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DNMS

4968 Rainbow Lane Chubbuck, ID 83202 208.237.9730 voice 208.237.9432 fax nukedoses@gmail.com

July 26, 2012

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Lizette Roldán-Otero, Ph.D. US Nuclear Regulatory Commission, Region IV Division of Nuclear Materials Safety 612 E. Lamar Blvd Suite 400 Arlington, TX 76011-4125

Dear Dr. Roldán-Otero,

Please find enclosed an amendment request for RAM License #11-29216-01MD (Advanced Isotopes of Idaho). We are requesting an expedited evaluation of Dr. Mark Carson's application for approval as an authorized nuclear pharmacist.

If you have any questions or need additional information, I can be reached at (208) 406-2543 at any time. Dr. Carson can be reached at (208) 220-2243 at any time. Thank you very much.

Sincerely,

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Troy Curnutt, RSO, 🟉

PUBLIC Immediate Release Normal Release

NON-PUBLIC

A.3 Sensitive-Security Related
 A.7 Sensitive Internal
 Other:

Sul 8 12 Reviewe Date:

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		AR REGULATORY COMMISSIO			
AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.55]					
ne of Proposed Authorized Nuclear Pharmac	ist	State or Territory Where Lice	ensed		
rk Carson, PharmD		Idaho, License Number P62	265		
		G AND EXPERIENCE two methods below)			
Training and Experience, including boa of application or the individual must hav training and experience was completed experience related to the nuclear pharm	ve obtained related related version ve	ed continuing education ar	nd experience si	nce the required	
1. Board Certification					
a. Provide a copy of the board certific	cation.				
b. Skip to and complete Part II Prece	ptor Attestation.				
2. Structured Educational Program	n for Proposed /	Authorized Nuclear Phan	macist		
a. Classroom and Laboratory Trainir					
Description of Training Location of Training Clock Date				Dates of Training*	
Radiation physics and instrumentation	Purdue University		85	April 2010 - April 2012	
Radiation protection	Purdue University		46	April 2010 - April 2012	
Mathematics pertaining to the use and measurement of radioactivity				April 2010 - April 2012	
Chemistry of byproduct material for medical use	rial for		40	April 2010 - April 2012	
Radiation biology	Purdue Univers	ity	21	April 2010 - April 2012	
	Total Hours	s of Training: 215			

NRC FORM 313A (ANP) (05-2012)

PAGE 1

NRC FORM 313A (ANP) (05-2012) U.S. NUCLEAR REGULATORY COMMISSION

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	Advanced Isotopes of Idaho 4968 Rainbow Ln Chubbuck, ID 83202 License Number: 11-29216-01MD	330	April 2006 - July 2012
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	Advanced Isotopes of Idaho 4968 Rainbow Ln Chubbuck, ID 83202 License Number: 11-29216-01MD	570	April 2006 - July 2012
Calculating, assaying, and safely preparing dosages for patients or human research subjects	Advanced Isotopes of Idaho 4968 Rainbow Ln Chubbuck, ID 83202 License Number: 11-29216-01MD	1840	April 2006 - July 2012
Using administrative controls <mark>t</mark> o avoid medical events in administration of byproduct material	Advanced Isotopes of Idaho 4968 Rainbow Ln Chubbuck, ID 83202 License Number: 11-29216-01MD	310	April 2006 - July 2012
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures	Advanced Isotopes of Idaho 4968 Rainbow Ln Chubbuck, ID 83202 License Number: 11-29216-01MD	330	April 2006 - July 2012
	Total Hours of Experience: 3380		
Supervising Individual Heyneman Cathy Cashmo re, PharmD, ANP			

