



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

December 12, 2011

Docket Nos. 03034187
03038114

License Nos. 52-25361-01MD
52-25361-02

Joel A. Cordero, R.Ph.
Associate Director for Operations
Lantheus Medical Imaging
150 Federico Costa, Suite #1
San Juan, PR 00918-1303

SUBJECT: NRC INSPECTION REPORT NOS. 03034187/2011001 & 03038114-2011001,
LANTHEUS MEDICAL IMAGING, SAN JUAN, PUERTO RICO SITE AND THE
PONCE, PUERTO RICO SITE, AND NOTICE OF VIOLATION

Dear Mr. Cordero:

On October 19-November 16, 2011, Todd Jackson of this office conducted a safety inspection at the above address and the Ponce, Puerto Rico site of activities authorized by the above listed NRC licenses. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. Additional information provided in your email correspondence dated November 8, 2011 and the telephone conversation on November 4, 2011 between you and Eduardo Diaz of your organization and this office were also examined as part of the inspection. The findings of the inspection were discussed with you and Eduardo Diaz of your organization at the conclusion of the inspection.

Based on the results of this inspection and in accordance with the NRC Enforcement Policy, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations involved: 1) the failure to maintain complete records of the disposal of licensed materials; and 2) the failure to calibrate some radiation survey instruments as required.

The violations are cited in the enclosed Notice of Violation (Notice), because the violations were identified by the NRC.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

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**;

J. Cordero, R.Ph

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).

Please contact Todd Jackson at 610-337-5308 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

Enclosure:
Notice of Violation

cc:
Eduardo Diaz, R.Ph., Radiation Safety Officer
Commonwealth of Puerto Rico

J. Cordero, R.Ph

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Enclosure:
Notice of Violation

cc:
Eduardo Diaz, R.Ph., Radiation Safety Officer
Commonwealth of Puerto Rico

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OFFICE	DNMS/RI	N	DNMS/RI	DNMS/RI		
NAME	TJackson TJJ*		JJoustra JAJ			
DATE	12/9/11		12/12/11			

*see prior concurrence

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Lantheus MI Radiopharmaceuticals, Inc
San Juan, PR

Docket No. 03034187
License No. 52-25361-01MD

During an NRC inspection conducted on October 19-November 16, 2011, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. Condition 18.C of NRC License 52-25361-01MD requires the licensee to maintain records of the disposal of licensed materials for three years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.

Contrary to the above, records of the disposal of licensed materials maintained by the licensee from October 6, 2008 through October 19, 2011, did not include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.

This is a Severity Level IV violation (Enforcement Policy, Section 6.7).

- B. Condition 20 of NRC License 52-25361-01MD requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the licensee's application dated January 13, 2002, (ML020220090), including any enclosures. The U. S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

Item 10.3.1 of the licensee's application dated January 13, 2002, requires that survey instruments be calibrated, before use, annually and following repair.

Contrary to the above, as of October 19, 2011, four instruments used for personnel contamination surveys prior to exiting the radiation control area were not calibrated annually. Specifically, the calibration for a meter used at the SPECT lab main entrance/exit expired on October 12, 2011, the calibration for the meter used at the exit from SPECT lab anteroom #2 expired June 8, 2011, and calibrations for two meters located at the cyclotron area entrance/exit expired on October 12, 2011.

This is a Severity Level IV violation (Enforcement Policy, Section 6.7).

Pursuant to the provisions of 10 CFR 2.201, Lantheus MI Radiopharmaceuticals, Inc is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice

Notice of Violation
Lantheus Medical Imaging

of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated This 12th day of December 2011