

October 5, 2016

REC RG1 10 07 '16 AM 06:23

Tara L. Weidner
Senior Health Physicist
Medical Branch
U.S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
License No. 52-25361-01MD
Docket No. 03034187
Control No. 589554

Br. 1

SUBJECT: Amendment to License 52-25361-01MD/03034187

Dear Mrs. Weidner:

I inform that our Satellite Nuclear Pharmacy located at 2525 Avenida Eduardo Ruberte, Coliseo Shopping Center, Office #115, Ponce, Puerto Rico is completely closed. No operations are held there since October 5, 2015. Surveys of the facility had been performed and no radioactive contamination was found. The isotopes used on this facility had half life less than 120 days. Supporting documents are submitted with this letter regarding close-out surveys. All sealed sources were transferred to San Juan Facility.

We want to amend our license, taking out the address of Ponce facility. The only valid address on the license will be 150 Federico Costa Street, Suite #1, San Juan, Puerto Rico, 00918.

In addition, the following pharmacists are no longer working in our radiopharmacy.

- Joel Cordero
- Karen Gonzalez
- Gustavo Alejandro

Make necessary update to our authorized nuclear pharmacists list.

If you need additional information, don't hesitate on contact me.

Regards,



Eduardo Díaz-Montes, R.Ph., BCNP, RSO
Senior Manager of Operations
Lantheus Medical Imaging
787.765.5598 ext. 2503
eduardo.diaz@lantheus.com

592108

NUCLEAR MATERIALS-002

Ponce Facility.