RC FORM 313A (ANP) 5-2012)		U.S. NUCLEAR REGULATORY COMMISSION
-2012)		R PHARMACIST TRAINING AND EXPERIENCE EPTOR ATTESTATION (continued)
	PART II -	PRECEPTOR ATTESTATION
individual as l	ong as the preceptor provide	dual's preceptor. The preceptor does not have to be the supervising es, directs, or verifies training and experience required. If more than experience, obtain a separate preceptor statement from each.
irst Section heck one of the fol	owing:	
Board Certifi	cation	
I attest that	t	has satisfactorily completed the requirements in
	Name of Proposed Authorized N	uclear Plarmacist
10 CFR 39 independe	5.55(a)(1), (a)(2), and (a)(3) ntly as an authorized nuclea	and has achieved a level of competency sufficient to function ar pharmacist.
		OR
Structured E	ducational Program	
✓ I attest that	t Mark Carson, PharmD	has satisfactorily completed a 700-hour structured
<u>.</u>	Name of Proposed Authorized Nu	uclear Pharmacist
competen	cy sufficient to function indep ng for preceptor attestatio	equired by 10 CFR 35.55(b)(1) and has achieved a level of pendently as an authorized nuclear pharmacist.
I am an Autho	rized Nuclear Pharmacist fo	or Advanced Isotopes of Idaho
		Nuclear Pharmacy or Medical Facility
#11-29216-01N License/P	ermit Number	\bigcap
ame of Preceptor Heyneman athy Cashmore, Pharm	D, ANP	Lephen 208 3903961 7/23/12
		-
C FORM 313A (ANP) (05-2012)		PAGE

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PURDUE UNIVERSITY

TO:	Mark Carson
FROM:	Kara Duncan Weatherman, PharmD, BCNP, FAPhA
DATE:	April 27,2012
SUBJECT:	Nuclear Pharmacy Certificate Program Completion

Mark -

Congratulations on completing the Purdue University Nuclear Pharmacy Certificate Program! Enclosed are a number of documents that will be necessary as you apply for Authorized Nuclear Pharmacist status:

- COMPLETION LETTER: this is an official letter (on Purdue letterhead) stating that you have successfully completed the training program and met all of the requirements that have been set forth by both the Nuclear Regulatory Commission and Purdue University. I generally send two original copies – one for submission and one for your records.
- FINAL CERTIFICATE: a copy of this can also be included in your request for AU status and if you so desire, can be framed for your personal use.
- SYNOPSIS OF CLOCK HOURS: this document summarizes the hourly breakdown of your training in the categories specified by the U.S. Nuclear Regulatory Commission. Please note, page 5 of the document, entitled "Training Received in Basic Radioisotope Handling Techniques", summarizes the total breakdown of course content for both the distance and campus sessions in chart form. This document contains my signature as Director of Nuclear Pharmacy Training Programs.

Keep in mind, Purdue certifies your 200 hours of didactic training only – you will need to have an Authorized Nuclear Pharmacist from your facility (or from previous training experiences if you are counting hours earned during a summer internship or other experience) submit an affidavit indicating 500 hours of practical experience. Please let me know if we can be of any additional assistance in this process. It is usually helpful if you make copies of all of the documents and keep them in your personal files in case you change jobs and need to resubmit your AU status to a different state. I also keep electronic files of all paperwork associated with the program. Just give us a call if you ever need them.

In conclusion, I would like to wish you the best as you embark on this new phase of your career. Nuclear pharmacy is a fantastic area of practice, and hopefully, you will find that you enjoy it as much as I have in my career. I would encourage you to continue your education in nuclear medicine and nuclear pharmacy. An excellent method is to become active in your local nuclear medicine technology organization or to become a member of the American Pharmacist Association's section on nuclear pharmacy. Purdue's Certificate Program has given you a foundation that you can build on, and our faculty remains available to you if you have questions at a later date. Please do not hesitate to contact us if we can be of ANY help.

