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San Juan, Puerto Rico 00918-1303

Tel. (787) 765-5598
Fax (787) 763-4042
www.lantheus.com

April 7, 2009

Br 2

United States Nuclear Regulatory Commission
Division of Nuclear Material Safety
Attn: Sattar Lodhi
475 Allendale Road
King of Prussia, PA 19406

03034187

Reference: **Radioactive Material License 52-25361-01 MD**

Subject: Request for License Amendment.

Dear Mr. Lodhi,

This is written to request an amendment to the above referenced Radioactive Material License. As a result of recent operational restructuring at our facility, we request a change in the Radiation Safety Officer. At this time we request that Eduardo Diaz, RPh BCNP, assume the Radiation Safety Officer and Responsible Individual duties and responsibilities. Mr. Diaz's certification is attached for your review.

If you required additional information, please contact me at (787) 765-5598 ext. 2507.

Sincerely,

Joel Cordero, RPh BCNP
Associate Director
Lantheus Medical Imaging

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PURDUE UNIVERSITY



SCHOOL OF PHARMACY AND
PHARMACAL SCIENCES

February 15, 2002

Eduardo Diaz-Montes
Bristol Myers Squibb Radiopharmacy
1500 Marginal Bori
Urb Antonsanti
Rio Piedras, Puerto Rico 00926

Dear Eduardo,

We are pleased to provide the enclosed certificate to recognize formally your completion of the Nuclear Pharmacy Certificate Program. 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.

Sincerely,

A handwritten signature in cursive script that reads "Stanley M. Shaw".

Stanley M. Shaw, Ph.D.
Head
Division of Nuclear Pharmacy

SMS/kld



NUCLEAR PHARMACY CERTIFICATE PROGRAM

Synopsis of Clock Hours of Training

**School of Pharmacy and Pharmacal Sciences
Department of Industrial and Physical Pharmacy
Division of Nuclear Pharmacy
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. Videocassette 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 School of Pharmacy and Pharmacal Sciences 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**.

There are two distinct phases of the certificate program. **The** first part utilizes self-study concepts, including lectures on videotape and carelated 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. **Successful** completion of the didactic phase qualifies **the** trainee to attend a two-week long training session at Purdue. While on campus, **the** trainee participates in laboratory exercises and has opportunities for personal **interaction** with the instructors **during** lectures presented. Certification is awarded to those **trainees** who have completed the program and are able to **demonstrate** their knowledge and competence by examination in **each** of the key areas addressed by the program.

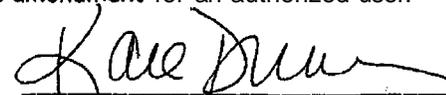
Form Updated 09/01

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES*

Trainee: EDUARDO DIAZ-MONTES

Location of Training	Date(s) of Attendance	Nuclear Pharmacy Certificate Program	Total Clock Hours of Course	Breakdown of Course Content in Clock Hours								
				Radiation Physics & Instrumentation		Radiation Protection		Math Pertaining to Radioactivity		Radiation Biology		Radio-pharmaceutical Chemistry
				A	B	A	B	A	B	A	B	A
Purdue University		Video-Workbook	150	56		35		11		23		25
		On-Site	73	29		16		13		4		11
Column "A" refers to a Lecture/Laboratory Course			223	85		51		24		27		36
Column "B" refers to a Supervised Laboratory Experience			TOTAL HOURS	85		51		24		27		36

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



Director - Nuclear Pharmacy Certificate Program

Nuclear Pharmacy Certificate Program

Videocassette and Workbook (Self-Study Portion) Clock Hours

<u>Instructor</u>	<u>Material</u>	<u>Clock</u>	<u>Hours</u>
Dr. Stan Shaw	Physics and Overview	RPI	30
	Radiation Energy	RP	2
	Atomic Structure	MA	4
	Nuclides	RC	12
	Radioactive Decay and Half-Life		
	Ideal Radionuclide for Imaging		
	Modes of Radioactive Decay		
	Interaction of Ionizing Radiation with Matter		
	Radiation Detection Methods		
	Radiopharmaceuticals: Characteristics and Chemistry		
	Central Nervous System		
	Pulmonary System		
	Liver and Hepatobiliary System		
	Spleen		
	Cardiac Imaging		
	Skeletal System		
	Renal System		
Endocrine System			
Miscellaneous Procedures and Radiopharmaceuticals			
In Vivo Radiopharmaceuticals Not Requiring Imaging			
Radiopharmaceuticals Used in Therapy			