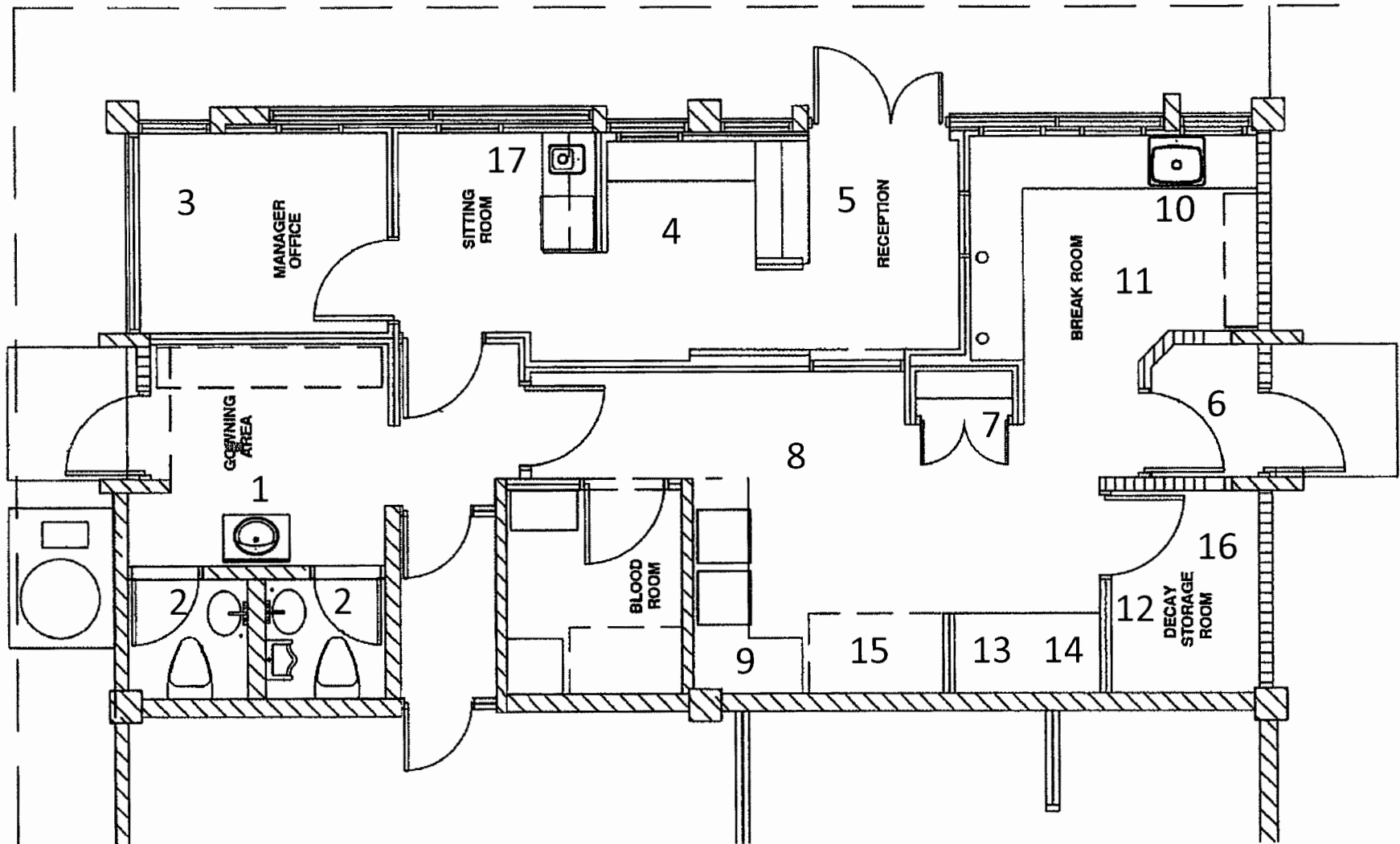
Wipe results: December 30, 2015

Background: 130 cpm

	<i>Location</i>	<i>CPM net</i>
1	Sink in Gowning Area	60
2	Bathrooms	60
3	Manager Office	-30
4	Reception	10
5	Lobby	0
6	Anteroom	-60
7	Biohazard waste area inside laboratory	50
8	Laboratory floors	-30
9	Laboratory top bench	-60
10	Sink package area	-10
11	Breaking room	20
12	Decay Storage room	0
13	Generators area	-40
14	Generators area (2 nd sample)	-10
15	Compounding Hood	30
16	Decay Storage room floor	-10
17	Kitchen (sitting room)	-40

No radioactive contamination was found.

Eduardo Diaz



Sealed Sources relocated to San Juan Facility.

<i>Isotope</i>	<i>Source #</i>	<i>Reference Date</i>	<i>Activity</i>	<i>Manufacturer</i>	<i>Type</i>
Cs-137	572-4-2	1-AUG-1997	101.0 nCi	Isotope Products Laboratories	Rod
Co-57	51553	1-JUN-2004	1.025 uCi	North American Scientific	Rod
Co-57	14259	1-DEC-2001	940.1 nCi	North American Scientific	Rod
Ba-133	572-4-3	1-AUG-1997	101.1 nCi	Isotope Products Laboratories	Rod
Co-60	120502	1-JAN-2008	105.6 nCi	North American Scientific	Rod
Co-57	1551-31-23	1-DEC-2011	5,465 mCi	Eckert & Ziegler	Vial
Ba-133	49399	1-MAR-2004	285.5 uCi	North American Scientific	Vial
Cs-137	61738	1-DEC-2004	264.5 uCi	North American Scientific	Vial

**Lantheus Medical Imaging**

Ponce - Lantheus Medical Imaging

2525 Avenue E. Ruberte Suite # 115, Ponce, PR 00728

NRC# 52-25362MD / PR-2002-02

October 05, 2016

Sealed Sources Inventory Check Report**Date Range : 12-01-2015 thru 12-31-2015**

Date	Chemical Name	Manufacturer	Model #	Serial #	Cal. date	Cal. Act.	Current Act.	Location	Present Y/N ?	Tech.
12/31/2015	Co - 57	ISOTOPE		1551-31-23	12-01-2011	5.47 mCi	0.12 mCi	LMI PONCE	Y	ED
	Ba - 133	NASI		49399	03-01-2004	285.50 uCi	130.64 uCi		Y	ED
	Cs - 137	ISOTOPE		572-4-2	08-01-1997	101.00 nCi	66.14 nCi		Y	ED
	Co - 60	NASI		120502	01-01-2008	105.60 nCi	36.78 nCi		Y	ED
	Co - 57	NASI		51553	06-01-2004	1.02 uCi	-----		Y	ED
	Ba - 133	ISOTOPE		572-4-3	08-01-1997	101.10 nCi	29.95 nCi		Y	ED
	Cs - 137	NASI		61738	12-01-2004	264.50 uCi	205.02 uCi		Y	ED
	Co - 57	NASI		14259	12-01-2001	940.10 nCi	0.00 nCi		Y	ED

The above Report indicates all of the Sealed Sources have been accounted for.

Tech Information:**Tech Initials** **Complete Name**

ED

EDUARDO DIAZ

Technologist Signature : 

**Lantheus Medical Imaging**

Ponce - Lantheus Medical Imaging

2525 Avenue E. Ruberte Suite # 115, Ponce, PR 00728

NRC# 52-25362MD / PR-2002-02

October 05, 2016

Sealed Sources Leak Test Report**Date Range : 12-01-2015 thru 12-31-2015**

Date	Instrument	Chemical Name	Model #	Serial #	Cal. Date	Cal. Act.	Predicted Act.	Reading	Removable Act	In use	Tech
12/31/2015		Co - 57		1551-31-23	12-01-2011	5.47 mCi	0.12 mCi	15.00 CPM	0.000000 uCi	Y	ED
		Ba - 133		49399	03-01-2004	285.50 uCi	130.64 uCi	55.00 CPM	0.000000 uCi	Y	ED
		Cs - 137		572-4-2	08-01-1997	101.00 nCi	66.14 nCi	60.00 CPM	0.000000 uCi	Y	ED
		Co - 60		120502	01-01-2008	105.60 nCi	36.78 nCi	100.00 CPM	0.000058 uCi	Y	ED
		Co - 57		51553	06-01-2004	1.02 uCi	-----	100.00 CPM	0.000058 uCi	Y	ED
		Ba - 133		572-4-3	08-01-1997	101.10 nCi	29.95 nCi		0.000000 uCi	Y	ED
		Cs - 137		61738	12-01-2004	264.50 uCi	205.02 uCi	85.00 CPM	0.000033 uCi	Y	ED
		Co - 57		14259	12-01-2001	940.10 nCi	0.00 nCi	75.00 CPM	0.000016 uCi	Y	ED

