICENSE MUST BE RECERTIFY THE DATE DUE OR BEFORE)

DADA EN SAN JUAN, PUERTO RICO HOY.

22 de julio del 2013

(GIVEN IN SAN JUAN, PUERTO RICO ON)



FIRMA AUTORIZADA (AUTHORIZED SIGNATURE)

NO TRANSFERIBLE (NON TRANSFERABLE)

ADVERTENCIA: CUALQUIER ALTERACION O BORRADURA CANCELA ESTA CERTIFICACIÓN

26 de junio de 2013

Certificación de Colegiación 2013 - 2014

Se certifica que el licenciado JEREMY A ERXLEBEN con número de licencia 005468 es miembro activo del Colegio de Farmacéuticos de Puerto Rico.

Esta certificación vence el 30 de junio de 2014

Lcda. Milagros Morales Directora Ejecutiva R PROPERTY OF THE PARTY OF THE

Sello Oficial

THE LINIVERSITY OF LOWA

ON THE RECOMMENDATION OF THE FACULTY OF THE

College of Pharmacy

AND UNDER THE AUTHORITY OF THE BOARD OF REGENTS
THE UNIVERSITY OF IOWA HAS CONFERRED THE DEGREE OF

Bachelor of Science in Pharmacy

UPON

PERSONAL INFORMATION WAS REMOVED BY NRC. NO COPY OF THIS INFORMATION WAS RETAINED BY THE NRC.

Jeremy Aaron Erxleben

WHO HAS HONORABLY FULFILLED ALL THE REQUIREMENTS PRESCRIBED BY THE UNIVERSITY FOR THIS DEGREE

AWARDED AT THE UNIVERSITY AT IOWA CITY IN THE STATE OF IOWA

THIS

Owew J. Mewlen
PRESIDENT OF THE STATE BOARD OF REGENTS

THE DEEL IS

Mary Sur Cleus

Silberd S. Lanker DEAN OF THE COLLEGE

NUCLEAR PHARMACY CERTIFICATE PROGRAM

Synopsis of Clock Hours of Training

Jeremy Erxleben Certificate Program #80 Campus session: August 2013

College of Pharmacy

Department of Pharmacy Practice

Nuclear Pharmacy Programs

Purdue University

West Lafayette, Indiana 47907

Copyright, (2007) by Purdue Research Foundation, West Lafayette, Indiana 47907. All Rights Reserved. Unless permission is granted, this material shall not be copied, reproduced or coded for reproduction by any electrical, mechanical or chemical processes, or combinations thereof, now known or later developed.

Nuclear Pharmacy Certificate Program Outline:

Contents:

- 1. Program Concept
- 2, Synopsis of Clock Hours of Training
- 3. DVD and Workbook (Self-Study Portion) Clock Hours
- 4. Campus Portion Laboratory and Lecture Clock Hours
- 5. Instructional Staff

Abbreviations Used:

RPI:

Radiation Physics / Instrumentation

RP:

Radiation Physics

MA:

Math

RB:

Radiation Biology

RC:

Radiochemistry

Nuclear Pharmacy Certificate Program Concept

The College of Pharmacy at Purdue University offers a Certificate Program in Nuclear Pharmacy. The goal of the certificate program is to provide fundamental information to post-graduate pharmacists that will serve as a foundation for attaining competency as practitioners in nuclear pharmacy. The program follows the guidelines for nuclear pharmacy training prepared by nuclear pharmacists in the American Pharmaceutical Association, Section on Nuclear Pharmacy Practice.

This student completed the videotaped distance learning portion of the certificate program. This training module utilizes self-study concepts, including lectures on videotape and correlated reading assignments. The nuclear pharmacy manager, or other qualified nuclear pharmacist at the practice site, serves as the clinical instructor and mentor for the pharmacist in training. This portion is self-paced by the trainee with regular examinations returned to Purdue to assist in monitoring the learning process.



COLLEGE OF PHARMACY

August 21, 2013

Jeremy Erxleben Cardinal Health NPS International Distribution Center Road 165 km 2.4 Building #10-local B Guaynabo, Puerto Rico 00965-6211

Dear Jeremy,

We are pleased to provide the enclosed certificate to recognize formally your completion of the Purdue University Nuclear Pharmacy Certificate Program. You have successfully completed all requirements of both the distance and oncampus components of the program as set forth by the Nuclear Regulatory Commission and Purdue University. We enjoyed the brief opportunity to share our knowledge from the world of academia. We wish you the very best for a gratifying and successful professional career.

As you continue on in your career, please do not hesitate to let us know if we can be of any assistance to you – we consider you part of the "Purdue family" and we look forward to hearing from you in the future!

