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San Juan, Puerto Rico 00918-1303
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Fax (787) 763-4042
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United States Nuclear Regulatory Commission
Division of Nuclear Material Safety
Attn: Sattar Lodhi
475 Allendale Road
King of Prussia, PA 19406

04/05/2010

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 a new nuclear pharmacist hiring at our company, we request an addition of this pharmacist to the license. In accordance with 10 CFR 35.55 (b)(1) and (2), Karen Gonzalez, Pharm D has been satisfactorily trained in the topics listed in 10 CFR 35.55 (b)(i) and (ii) under supervision of Joel Cordero, RPh, BCNP. Mrs. Gonzalez's certification is attached for your review.

In addition we request the inclusion of BCNP title to Mr. Rolando Garcia, RPh. Mr. Garcia's certification is attached for your review.

If you required additional information, please contact me at (787) 765-5598 ext. 2503.

Sincerely,

Eduardo Diaz, RPh BCNP, RSO
Site Manager
Lantheus Medical Imaging

144579

NRC FORM 313 (3-2009) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120	EXPIRES: 3/31/2012
<h2 style="margin: 0;">APPLICATION FOR MATERIALS LICENSE</h2>		Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects.resource@nrc.gov , and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.	

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH: OFFICE OF FEDERAL & STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001 ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS: IF YOU ARE LOCATED IN: ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO: LICENSING ASSISTANCE TEAM DIVISION OF NUCLEAR MATERIALS SAFETY U.S. NUCLEAR REGULATORY COMMISSION, REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PA 19406-1415	IF YOU ARE LOCATED IN: ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO: MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, IL 60532-4352 ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO: NUCLEAR MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 612 E. LAMAR BOULEVARD, SUITE 400 ARLINGTON, TX 76011-4125
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PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item) <input type="checkbox"/> A. NEW LICENSE <input checked="" type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER <u>52-25361-01MD</u> <input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____	2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code) Lantheus MI Radiopharmaceuticals, Inc. 150 Federico Costa - Suite 1 San Juan, PR 00918-1303
3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED	4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION Eduardo Diaz TELEPHONE NUMBER <p style="text-align: center; font-weight: bold;">(787) 765-5598</p>

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.				
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.				
9. FACILITIES AND EQUIPMENT.	10. RADIATION SAFETY PROGRAM.				
11. WASTE MANAGEMENT.	12. LICENSE FEES (See 10 CFR 170 and Section 170.31) <table style="width:100%; border: none;"> <tr> <td style="border: none;">FEE CATEGORY</td> <td style="border: none;">N/A</td> <td style="border: none;">AMOUNT ENCLOSED</td> <td style="border: none;">\$</td> </tr> </table>	FEE CATEGORY	N/A	AMOUNT ENCLOSED	\$
FEE CATEGORY	N/A	AMOUNT ENCLOSED	\$		

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

 THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

 WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE Eduardo Diaz, RPh, BCNP, RSO	SIGNATURE 	DATE 04/05/2010
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FOR NRC USE ONLY					
TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	144579

**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND
EXPERIENCE AND PRECEPTOR ATTESTATION
[10 CFR 35.55]**

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 3/31/2012

Name of Proposed Authorized Nuclear Pharmacist
Karen Gonzalez, PharmD

State or Territory Where Licensed
Puerto Rico

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 DVD-Workbook	51	November 2009 thru January 2010
	On-Site	+ 34	+ December 2009
Radiation protection	Purdue University DVD-Workbook	33	November 2009 thru January 2010
	On-Site	13	December 2009
Mathematics pertaining to the use and measurement of radioactivity	Purdue University DVD-Workbook	13	November 2009 thru January 2010
	On-Site	10	December 2009
Chemistry of byproduct material for medical use	Purdue University DVD-Workbook	32	November 2009 thru January 2010
	On-Site	8	December 2009
Radiation biology	Purdue University DVD-Workbook	21	November 2009 thru January 2010
	On-Site	0	December 2009
Total Hours of Training: 215			