Enclosures

memo

NUCLEAR PHARMACY CERTIFICATE PROGRAM

Synopsis of Clock Hours of Training

Mark Carson Certificate Program #70 Campus session: May, 2010

College of Pharmacy

Department of Pharmacy Practice

Nuclear Pharmacy Programs

Purdue University

West Lafayette, Indiana 47907

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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 / InstrumentationRP:Radiation PhysicsMA:Math
- RB: Radiation Biology
- RC: Radiochemistry

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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. Form Updated 08/11

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES*

Trainee: MARK CARSON Date issued: April 27, 2012

				Breakdown of Course 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	April 2010 - April 2012	DVD- Workbook	150	51	33	13	21	32
	May, 2010	On-Site	65	34	13	10	o	8
	Total Hours R	eceived	215	-				
	Hourly breakd	lown by topic		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: __.

Hara Weath

Kara Duncan Weatherman, PharmD, BCNP, FAPhA Clinical Assistant Professor of Pharmacy Practice Purdue University Nuclear Pharmacy Programs

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

DVD	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 Disc 1	Dr. Kara Weatherman	RP/I: 4
Radiopharmaceuticals	Dr. Kara Weatherman	RP: 3
Disc 1-3		RB: 3
Disc 1'5		RC: 6
Math Review Disc 1	Dr. Kara Weatherman	MA: 4
Radionuclide Generators	Ms. C. Anne Smith	RP/I: 2
Disc 1	Mis. C. Minie Binitin	MA: 2
	Dr. Kara Weatherman	MA: 4
Kit Preparation Disc 1	Dr. Kala weatherman	ма, т
Quality Control	Ms. C. Anne Smith	RP/I: 2
Disc 1		MA: 1
101001		RC: 1
Radiopharmaceutical	Mr. James Ponto	RP/I: 1
Formulations	MIL Sames Fonto	MA: 1
		RC: 2
(Disc 1)	Dr. Briggtte McChao	RP/I: 2
Health Physics and	Dr. Brigette McGhee	RP: 2
Recordkeeping (Disc 1)		KF. 2
Radiation Biology	Dr. Stamley M. Shaw	RP/I: 3
Disc 1-3		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		RP: 3
(Disc 1)		
Adverse Drug Reactions	Mr. James Ponto	RP/I: 1
(Disc 1)		RP: 2
		RB: 1
Radiopharmaceutical Updates	Dr. Richard Kowalsky	RP/I: 9
(Disc 1-3)	Di. Romand Rowalsky	RB: 3
	Dr. Ronald Calahan	RP/I: 1
Blood Pool Imaging	Di. Konalu Calanan	MA: 1
(Disc 1)		RC: 2
Clinical PET	Dr. Laura Boles Ponto	RP/I: 1
		RP: 1
		RC: 2
Nuclear Pharmacy Regulations (Disc 1-2)	Dr. Stanley M. Shaw	RP: 8
Radiopharmaceutical Chemistry (Disc 1-4)	Dr. Mark A. Green	RC: 16

No.577955

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 West Lafayette, Indiana 47907

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

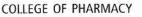
Dr. William R. Widmer, D.V.M. Associate Professor of Diagnostic Imaging Department of Veterinary Clinical Sciences School of Veterinary Medicine Purdue University West Lafayette, Indiana 47907

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





April 27, 2012

Mark Carson Advanced Isotopes of Idaho 4968 Rainbow Drive Chubbuck, ID, 83202

Dear Mark,

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,

Jaia & Weatherman

Kara Duncan Weatherman, PharmD, BCNP, FAPhA Clinical Assistant Professor of Pharmacy Practice Nuclear Pharmacy Programs Purdue University