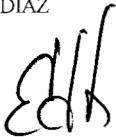
Instrument Details :

#	Instrument	Manufacturer	Next Cal Date	Serial No	Efficiency
6	CAPRAC	Capintec	10-28-2011	001761	2.22%

This Report indicates that all above sealed sources have PASSED a Leak Test.
Removed Activity for sources was below the 0.005 uCi NRC/STATE Trigger Limit

Tech Information:

Tech Initials	Complete Name
ED	EDUARDO DIAZ



Technologist Signature : _____



Lantheus Medical Imaging

Ponce - Lantheus Medical Imaging

2525 Avenue E. Ruberte Suite # 115, Ponce, PR 00728

NRC# 52-25362MD / PR-2002-02

October 05, 2016

Sealed Sources Inventory Check Report

Date Range : 05-01-2016 thru 05-31-2016

Date	Chemical Name	Manufacturer	Model #	Serial #	Cal. date	Cal. Act.	Current Act.	Location	Present Y/N ?	Tech.
5/4/2016	Co - 57	ISOTOPE		1551-31-23	12-01-2011	5.47 mCi	0.09 mCi	LMI PONCE	Y	ED
	Ba - 133	NASI		49399	03-01-2004	285.50 uCi	127.72 uCi		Y	ED
	Cs - 137	ISOTOPE		572-4-2	08-01-1997	101.00 nCi	65.62 nCi		Y	ED
	Co - 60	NASI		120502	01-01-2008	105.60 nCi	35.16 nCi		Y	ED
	Co - 57	NASI		51553	06-01-2004	1.02 uCi	-----		Y	ED
	Ba - 133	ISOTOPE		572-4-3	08-01-1997	101.10 nCi	29.28 nCi		Y	ED
	Cs - 137	NASI		61738	12-01-2004	264.50 uCi	203.41 uCi		Y	ED
	Co - 57	NASI		14259	12-01-2001	940.10 nCi	0.00 nCi		Y	ED

The above Report indicates all of the Sealed Sources have been accounted for.

Tech Information:

Tech Initials Complete Name

ED

EDUARDO DIAZ

Technologist Signature : 

**Lantheus Medical Imaging**

Ponce - Lantheus Medical Imaging

2525 Avenue E. Ruberte Suite # 115, Ponce, PR 00728

NRC# 52-25362MD / PR-2002-02

October 05, 2016

Sealed Sources Leak Test Report**Date Range : 05-01-2016 thru 05-31-2016**

Date	Instrument	Chemical Name	Model #	Serial #	Cal. Date	Cal. Act.	Predicted Act.	Reading	Removable Act	In use	Tech
5/4/2016		Co - 57		1551-31-23	12-01-2011	5.47 mCi	0.09 mCi	45.00 CPM	0.000000 uCi	Y	ED
		Ba - 133		49399	03-01-2004	285.50 uCi	127.72 uCi	120.00 CPM	0.000049 uCi	Y	ED
		Cs - 137		572-4-2	08-01-1997	101.00 nCi	65.62 nCi	15.00 CPM	0.000000 uCi	Y	ED
		Co - 60		120502	01-01-2008	105.60 nCi	35.16 nCi		0.000000 uCi	Y	ED
		Co - 57		51553	06-01-2004	1.02 uCi	-----		0.000000 uCi	Y	ED
		Ba - 133		572-4-3	08-01-1997	101.10 nCi	29.28 nCi	35.00 CPM	0.000000 uCi	Y	ED
		Cs - 137		61738	12-01-2004	264.50 uCi	203.41 uCi	110.00 CPM	0.000033 uCi	Y	ED
		Co - 57		14259	12-01-2001	940.10 nCi	0.00 nCi	95.00 CPM	0.000008 uCi	Y	ED

Instrument Details :


#	Instrument	Manufacturer	Next Cal Date	Serial No	Efficiency
6	CAPRAC	Capintec	10-28-2011	001761	2.22%

This Report indicates that all above sealed sources have PASSED a Leak Test.

Removed Activity for sources was below the 0.005 uCi NRC/STATE Trigger Limit

Tech Information:

Tech Initials	Complete Name
ED	EDUARDO DIAZ

Technologist Signature : 



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee Lantheus MI Radiopharmaceuticals, Inc. ATTN: Joel A. Cordero, R.Ph., Assoc. Director - Operations 150 Federico Costa St., Suite 1 San Juan, PR 00918-1303	Date October 11, 2016
	License Number(s) 52-25361-01MD
	Mail Control Number(s) 592108
	Licensing and/or Technical Reviewer or Branch Medical Branch (Branch 1)

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: October 5, 2016

The initial processing, which included an administrative review, has been performed.

☒ Amendment ☐ Termination ☐ New License ☐ Renewal

☒ There were no administrative omissions identified during our initial review.

☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

☐ Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
Follow the instructions on the form for submission.

☐ The following administrative omissions have been identified:

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Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
U. S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, or (610) 337-5239