**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	Lantheus MI Radiopharmaceuticals, Inc. 2525 Ruberte Ave. Ponce PR 00728 License: 52-25361-01	75	January 4, 2010 thru January 15, 2010
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	Lantheus MI Radiopharmaceuticals, Inc. 2525 Ruberte Ave. Ponce PR 00728 License: 52-25361-01	75	January 18, 2010 thru January 29, 2010
Calculating, assaying, and safely preparing dosages for patients or human research subjects	Lantheus MI Radiopharmaceuticals, Inc. 2525 Ruberte Ave. Ponce PR 00728 License: 52-25361-01	200	February 1, 2010 thru March 5, 2010
Using administrative controls to avoid medical events in administration of byproduct material	Lantheus MI Radiopharmaceuticals, Inc. 2525 Ruberte Ave. Ponce PR 00728 License: 52-25361-01	75	March 8, 2010 thru March 19, 2010
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures	Lantheus MI Radiopharmaceuticals, Inc. 2525 Ruberte Ave. Ponce PR 00728 License: 52-25361-01	75	March 22, 2010 thru April 5, 2010
Total Hours of Experience: 500			
Supervising Individual Joel Cordero, RPh, BCNP			

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

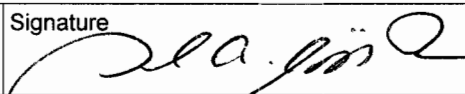
Structured Educational Program

I attest that Karen Gonzalez, PharmD. 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 Lantheus MI Radiopharmaceuticals, Inc. ,
Nuclear Pharmacy or Medical Facility
52-25361-01 ,
License/Permit Number

Name of Preceptor	Signature	Telephone Number	Date
Joel Cordero, RPh, BCNP		(787) 505-2061	04/05/2010

Form Updated 08/07

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES*

Trainee: KAREN GONZALEZ DOMENECH

Date issued: January, 2010

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
Purdue University	November 2009 thru January 2010	DVD-Workbook	150	51	33	13	21	32
	December, 2009	On-Site	65	34	13	10	0	8
Total Hours Received			215					
Hourly breakdown 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:

Kara D. Weatherman

Kara Duncan Weatherman, PharmD, BCNP, FAPHA
 Assistant Professor of Nuclear Pharmacy
 Purdue University
 Division of Nuclear Pharmacy

PURDUE UNIVERSITY

WEST LAFAYETTE, INDIANA

SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES

DEPARTMENT OF INDUSTRIAL AND PHYSICAL PHARMACY

DIVISION OF NUCLEAR PHARMACY

This certificate is awarded to:

Karen Gonzalez Domenech

as evidence of completion of the

NUCLEAR PHARMACY CERTIFICATE PROGRAM

January 27, 2010

Lisa D. Weatherman
Director of Nuclear Pharmacy Training Programs

Board of Pharmaceutical Specialties

Hereby certifies that

Rolando Garcia

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

Nuclear Pharmacy

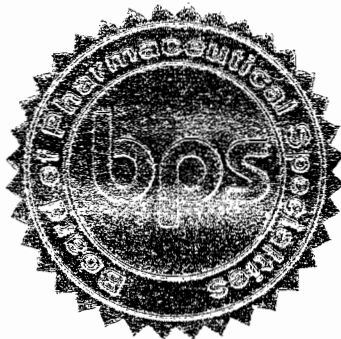
*and upon the recommendation of the Specialty Council on Nuclear Pharmacy
is designated a*

Board Certified Nuclear Pharmacist

for the period of 2004-2011

BCNP 1 04 005435

Given this 31st day of December, 2004



Michele M. Beauvois R.Ph., BCN
Council Chairperson

R. E. Marcom

BPS Chairperson

Richard J. Lertin

BPS Secretary

Founded by American Pharmaceutical Association, 1976

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

4/5/2010, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 52-25361-01MD
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** 144579.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.