Dr. Robert Landolt	<u>Radiation Protection</u>	RPI	2
	Terms and Units	RP	14
	Protection from External Exposure		
	Portable Survey Instruments		
	Personnel Monitoring		
	Internal Dose Calculations		
	Contamination Control		
	Waste Management		
	Packaging, Labels and Placards		
	10 CFR Standards for Protection Against Radiation		
	10 CFR Notices, Instructions, and Reports to Workers		
Mr. Jim Poato	<u>Drugs & Radiopharmaceuticals</u>	RPI	4
	Drugs & Radiopharmaceuticals, Parts 1 and 2:	RP	4
	<i>Interactions and their effect on diagnostic accuracy of</i>	MA	4
	<i>Nuclear Medicine Procedures</i>	RC	8
	Drugs & Radiopharmaceuticals, Part 3:		
	<i>Interventions used to improve differential diagnosis in</i>		
	<i>Nuclear Medicine Imaging</i>		
	Criteria for Product Selection		
	Instrument Quality Assurance		
	Technetium Chemistry; Radiolytic Decomposition		
	Pediatric Dosage Calculations		
Adverse Reactions to Radiopharmaceuticals			
Record Keeping			
Preparation and Dispensing of Radiopharmaceuticals			
Formulation Problems			

Anne Smith	Radionuclide Generator: Mo-99/Tc-99m Generator	RPI	3
	Quality Control Testing of Radiopharmaceuticals	RP	2
		MA	1
Dr. Richard Kowalsky	Radiopharmaceuticals for Brain Imaging	RPI	5
	Radiopharmaceuticals for Heart Imaging Update	RP	5
	Radiopharmaceuticals for Kidney Imaging Update	RC	5
	Radiopharmaceuticals for Treatment of Bone Pain	RB	1
	Monoclonal Antibodies for Radioimmunodiagnosis Somostatin Receptor Imaging		
Dr. Wayne Kessler	Instrumentation	RPI	8
	Spectrometry	MA	2
	Counting Efficiency		
	Coincidence Loss		
	Background		
	Liquid Scintillation Counting		
	Statistics of Radioactivity		
Dr. Paul Simms	Radionuclide Production, Part 1	RPI	4
	Radionuclide Production, Part 2		
Dr. Stan Shaw	Radiation Biology and Protection	RB	20
	Energy Transfer	RP	8
	Mechanisms of Change		
	Aqueous Radiation Chemistry		
	Target Theory and Dose-Response		
	Radiation Effects on Macromolecules		
	Radiation Effects on Cells		
	Acute Effects		
Delayed Effects			
Genetic Effects			
Dr. William Widmer	Late Effects of Ionizing Radiation	RB	2

Nuclear Pharmacy Certificate Program

On-Site Laboratory Schedule

Instructor	Laboratory	Clock	Hours
Dr. Stan Shaw	Contamination and Decontamination	RP	3
	Basic Radiation Safety	RPI	3
	G.M. Counting	RP	1
		RPI	3
Dr. Kara Duncan	Gamma Ray Scintillation Spectrometry I	RPI	4
	Gamma Ray Scintillation Spectrometry II	RPI	3
	Multichannel Analyzer	RPI	3
	Dose Calibrator	RPI	3
	Shipping and Receiving	MA 1	RP 2
	Elution of the Tc-99m Generator and Quality Control of the Eluate	RPI 2	MA 2
	Radiochemical Purity Testing	RPI 2	RC 1
	Preparation and Dispensing of Selected Radiopharmaceuticals	RPI 2	MA 2
	Aseptic Technique and Sterility Testing	RC	3
	Gamma Camera Instrumentation	RPI	3
	Review of Math Used in Nuclear Pharmacy	MA	3
	Counting Statistics in Nuclear Pharmacy Practice	MA	3
	Iodine Compounding and Instrumentation	MA	2
		RB	2