Sincerely,

Kara Duncan Weatherman, PharmD, BCNP, FAPhA Clinical Assistant Professor of Pharmacy Practice

Laca D. Weatherman

Nuclear Pharmacy Programs

Purdue University



PURDUE UNIVERSITY

WEST LAFAYETTE, INDIANA

COLLEGE OF PHARMACY PRACTICE
NUCLEAR PHARMACY PROGRAMS

PHIS CERTIHICATE IS AWARDED TO

Jeremy Erxleben

AS EVIDENCE OF COMPLETION OF THE

NUCLEAR PHARMACY CERTIFICATE PROGRAM

August 21, 2013

Have D. Weatherman

Director of Nuclear Pharmacy Training Programs

Nuclear Pharmacy Certificate Program DVD and Workbook (Self-Study Portion) Clock Hours

DAD	Instructor	Hours
Physics and Overview	Dr. Stanley M. Shaw	RP/I: 11
Disc 1-4	•	RP; 4
		MA: 1
Radiation Protection	Dr. Paul Ziemer	RP: 8
Disc 1-2		
Instrumentation	Dr. Kara Weatherman	RP/I: 4
Disc 1		
Radiopharmaceuticals	Dr. Kara Weatherman	RP: 3
Disc 1-3		RB: 3
1	1	RC: 6
Math Review	Dr. Kara Weatherman	MA; 4
Disc 1		
Radionuclide Generators	Ms. C. Anne Smith	RP/I: 2
Disc 1		MA: 2
Kit Preparation	Dr. Kara Weatherman	MA: 4
Disc 1		
Quality Control	Ms. C. Anne Smith	RP/I; 2
Disc 1	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	MA: 1
1	ŀ	RC: 1
Radiopharmaceutical	Mr. James Ponto	RP/I; 1
Formulations	Mar animo r onto	MA: 1
(Disc 1)	1	RC: 2
Health Physics and	Dr. Brigette McGhee	RP/I: 2
Recordkeeping	Dr. Brigotto inconev	RP; 2
(Disc 1)		10.1 2
Radiation Biology	Dr. Stamley M. Shaw	RP/I; 3
Disc 1-3	Direction of the state of the s	RB: 9
Late Effects of Ionizing Radiation	Dr. William R. Widmer	RP/I; 1
(Disc 1)		RB: 3
Radiation Safety in Prergnant and	Mr. James Ponto	RP/I: 1
Breastfeeding Patients	III, Junios I Onto	RP: 3
(Disc 1)	1	212.
Adverse Drug Reactions	Mr. James Ponto	RP/I; 1
(Disc 1)	THE PRINCE A CARO	RP: 2
(5/30 1)		RB: 1
Radiopharmaceutical Updates	Dr. Richard Kowalsky	RP/I: 9
(Disc 1-3)	171, Advisors axon many	RB: 3
Blood Pool Imaging	Dr. Ronald Calahan	RP/I: 1
(Disc 1)	21, Francis Cultural	MA: 1
(2.00 1)	1	RC: 2
Clinical PET	Dr. Laura Boles Ponto	RP/I: 1
		RP: 1
		RC: 2
Nuclear Pharmacy Regulations	Dr. Stanley M. Shaw	RP: 8
(Disc 1-2)		
Radiopharmaceutical Chemistry	Dr. Mark A. Green	RC: 16
(Disc 1-4)	21, 1, 2, 1,	
(17)00 1-17		

Nuclear Pharmacy Certificate Program On-Campus Portion Clock Hours

Session	Instructor		
On-Campus portion:	Dr. Kara Weatherman	RP/I: 34	
• •		RP: 13	
		MA: 10	
		RB: 0	
		RC: 8	

Nuclear Pharmacy Certificate Program Instructional Staff

Dr. Stanley M. Shaw, Ph.D. Professor of Nuclear Pharmacy Purdue University West Lafayette, Indiana 47097

Dr. Paul Ziemer, Ph.D.
Professor Emeritus of Health Physics
Purdue University
West Lafayette, Indiana 47097

Dr. Kara Weatherman, PharmD, BCNP, FAPhA Assistant Professor of Nuclear Pharmacy Purdue University

Ms. C. Anne Smith, M.S., B.C.N.P. Nuclear Pharmacy Program Director Purdue University West Lafayette, IN 47907

West Lafayette, Indiana 47907

Mr. James A. Ponto, M.S., B.C.N.P. Division of Nuclear Medicine University of Iowa Hospitals and Clinics Iowa City, Iowa 52242 Brigette McGhee Staff Pharmacist Central Pharmacy Services, Inc Jacksonville, FL

Dr. William R. Widmer, D.V.M.
Associate Professor of Diagnostic Imaging
Department of Veterinary Clinical Sciences
School of Veterinary Medicine
Purdue University
West Lafayette, Indiana 47907

Dr. Richard J. Kowalsky, PharmD, BCNP, FAPhA Associate Professor Pharmacy and Radiology University of North Carolina Chapel Hill, North Carolina 27599

Dr. Ronald Callahan, PhD
Harvard Medical School
- Associate Professor of Radiology
Massachusetts General Hospital
- Director of Nuclear Pharmacy
Boston, Massachusetts 02114

Dr. Laura Boles Ponto, PhD Division of Nuclear Medicine University of Iowa Hospitals and Clinics Iowa City, Iowa 52242

Dr. Mark A Green, PhD
Professor of Industrial and Physical Pharmacy
Division of Nuclear Pharmacy
Purdue University
West Lafayette, Indiana 47907

includes an administrative review has a support of the control of	and to inform you that the initial processing which has been performed. H-31473-02 MD) missions. Your application was assigned to a that the technical review may identify additional
Branch, who will contact you separ Your action has been assigned Ma	action, please refer to this control number.