



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

February 26, 2013

Docket No. 03034187

License No. 52-25361-01MD

Joel Cordero, R.Ph.
Pharmacy Manager
Lantheus MI Radiopharmaceuticals, Inc.
150 Federico Costa St., Suite #1
San Juan, PR 00918-1303

SUBJECT: NRC INSPECTION REPORT NO. 03034187/2013001, LANTHEUS MI
RADIOPHARMACEUTICALS, INC., SAN JUAN, PUERTO RICO SITE

Dear Dr. Cordero:

On February 5, 2013, Thomas Thompson of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was limited to a review of circumstances surrounding the pharmaceutical preparation problems on January 8, 2013 that you reported to NRC on January 14, 2013. The findings of the inspection were discussed with you and Eduardo Diaz-Montes, R.Ph. of your organization at the conclusion of the inspection.

Within the scope of this inspection, no violations were identified, however, it was determined that several prepared doses labeled Cardiolite (Technetium-99m labeled imaging agent for heart studies) were prepared on January 8, 2013 that became degraded as a result of exceeding the manufacturer's recommended use time interval for the product prior to use by customers. We note that you have provided additional training and instituted the use of a warning banner that displays in the Radiopharmacy Management Information System (RMIS) computer display screen. The computer screen banner warns that the prepared pharmaceutical must be discarded if not used within an hour after preparation. Additionally, it is our understanding that you informed the Board of Pharmacy of this issue.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Regulations, Guidance and Communications**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents**; then **Enforcement Policy (Under 'Related Information')**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

J. Cordero

2

No reply to this letter is required. Please contact Thomas Thompson at 610 337-5303 if you have any questions regarding this matter.

Sincerely,

Original signed by Judith A. Joustra

Judith A. Joustra, Chief
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:
Eduardo Diaz-Montes, Radiation Safety Officer
Commonwealth of Puerto Rico

J. Cordero

2

No reply to this letter is required. Please contact Thomas Thompson at 610 337-5303 if you have any questions regarding this matter.

Sincerely,

Original signed by Judith A. Joustra

Judith A. Joustra, Chief
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:

Eduardo Diaz-Montes, Radiation Safety Officer
Commonwealth of Puerto Rico

DOCUMENT NAME: G:\WordDocs\Current\Insp Letter\L52-25361-01.2013001.doc

ML13057A066

SUNSI Review Complete: TThompson

After declaring this document "An Official Agency Record" it will be released to the Public.

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI		
NAME	TThompson/tt		JJoustra/jj				
DATE	2/27/13		2/27/13				

OFFICIAL RECORD COPY