Nuclear Pharmacy Certificate Program

On-Site Lecture Schedule

Instructor	Topic	Clock	Hours
Dr. Mark Green	Chemistry of Metal-Labeled Radiopharmaceuticals	RC	5
	PET Radiopharmaceutical Chemistry	RPI	1
	PET Imaging and Concept		
	Radionuclide Generator for PET		
Dr. Stan Shaw	Regulatory Agencies	RP	4
	10 CFR Parts 19 and 20		
Mack Richard	10 CFR Part 35 Medical Regulations	RP	2
	Performance Criteria for Radiobioassay	RB	2
Dr. Kara Duncan	Formed Element Labeling and Aids Safety Procedures	RC	2
Dr. Gordon Born	DOT Hazardous Materials Handling	RP	2
Dr. Jim Schweitzer	Film Badge Dosimetry	RP	2

Nuclear Pharmacy Certificate Program

Instructional Staff

Videocassette - Workbook

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

Dr. Robert **Landolt**, Ph.D.
Professor of Health Physics
Purdue University
West Lafayette, Indiana 47097

Dr. Wayne V. Kessler, Ph.D.
Professor of **Bionucleonics**
Purdue University
West Lafayette, Indiana 47097

Dr. Paul C. **Simms**, Ph.D.
Professor of Physics
Purdue University
West Lafayette, Indiana 47097

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

Mr. **James** A. Ponto, **M.S.**, B.C.N.P.
Division of Nuclear Medicine
University of Iowa Hospitals and Clinics
Iowa City, Iowa 52242

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

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

On-Site

Dr. **Mark** A. Green, Ph.D.
Professor of Nuclear Pharmacy
Purdue University
West Lafayette, Indiana 47097

Dr. Jim **Schweitzer**, Ph.D.
Radiation **Safety** Officer
Purdue University
West Lafayette, Indiana 47097

Mr. Mack Richard, **M.S.**
Radiation Safety **Officer**
Indiana University Medical Center
Indianapolis, Indiana 46202

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

Dr. Gordon Born, Ph.D.
Professor of **Medicinal Chemistry** and Health
Sciences
Purdue University
West Lafayette, Indiana 47907

Dr. Kara **Duncan**, PharmD, BCNP
Adjunct Assistant **Professor**
Purdue University
West Lafayette, Indiana 47097

PURDUE UNIVERSITY

WEST LAFAYETTE, INDIANA

SCHOOL OF PHARMACY AND PHARMACAL SCIENCES

Department of Industrial and Physical Pharmacy

Division of Nuclear Pharmacy



This certificate is awarded to

Eduardo Diaz-Montes

as evidence of completion of the

NUCLEAR PHARMACY CERTIFICATE PROGRAM

February 15, 2002

Charles O. Rutledge

Dean, School of Pharmacy
and Pharmacal Sciences

Karl D. Jurek

Nuclear Pharmacy Program
Director

Board of Pharmaceutical Specialties

Hereby certifies that

Eduardo Diaz-Montes

having satisfied all the requirements for certification in the specialty practice area of

Nuclear Pharmacy

*and upon the recommendation of the Specialty Council on Nuclear Pharmacy
is designated a*

Board Certified Nuclear Pharmacist

for the period of 2004-2011

BCNP 1 04 005946

Given this 31st day of December, 2004



Michelle M. Leavins R.Ph., BCN
Council Chairperson

[Signature]
BPS Chairperson

[Signature]
BPS Secretary

Founded by American Pharmaceutical Association, 1976

Certificate of Training

Awarded To

Eduardo Diaz

Recognizing completion of 40 hours of specialized instruction in

Radiation Safety Officer

March 27, 2009

Presented By

Radiation Safety Academy

A Division of Dade Moeller & Associates

438 N. Frederick Avenue, Suite 220, Gaithersburg, MD 20877

www.radiationsafetyacademy.com -- 301-990-6006

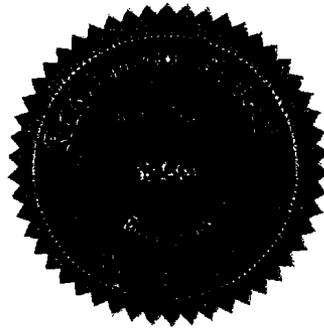
AAHP has awarded this course 32 Continuing Education Credits, 2007-00-031

ABIH has awarded this course 4.5 CM Points, CM Approval # 09-211

ARRT and SNMT have awarded 46.75 CEH's, 027194-027227



Ray Johnson, MS, PE, FHPS, CHP
Vice President, Training Programs



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

4/7/2009, and to inform you that the initial processing which includes an administrative review has been performed.

AMEX. 52-25361-CMD
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

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** 143642.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.