



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

October 16, 2012

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. 03034187/2012001, LANTHEUS MI
RADIOPHARMACEUTICALS, INC., SAN JUAN, PUERTO RICO SITE AND
NOTICE OF VIOLATION**

Dear Mr. Cordero:

On September 5-6, 2012, Todd Jackson of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. You provided additional information by telephone on October 9, 2012. The inspection was limited to a review of the preparation of radiopharmaceutical doses and shipping papers. The findings of the inspection were discussed with you 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 include all required information on shipping papers for packages transported on June 25, 26, and August 14, 2012; and, 2) the failure to retain a copy of the shipping paper, or an electronic image thereof, that is accessible at or through your principal place of business.

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, if you choose to provide one, 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;**

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 note that the office of the Region I Division of Nuclear Materials Safety has moved effective May 9, 2012. Our new address is:

U. S. Nuclear Regulatory Commission
Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

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-Montes, 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	10/16/12		10/16/12				

J. Cordero

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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 September 5-6 and October 9, 2012, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

10 CFR 71.5(a) requires each licensee who transports licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the Department of Transportation regulations in 49 CFR parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport.

- A. 49 CFR 172.200(a) requires each person who offers a hazardous material for transportation shall describe the hazardous material on the shipping paper in the manner required by this subpart. 49 CFR 172.203(d) requires that shipping papers contain, in part, (2) a description of the physical and chemical form of the material, if the material is not in special form; (3) the activity contained in each package of the shipment; (4) the category of label applied to each package in the shipment (for example: "RADIOACTIVE WHITE-I."); and (5) the transport index assigned to each package in the shipment bearing RADIOACTIVE YELLOW-II or RADIOACTIVE YELLOW-III labels.

Contrary to the above, the licensee transported packages and shipping papers that did not state the activity contained in the packages on June 26, 2012, and August 14, 2012, and transported a package and shipping papers on June 25, 2012, that did not contain information regarding the category of label applied to the package and the transport index assigned to the package. Specifically,

On June 26, 2012, the licensee transported a package containing prescription number 2498755 and shipping papers that incorrectly stated the activity contained in the package. The shipping papers stated that the prescription activity shipped was 7.526 microcuries (μCi) I-131 when the activity was actually between zero and 3 μCi .

On August 14, 2012, the licensee transported prescription number 2523159 with shipping papers stating the syringe contained 6.00 millicuries of Ga-67 at the calibration time of 2:00 PM. The recipient measured the activity in the prescription as 4.97 millicuries at the calibration time, which was not as ordered and was different than recorded on the shipping papers.

On June 25, 2012, the licensee transported a package containing prescription numbers 2498610, 2498611, and 2498612. The shipping papers accompanying this package and delivered to the recipient did not include information regarding the category of shipping label applied to the package and the transport index assigned to the package.

This is a Severity Level IV violation (Enforcement Policy Section 6.8).

- B. 49 CFR 171.201(e) requires that each person who provides a shipping paper must retain a copy of the shipping paper required by § 172.200(a), or an electronic image thereof, that is accessible at or through its principal place of business and must make the shipping paper available, upon request, to an authorized official of a federal, State, or local government agency at reasonable times and locations.

Contrary to the above, as of September 7, 2012, the licensee did not retain a copy of a shipping paper as required. Specifically, the inspector requested the licensee provide a copy of the shipping papers for the package containing prescription numbers 2498610, 2498611, and 2498612, transported on June 25, 2012, and the licensee was not able to provide a copy.

This is a Severity Level IV violation (Enforcement Policy Section 6.8).

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 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.

Notice of Violation
Lantheus MI Radiopharmaceuticals, Inc.

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Dated This 16 day of October 2012