Nuclear Pharmacy Programs, Department of Pharmacy Practice

PURDUE UNIVERSITY WEST LAFAYETTE, INDIANA

COLLEGE OF PHARMACY DEPARTMENT OF PHARMACY PRACTICE NUCLEAR PHARMACY PROGRAMS

THIS CERTIFICATE IS AWARDED TO

Mark Carson

AS EVIDENCE OF COMPLETION OF THE

NUCLEAR PHARMACY CERTIFICATE PROGRAM

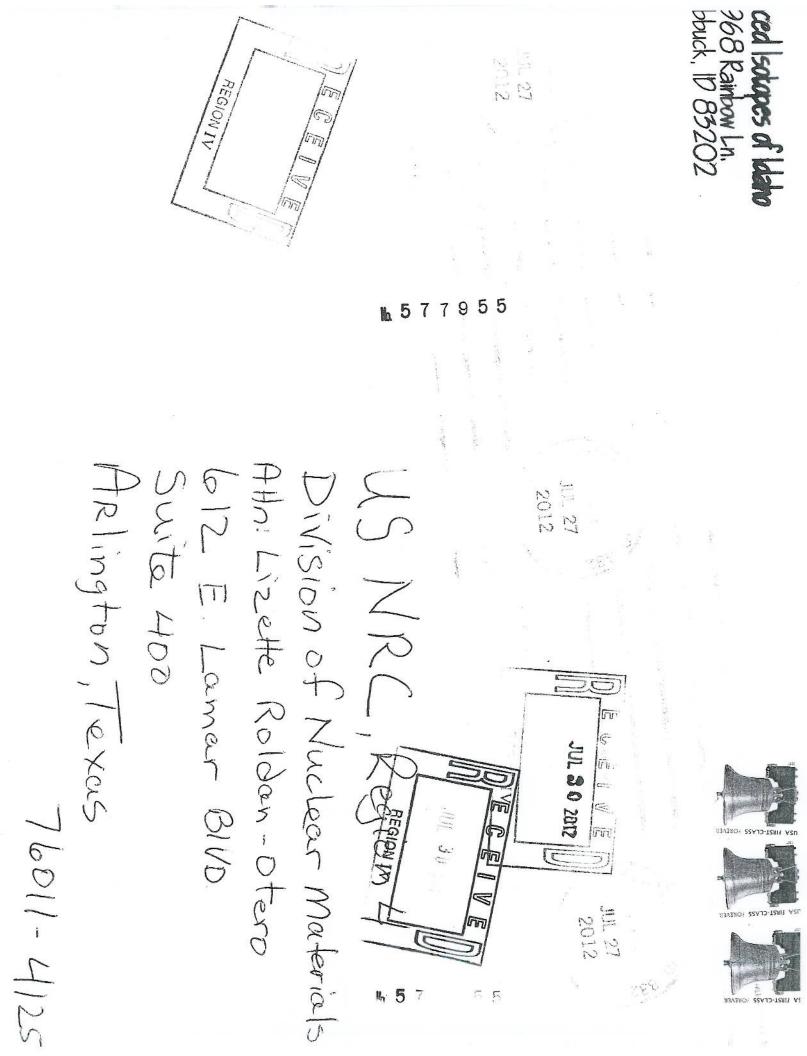
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Hava D. Weatherman

1 Director of Nuclear Pharmacy Training Programs



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enewal of the material(s) license identified
cordingly, the license will not expire until
your taxpayer identification number. ink:
collections/forms/nrc531.pdf
ne following number: (301) 415-5387
e Fee and Accounts Receivable Branch, in contacted separately if there is a fee issue
IAIL CONTROL NUMBER. When control number. Your application has hat the technical review, which is lication (90 days for all other requests), information. If you have any questions tact information is listed below:
sion

BETWEEN:		

Accounts Receivable/Payable and Regional Licensing Branches

[FOR ARPB USE] INFORMATION FROM LTS

Program Code: 02500 Status Code: Pending Amendment Fee Category: 2B 3C 3P Exp. Date: 12/31/2015 Fee Comments: Decom Fin Assur Reqd: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTAC	CHED
Applicant/Licensee:	ADVANCED ISOTOPES OF IDAHO
Received Date:	07/30/2012
Docket Number:	3037048
Mail Control Number:	577955
License Number:	11-29216-01MD
Action Type:	Amendment

2.	F	EE	AT	TA	СН	ED

Amount: _____

3. COMMENTS

Signed: Date:

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered 1 1)

1. Fee Category and Amount:

2. Correct Fee Paid. Application may be processed for:

Amendment:		
Renewal:		
License:		
3. OTHER		
	Signed:	